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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 celebrate our twenty-sixth year in service, the entire team at **HEALTH CAPITAL CONSULTANTS** *dedicates this 8th edition of Health Capital Topics to the many clients nationwide whom we have had the privilege to serve; to their attorneys, accountants, consultants, and vendors with whom HCC has worked to serve the needs of the projects we undertake on their behalf; and, to our professional colleagues nationwide, who both inform and inspire us toward excellence.*

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, FACHE, CVA, ASA.

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

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

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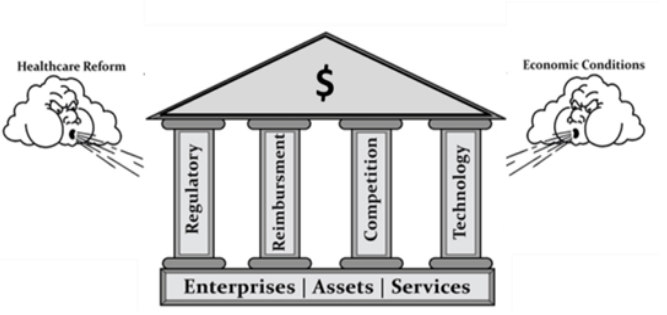
INTRODUCTION

In 2019, the call for regulatory changes in the U.S. healthcare industry reached a crescendo not witnessed since the 2010 enactment of the *Patient Protection and Affordable Care Act* (ACA), partly due to the constant pressure to reduce administrative burdens on providers and modernize the healthcare delivery system. We have witnessed our clients continuing to increase their efforts to maintain compliance with these regulatory changes at a high cost, both financially and through the commitment of other resources.

In response to these calls for change, the "*rules*" by which healthcare providers must play continue to evolve. The ACA, as of the date of this book's publication, is still on uncertain ground, as its constitutionality has yet to be decided by the 5th Circuit; despite that decision, the case will likely be appealed to the U.S. Supreme Court for final ruling. Additionally, CMS recently published a proposal to reform the Stark Law and the Anti-Kickback Statute in light of the progression of value-based arrangements. These changes are occurring within a healthcare industry landscape that is being impacted by a growing demand (an aging population experiencing a greater incidence and prevalence of chronic diseases) and a shrinking supply (the physician manpower shortage). Providers must be responsive to these paradigm shifts, through emerging payment models and exponential advances in innovation driven by emerging technologies.

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 each of the *Four Pillars*, as described above.

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. As always, we solicit your continued input and recommendation of topics or subject matter that you may find useful.

Sincerely,

Todd A. Zigrang
MBA, MHA, FACHE, CVA, ASA
President

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I. VALUATION TOPICS

Valuation of Dialysis Centers: Introduction

[This is the first article in a five-part series regarding Valuation of Dialysis Centers. This installment was published in October 2018.]

Approximately 10% of the global population is affected by *chronic kidney disease* (CKD), and over 2 million individuals suffer from *end-stage renal disease* (ESRD), which must be treated through either dialysis or kidney transplant.[1] Additionally, healthcare spending on kidney disease in general, and specifically on ESRD, is rising. Overall Medicare spending on the treatment of ESRD in the U.S. was over $34 billion in 2015, while the United Kingdom's *National Health Service* (NHS) spent approximately 3% of its budget on kidney failure services in 2014.[2] The burden of kidney diseases is rising in developing countries as well, with nearly 440,000 patients in China undergoing dialysis.[3] The rise in the use of ESRD treatment is driven by increases in both the prevalence of diabetes and the geriatric population.[4] According to the *International Diabetes Federation*, globally, the number of adults with diabetes (diagnosed or undiagnosed) is projected to increase from 425 million in 2017 to 629 million by 2045,[5] while individuals aged 60 years and older are expected to account for at least 20% of the global population by 2050, up from 13% in 2017.[6]

Dialysis centers provide in-center outpatient hemodialysis, peritoneal dialysis, pharmacy, and laboratory services, as well as home hemodialysis and home peritoneal dialysis training and services,[7] to patients with ESRD. ESRD is the final stage of CKD, marked by the complete or nearly complete irreversible loss of renal function, which results in the body retaining fluid and harmful waste build up.[8] In 2015, Medicare expenditures for ESRD totaled approximately $33.8 billion, of which approximately $11.1 billion were spent on outpatient dialysis services.[9] CKD may be more likely to progress to ESRD in the presence of various cardiovascular issues, as a 2014 study published in the *American Journal of Nephrology* noted that CKD patients with self-reported heart failure are "*more likely to…reach ESRD over time*."[10]

Treatment of ESRD is predominantly marked by either: (1) the use of dialysis; or, (2) a kidney transplant.[11] For patients treating ESRD with dialysis, two broad categories of the treatment are available to address their condition: (1) *hemodialysis*; or, (2) *peritoneal dialysis*.[12] *Hemodialysis* is the process of filtering blood through an artificial membrane, known as a dialyzer, to remove wastes and excess fluids,[13] and is most often provided in a dialysis center three times a week for three to four hours per treatment.[14] To perform hemodialysis, a physician creates a vascular access pathway using an arteriovenous (AV) fistula, AV graft, or central venous catheter, to transport blood from the body to the dialyzer and back to the body.[15] Hemodialysis performed in an outpatient setting is the most common form of dialysis treatment undergone by ESRD patients by 88%,[16] with approximately 69% of all industry revenue for dialysis centers derived from outpatient hemodialysis treatments.[17]

Peritoneal dialysis uses the lining of the patient's abdomen as a filter to clear wastes and extra fluids.[18] Through a surgically implanted catheter, a cleaning solution, called *dialysate*, is gravity-drained from a bag into the patient's abdomen.[19] Fluids and wastes flow through the lining of the abdominal cavity and remain trapped, purifying the dialysis solution and the patient's blood.[20] There are two types of peritoneal dialysis – *continuous ambulatory peritoneal dialysis* (CAPD), which can be done at home or at work, and *automated peritoneal dialysis* (APD), which uses a machine called a cycler to empty and fill the abdomen while the patient sleeps.[21] One of the advantages of peritoneal dialysis is that patients may perform this technique outside of the home; however, such technique is less prevalent, in part, due to its reduced effectiveness in removing wastes produced by the body.[22]

The *Centers for Medicare & Medicaid Services* (CMS) requires dialysis centers to be certified by Medicare in order to receive Medicare reimbursement for dialysis services;[23] this requirement is critical for many dialysis centers, as Medicare served as the primary or secondary payor for approximately 68% of all ESRD patients in 2015.[24]

Dialysis centers will face significant opportunities and challenges in the near future as a result of the current conditions in the reimbursement, regulatory, competitive, and technological environments in which these providers operate. Chief among these challenges is the projected rise in demand for healthcare services resulting from the increased life expectancy of dialysis patients, the aging of the "*baby boomer*" population, and the growing prevalence of ESRD, which indicates that higher utilization of ESRD-related services for the aging population is likely to occur.[25] Although this potential influx of patients may provide valuable revenues, current conditions in the reimbursement environment, i.e., reductions in the market basket update for the base rate of payment from Medicare for dialysis services (creating a setting in which dialysis centers must simultaneously provide high-quality healthcare and control the costs associated with providing healthcare), will require dialysis centers to control their costs and provide high-quality care in order to convert these revenues into profit. Further, dialysis centers must continue to navigate increasing regulatory scrutiny of healthcare fraud and abuse. To meet these challenges, dialysis centers may be able to leverage certain technological advancements in order to provide the high-quality, efficient healthcare that is demanded by the modern healthcare industry. The following articles in this series will provide more detail regarding the current conditions in the competitive, reimbursement, regulatory, and technological, environments in which dialysis centers operate.

Valuation of Dialysis Centers: Competitive Environment

[This is the second article in a five-part series regarding Valuation of Dialysis Centers. This installment was published in November 2018.]

As discussed in the first installment of this five-part series, the increasing population affected by kidney diseases such as *chronic kidney disease* (CKD) and *end-stage renal disease* (ESRD), as well as the increase in the healthcare spending on kidney diseases, has led to growth in dialysis centers.[26] This second installment in the five-part series will review the *competitive environment* of dialysis centers.

Demand for Dialysis Services

Demand for dialysis services is likely to increase significantly in the near future, primarily as a result of: (1) the increasing life expectancy for ESRD patients; (2) the disease-specific entitlement to Medicare coverage for ESRD patients, regardless of age; and, (3) the changing demographic trends in the U.S.[27]

Statistics related to the *incidence* and *prevalence* of ESRD indicate the potential for increased demand for dialysis services. Notably, the *incidence*, i.e., the occurrence of new instancs, of ESRD patients nationally per year has been rising since 2011.[28] The improvements in life expectancy of ESRD patients receiving dialysis treatments has led to a similar growth in the *prevalence*, i.e., the total number of affected persons, of ESRD, as the unadjusted death rate from ESRD in the U.S. declined 20% from 2003 to 2012.[29] This increase in the life expectancy of ESRD patients, coupled with stable *incidence* rates for ESRD, is driving increased *prevalence* of ESRD, which may drive demand for dialysis services.[30]

Table 1, below, details trends in the *incidence* and *prevalence* of ESRD in the U.S. from 2000 to 2015.

From 2015 to 2016, the number of Medicare beneficiaries receiving dialysis treatments increased by one percent, while the number of dialysis treatments provided to Medicare beneficiaries, increased by approximately three percent.[31] Although Medicare dialysis beneficiaries are generally younger than most Medicare beneficiaries (in 2016, over 50% of all Medicare ESRD beneficiaries receiving dialysis treatments were under the age of 65),[32] improved life expectancy among ESRD patients may increase the number of dialysis beneficiaries over the age of 65, a population cohort disproportionately driving healthcare expenditures due, in part, to the sufferance of chronic conditions at rates higher than the average population.[33] With this cohort expected to constitute an increasing proportion of the U.S. population, meeting the needs of aging dialysis beneficiaries managing multiple comorbidities may influence dialysis care models in the future.

Supply of Dialysis Centers

As of 2018, *Centers for Medicare & Medicaid Services* (CMS) certified 6,825 dialysis facilities across the U.S.[34] A significant majority of dialysis facilities are *freestanding, for-profit facilities*; in 2016, freestanding facilities provided 94% of dialysis treatments to Medicare ESRD beneficiaries, while over the same period, for-profit facilities provided 90% of dialysis treatments to this cohort.[35]

Consolidation among dialysis providers has led to high levels of market concentration in this industry.[36] In 2014, *DaVita HealthCare Partners* (DaVita) and *Fresenius Medical Care* (Fresenius), the country's two largest dialysis organizations, treated 69% of all patients in 65% of all dialysis facilities in the U.S.[37]

According to a 2007 article in the *Journal of the American Society of Nephrology*, industry consolidation among dialysis centers may have potential advantages, e.g., certain *economies of scale*; *technical efficiencies*; *improved information and tracking systems*; *access to capital*; and, *vertical integration opportunities*.[38] Industry consolidation also has the potential to offer certain clinical advantages, including the potential for *improved compliance with process and protocols*; *accountability*; *standardization of care across a large system*; and, *integrated information* and *reporting systems*.[39] Such horizontal integration may impact the local competitive environment for dialysis facilities, as the scope of treatment options and services provided may influence the decisions of the patient and their physician as to the appropriate facility to receive dialysis treatments.[40]

Competition with Other Providers of ESRD Treatment

The varied forms of treatment for ESRD, as well as the varied sites of service for dialysis care, create various competitive pressures for dialysis centers. Regarding the various forms of treatment for ESRD, dialysis centers face competition from providers of *kidney transplantation* services, as the patient's receipt of a new kidney would eliminate the need to receive dialysis care.[41] Further, receipt of a kidney transplant "*is associated with a substantial survival benefit relative to chronic dialysis*," making access to kidney transplants a "*prominent public health priority*."[42] With the increasing strength of this competitive force nationally, the impact of kidney transplants on the operations of dialysis centers in the U.S. may also be increasing. After stagnating growth from 2006 to 2012,[43] the number of U.S. kidney transplants increased from 16,896 in 2013 to 19,849 in 2017, a *compound annual growth rate* (CAGR) of approximately 4.11% over the time period.[44]

Regarding the varied sites of service for dialysis care, dialysis centers face competition from hospital providers of dialysis treatments. In 2016, hospital-based dialysis centers accounted for 6% of treatments to Medicare ESRD beneficiaries, 5% of all dialysis stations, and 6% of all CMS-certified dialysis facilities, with the remaining percentages held by freestanding dialysis centers.[45] While patients with additional health issues beyond ESRD may find

a benefit in receiving dialysis care in a hospital setting, companies providing outpatient dialysis care may limit this competitive pressure by contracting with the hospital to manage its dialysis clinic.[46]

Competing with other providers of dialysis care (e.g., hospitals) and the rising number of dialysis centers (i.e., potential competitors) pose a challenge to dialysis centers, but the aging "*baby boomer*" population and growing prevalence of ESRD are likely to create more opportunities for these dialysis centers to exploit.

Table 1: Incidence and Prevalence of ESRD in the U.S. (per 1,000,000), 2000-2015

	A	B	C	D	E	F	G
	Utilization Demand Metric	**2000**	**2005**	**2010**	**2014**	**2015**	**CAGR 2000-2015**
1	Incidence of ESRD per 1,000,000	329.6	356.8	372.7	378.8	385.9	1.06%
2	Prevalence of ESRD per 1,000,000	1,250.3	1,542.2	1,819.3	2,034.5	2,087.4	3.48%

Valuation of Dialysis Centers: Reimbursement

[This is the third article in a five-part series regarding Valuation of Dialysis Centers. This installment was published in December 2018.]

As discussed in the first installment of this five-part series, the increasing population affected by kidney diseases such as *chronic kidney disease* (CKD) and *end-stage renal disease* (ESRD), as well as the increase in the healthcare spending on kidney diseases, has led to a growth in dialysis centers.[47] This third installment will review the *reimbursement environment* of dialysis centers.

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.[48] In 2016, Medicare and Medicaid accounted for an estimated $672.1 billion and $565.5 billion in healthcare spending, respectively, combining for approximately 37% of all healthcare expenditures.[49] 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*.[50] This ability to influence healthcare reimbursement may be leveraged to shift payment from volume-based, *fee-for-service* (FFS) to *value-based reimbursement* (VBR) models, in accordance with the goals of the

U.S. Department Health and Human Services (HHS), which stated in January 2015 that it:

> "*...has set a goal of tying 30 percent of traditional, or fee-for-service, Medicare payments to quality or value through alternative payment models, such as Accountable Care Organizations (ACOs) or bundled payment arrangements by the end of 2016, and tying 50 percent of payments to these models by the end of 2018. HHS also set a goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016 and 90 percent by 2018 through programs such as the Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs*."[51]

In March 2016, it was announced that the 30 percent target of HHS had already been met, nearly a year ahead of schedule.[52] Such efforts by HHS may influence other payors, including private health insurers, to institute value-based payment models in their own products.

Medicare Reimbursement for Dialysis Services

Medicare reimburses providers of dialysis services for ESRD under a bundled ESRD *prospective payment system* (ESRD PPS). The ESRD PPS pays providers for each dialysis treatment provided to an ESRD beneficiary.[53]

The ESRD PPS replaced the original composite rate payment system for dialysis services provided at Medicare outpatient ESRD facilities by the *Medicare Improvements for Patients and Providers Act* (MIPPA).[54] The new reimbursement model was fully implemented on January 1, 2014, after a four-year transition period.[55]

The base rate of payment under the ESRD PPS covers the following services:

(1) Items and services included in the composite rate for renal dialysis services, including:
   (a) Nursing;
   (b) Diet counseling;
   (c) Other clinical services;
   (d) Social services;
   (e) Supplies;
   (f) Equipment;
   (g) Certain laboratory tests; and,
   (h) Drugs;[56]

(2) "*Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD*";[57]

(3) Other drugs utilized in the treatment of ESRD and not included in the composite rate;

(4) Other laboratory services utilized in the treatment of ESRD and not included in the composite rate; and,

(5) Other medical equipment and supplies utilized in the treatment of ESRD and not included in the composite rate.[58]

Additionally, the base rate under the ESRD PPS is determined based on the following factors:

(1) A "*market basket increase*", which "*reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services*;"[59] and,

(2) A "*wage index budget-neutrality adjustment factor*."[60]

For 2018, the base rate of payment under the ESRD PPS is $232.37.[61] For 2019, CMS increased the base rate of payment under the ESRD PPS to $235.27.[62] This payment rate reflects the application of 1.3% productivity-adjusted market basket increase and a wage index budget-neutrality adjustment factor (0.999506).[63]

Similar to other forms of Medicare payment, the base rate under the ESRD PPS bundle is adjusted for *patient case-mix*, *high cost patients*, and *low volume* facilities.[64] Various factors that adjust the ESRD PPS base rate are set forth and described below, in Table 1.[65]

Medicare Quality Programs for Dialysis Services

MIPPA also introduced a *quality incentive program* (QIP) for dialysis services reimbursed under the ESRD PPS.[66] Starting in 2012, the QIP for dialysis services reduced the bundled payment under the ESRD PPS by as much as 2% for facilities "*that do not achieve or make progress toward specified quality measures*."[67] For calendar year 2016 (payment year 2018), the QIP for dialysis services includes 16 measures, 11 of which involve clinical outcomes and 5 of which involve adequacy of reporting care process data.[68]

Additionally, in October 2015, CMS, through the *Center for Medicare and Medicaid Innovation* (CMMI), launched the *Comprehensive ESRD Care* (CEC) Model, a specific type of *accountable care organization* (ACO) tailored to incentivize quality care and coordination for ESRD patients.[69] The CEC model created *ESRD Seamless Care Organizations* (ESCOs) that are held accountable for "*quality outcomes and Medicare Part A and Part B spending, including all spending for dialysis services, for their ESRD beneficiaries*."[70] Specifically, an ESCO will either share savings with, or provide financial payments to cover losses to, Medicare based on actual expenditures relative to a "*baseline*" expenditure amount built from historical Medicare Part A and Part B payments.[71] Such expenditures are then adjusted by performance on various quality metrics to determine the ultimate amount of shared savings or losses to the ESCO.[72]

The base rate increase over the past few years represent an upward trend in the reimbursement rate for dialysis centers. However, in order to receive enhanced reimbursement, dialysis centers must meet the regulatory requirements dictated by Medicare. Over the past several years, there has been an increase in regulatory review, which *regulatory environment* will be discussed in the fourth installment of the series

Valuation of Dialysis Centers: Regulatory Environment

[This is the fourth article in a five-part series regarding Valuation of Dialysis Centers. This installment was published in January 2019.]

Healthcare organizations, including dialysis centers, face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. With existing federal and state regulations related to medical liability, licensure, accreditation, certificate of need, fraud and abuse, and antitrust laws, the expansive regulatory landscape of the U.S. healthcare industry greatly shapes the practice of medicine and the delivery of healthcare services. This fourth installment in the five-part series regarding dialysis centers will review the *regulatory environment* in which these enterprises operate.

Government regulators perceive many types of healthcare business arrangements, which in other industries are often regarded as typical motivations inherent in commercial relationships between parties, as exhibiting the potential for a significant risk of fraud. Fraud and abuse laws, specifically those related to the federal Anti-Kickback Statute (AKS) and physician self-referral laws (the "Stark Law"), may have the greatest impact on the operations of healthcare organizations.

The federal AKS and Stark Law are generally concerned with the same issue – the financial motivation behind patient referrals. However, while the AKS is broadly applied to remuneration between providers or suppliers in the healthcare industry and relates to any item or service that may be paid for under any federal healthcare program, the Stark Law specifically addresses the referrals from physicians to healthcare entities with which the physician has a financial relationship for the provision of defined services that are paid for by the Medicare program. Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.

Anti-Kickback Statute

Enacted in 1972, the federal AKS makes it a felony for any person to "*knowingly and willfully*" solicit or receive, or to offer or to pay, any "*remuneration*," directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[73] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[74] Congress amended the original statute in 1987 with the passage of the *Medicare and Medicaid Patient & Program Protection Act of 1987* to include exclusion from the Medicare and Medicaid program as an alternative civil remedy to criminal penalties.[75] Further, the *Balanced Budget*

Act of 1997 added a *civil monetary penalty* of treble damages, or three times the illegal remuneration, plus a fine of $50,000 per violation.[76]

Subsequent interpretation and application of the AKS under case law has created a precedent for a regulatory hurdle known as the *one purpose test*. Under the *one purpose test*, healthcare providers will have violated the AKS if even one purpose of the arrangement in question is to offer illegal remuneration.[77] Additionally, the *Patient Protection and Affordable Care Act* (ACA) made two noteworthy changes to the intent standards related to the AKS. First, the legislation amended the AKS by stating that a person need not have *actual knowledge* of the AKS or *specific intent* to commit a violation of the AKS for the government to prove a kickback violation.[78] However, the ACA did not remove the requirement that a person must "*knowingly and willfully*" offer or pay remuneration for referrals in order to violate the AKS.[79] Therefore, in order to show a violation of the AKS, the government must show that the defendant was aware that the conduct in question was "*generally unlawful*," but not that the conduct specifically violated the AKS.[80] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the *False Claims Act* (FCA).[81] The amended AKS is clear to point out that liability under the FCA is "*[i]n addition to the penalties provided for in [the AKS]…*"[82] This suggests that, in addition to *civil monetary penalties* paid under the AKS, violation of the AKS would create additional liability under the FCA, which itself carries *civil monetary penalties* of over $21,500 plus treble damages.[83]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[84] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to the *Department of Health and Human Services* (HHS) to protect certain business arrangements by means of promulgating several *safe harbors*.[85] These *safe harbors* set forth regulatory criteria that, if met, shield an arrangement from regulatory liability, and are meant to protect transactional arrangements unlikely to result in fraud or abuse.[86] However, failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[87] It should be noted that, in order for a payment to meet the requirements of many AKS *safe harbors*, the compensation must not exceed the range of *Fair Market Value* and must be *commercially reasonable*.[88]

Stark Law

The Stark Law, originally passed as the *Ethics in Patient Referral Act of 1989*, as part of the *Omnibus Budget Reconciliation Act* (OBRA) *of 1989*, prohibits physicians from referring Medicare patients to entities with which the physicians or their family members have a financial relationship for the provision of *designated health services* (DHS).[89] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral. Under the Stark Law, DHS include:

(1) Certain therapy services, such as physical therapy;
(2) Radiology and certain other imaging services;
(3) Radiation therapy services and supplies;
(4) Outpatient prescription drugs; and,
(5) Inpatient and outpatient hospital services.[90]

Under the Stark Law, financial relationships include *ownership interests* through equity, debt, other means, and ownership interests in entities which then have an ownership interest in the entity that provides DHS.[91] Additionally, financial relationships include *compensation arrangements*, which are defined as arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or in kind.[92] Notably, the Stark Law contains a number of *exceptions,* which describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.[93] However, unlike the AKS *safe harbors*, an arrangement *must* fall within one of the *exceptions* in order to be legally permissible under the Stark Law.[94]

Of note, *erythropoietin* (EPO) and other dialysis-related drugs that meet the following conditions fall within an exception to the referral prohibition, related to both ownership/investment interests and compensation arrangements under the Stark Law:

(1) *The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph, "EPO and other dialysis-related drugs" means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of [Current Procedural Terminology/ Healthcare Common Procedure Coding System] CPT/HCPCS Codes; and "furnished" means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.*

(2) *The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute....*

(3) *All billing and claims submission for the EPO and other dialysis-related drugs does not violate any Federal or State law or regulation governing billing or claims submission.*

(4) *The exception set forth in this paragraph does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.*"[95]

The 2016 *Medicare Physician Fee Schedule* (MPFS) final rule, published by CMS on November 16, 2015, added two new exceptions to the Stark Law, an exception for certain timeshare arrangements, and included several alterations to existing provisions of the Stark Law, including:

(1) A relaxation of the writing requirements of many exceptions, specifically that "*parties need not reduce the key terms of an arrangement to a single formal contract to satisfy the writing requirement of the compensation exceptions at § 411.357 that require a writing*";[96]

(2) A relaxation of the *holdover* requirements found in some exceptions (i.e., the continuation of agreements that have expired) to allow for indefinite holdovers, so long as the arrangements "*continue on the same terms and conditions*" as the original arrangement and continue to comply with an exception;[97] and,

(3) A revision to the *stand in the shoes* definition (i.e., the provision that physicians are treated as standing in the shoes of their physician organizations for the purposes of applying the rules regarding compensation arrangements), such that "*all physicians in a physician organization are considered parties to the compensation arrangement between the physician organization and the DHS entity*."[98]

Continued Regulatory Scrutiny of Dialysis Services

Governmental scrutiny of dialysis services is likely to continue, of not increase, going forward. In June 2018, the *Office of Inspector General* (OIG) of HHS stated that it will review claims for Medicare Part B dialysis services provided to beneficiaries with ESRD to determine whether such services complied with Medicare requirements, as a result of identified unallowable Medicare payments.[99] The increase in federal regulatory scrutiny of dialysis centers is being mirrored on the state level in some cases as well. For example, California currently has a proposed bill to introduce more state regulations for dialysis centers, especially to improve staffing ratios, which currently averages one dialysis nurse for 12 patients, and is adversely affecting the quality of care provided to ESRD patients.[100]

Certificate of Need (CON) Laws

Certificate of Need (CON) laws are one of the most significant market entrance barriers affecting the U.S. healthcare delivery system. A state CON program is one in which a government determines where, when, and how capital expenditures will be made for public healthcare facilities, services, and major equipment. CON requirements are based on the highly contested theory that in an unregulated market, healthcare providers will provide healthcare service using costly technology and equipment, regardless of duplication or need. Twelve state CON programs currently regulate renal failure and dialysis centers, which pose a significant barrier to entry for dialysis centers in these states.[101]

Conclusion

The regulatory scrutiny of healthcare entities has significantly increased in recent years. Therefore, the severe penalties that may be levied against healthcare providers, including dialysis centers, under the AKS or the Stark

Law will likely raise a hypothetical investor's estimate of the risk of investing in a Dialysis Center. There has been a continuous change and innovation in the *technological environment* of dialysis centers, which will be discussed in the fifth and final installment of the series.

Valuation of Dialysis Centers: Technological Environment

[This is the final article in a five-part series regarding Valuation of Dialysis Centers. This installment was published in February 2019.]

As in other industries, there are continuous technological innovations and developments in healthcare. Technology has helped to change the patient experience and has had a significant impact on medical processes. Clinical dialysis methods, such as hemodialysis, peritoneal dialysis, etc., all require machines that are technologically evolved and are heavily dependent on technological innovations.[102] This fifth installment in the five-part series regarding dialysis centers will review the *technological environment* in which these enterprises operate, including some recent technological advancements.

Since the emergence of clinical dialysis over 60 years ago, the provision of dialysis care has evolved significantly, due to advances in clinical technologies.[103] While many early challenges prevented dialysis therapies from becoming a viable treatment for end-stage renal disease (ESRD) patients, such as ultrafiltration control systems and accurate dialysis fluid modules,[104] significant problems with the provision of dialysis therapy remains, notably, the creation and maintenance of safe and functional vascular access pathways.[105] However, advances in vascular access, along with the utilization of *health information technology* (HIT), may help dialysis centers overcome these challenges and provide high-quality care for patients with increased efficiency. The ability of dialysis centers and their affiliated providers to leverage these technologies while simultaneously providing high-quality care may serve as a defining feature of the successful dialysis center in the era of healthcare reform.

Advances in Vascular Access

The technological environment related to vascular access (e.g., *autogenous arteriovenous* [AV] fistula, AV graft, or central venous catheter) for dialysis patients is developing, in part, as a response to problems associated with this central feature of the hemodialysis technique, such as higher risks of death, infection, and cardiovascular events.[106] For example, the percentage of hemodialysis patients with an AV fistula (i.e., "an abnormal connection between an artery and a vein"[107]) has increased from 28.9% to 32.8% between 2005 and 2016.[108] In response, new therapies and devices have developed to decrease vascular access complications, including:

(1) Devices developed as an alternative to surgical fistula creation, to offer a less-invasive vascular access option to patients requiring hemodialysis;[109]
(2) Bioengineered blood vessels built from stem cells, which allow patients with AV fistula complications to continue to receive dialysis treatments;[110] and,
(3) Drug-coated balloons to treat *stenosis* (i.e., narrowing) of AV fistulas before the condition devolves into full *thrombosis* (i.e., formation of a clot inside a blood vessel).[111]

Further, it may be possible to develop specific devices to measure vascular access blood flow rates, a significant step toward the prediction of the development of thrombosis of AV fistulas and AV grafts, by using technologies similar to those utilized with cardiovascular patients.[112]

Home-Based Dialysis Treatment

In the past decade, advances in dialysis techniques and machinery have allowed increasing numbers of ESRD patients to receive, or personally perform, home-based services. *Peritoneal dialysis*, which uses the lining of the patient's abdomen as a filter to clear wastes and extra fluids,[113] allows the ESRD beneficiary the luxury of receiving dialysis treatments at home or at work, without visiting an outpatient dialysis center.[114] Similarly, *hemodialysis* machines have evolved such that patients may receive this form of treatment in their homes through a machine similar to that found in outpatient dialysis centers, but the machine is smaller and portable.[115]

Although portable hemodialysis and peritoneal dialysis technology has existed since the 1970s,[116] only recently have more patients begun to rely on home-based dialysis treatments. From 2007 to 2016, the incidence, i.e., the occurrence of new instances, of ESRD patients using home dialysis therapies increased from 6,700 to 12,500 new ESRD patients, with the large majority of patients in 2016 (12,100) opting for peritoneal dialysis treatments.[117] The sudden increase in the number of patients using home dialysis led to the *U.S. Food and Drug Administration* (FDA) declaring a shortage in *dialysates*, i.e., peritoneal dialysis solutions, for *Automated Peritoneal Dialysis* (APD) and *Continuous Ambulatory Peritoneal Dialysis* (CAPD), due to increasing demand and limited supply from the primary supplier, *Baxter International, Inc.* (Baxter), in 2014.[118] The shortage may have subsided by 2016, but was not completely eradicated;[119] this could have a negative effect on the growth of new peritoneal dialysis treatment regimens.

Telehealth Technology in Dialysis

Telehealth is used to provide healthcare services remotely via electronic information and telecommunication technologies, such as computers and mobile devices.[120] In case of kidney diseases, telemedicine is used as a means of remote patient monitoring, e.g., monitoring blood pressure levels at home.[121] Telehealth is also useful in the provision of services to patients in rural areas. Since, approximately 25% of the U.S. population lives in areas considered to

be rural, and rural locations generally have increased incidence of ESRD, telemedicine provides an opportunity to service the rural population.[122]

Health Information Technology in Dialysis

Incorporation of HIT into dialysis care may improve retention and analysis of vital patient information relevant to the treatment of ESRD.[123] In light of the highly consolidated and integrated nature of the dominant companies operating dialysis centers, proper HIT utilization is essential to maintain patient volumes, coordinate patient care, and make informed care decisions.[124] In particular, proper documentation of *Chronic Kidney Diseases* (CKD) and ESRD on *electronic health records* (EHR) utilized by providers led to improved outcomes for dialysis patients, including better coordination of care between primary care providers and specialists and better control of risk factors.[125] Although a 2014 *American Journal of Nephrology* study found that proper notation of CKD by primary and specialty care physicians in a patient's EHR did not reduce the number of ESRD patients, the study also found that proper notation of CKD in an EHR did lead to increased incorporation of CKD treatment guidelines, such as review of Vitamin D and phosphorous levels.[126]

Future of Dialysis Technology

Technological innovations in stem cell and bioengineering techniques are laying the path for new sources of autologous tissues for *regenerative therapies* (i.e., replacement or regeneration of human cells, tissue, or organs, to restore or establish normal function)[127] and *precision medicine* (i.e., disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person).[128] Researchers and companies are following this path and introducing solutions that could completely transform the dialysis industry. Scientists at Manchester University, with the help of embryonic stem cells, are successfully growing human kidney tissue within a living organism, replicating the function of a kidney (e.g., producing urine), which would effectively reduce the need for dialysis.[129] Researchers have also been trying to develop a wearable artificial kidney for a number of decades. A Canadian startup, *Qidini Labs*, is working to develop an artificial kidney with wearable technology, made from nano-filters, which work like a tiny dialysis machine.[130] These types of technological developments could help patients bypass the need for dialysis altogether.

Conclusion

The future developments discussed above may significantly change how kidney disease is diagnosed and treated. It may serve to greatly reduce the need for these services, at least in dialysis facilities, in the face of increasing demand and decreasing supply. Dialysis providers must continually adjust to deal with pressures related to changes in the utilization levels, stagnant reimbursement levels, increasing regulatory scrutiny, and technological developments in the dialysis industry.

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Valuation of Rural Health Clinics: Introduction

[This is the first article in a five-part series regarding Valuation of Rural Health Clinics. This installment was published in March 2019.]

Rural health clinics (RHCs) are specially certified entities that were created in order to increase access to primary care services for patients located in rural communities.[1] RHCs were established via the *Rural Health Clinic Service Act of 1977*, which law was promulgated to address the increasing shortage of healthcare services in rural areas.[2] These clinics are specially licensed healthcare organizations through Medicare, and may be operated as either a for-profit or a non-profit entity.[3] RHCs may be *provider-based*, i.e., owned and operated as part of a Medicare-certified hospital, nursing home, or home health agency, or *independent*, i.e., as a free-standing clinic owned by a provider (or provider entity).[4] Although RHCs are typically not profitable entities, obtaining RHC certification may be particularly advantageous in areas with high proportions of patients insured by either Medicare or Medicaid, as these insurers provide enhanced reimbursement to RHCs.[5]

This *Health Capital Topics* article is the first installment in a five-part series regarding the healthcare *competitive*, *reimbursement*, *regulatory*, and *technological* environments in which RHCs operate, and will define RHCs and the market for these enterprises.

There are a number of requirements that RHCs must meet in order to become licensed and maintain their certified status with Medicare. First, the RHC must be located in a rural, underserved area (as defined by the *U.S. Census Bureau* and the *Health Resources and Services Administration*).[6] *Health Professional Shortage Areas* (HPSAs) are federal designations that indicate healthcare provider shortages based on geographic location, population, or facilities.[7] The area in which an RHC resides must be designated as a geographic-based HPSA, population-group HPSA, *medically underserved area* (MUA), or governor-designated and secretary-certified area within the last four years.[8] Additionally, the clinic must utilize *non-physician providers* (NPPs) in rendering patient services, including *nurse practitioners* (NP), *physician assistants* (PA), and *certified nurse midwives* (CNM).[9] In fact, the RHC is required to be staffed with one NPP, who must be located onsite to see patients 50% of the time the clinic is open (at a minimum) under physician supervision.[10] Although at least one NPP must be employed by the RHC, RHC physicians are able to provide services through an employment agreement or via contract, where the contractual arrangement may be directly between the RHC and physician or between the RHC and a third party that supplies the clinic with physician services, e.g., locum tenens agency.[11] RHC physicians and NPPs typically provide outpatient medical, mental health, or qualified preventive services.[12] In addition to these services, an RHC must be able to provide basic laboratory and diagnostic services such as:

(1) Chemical examination of urine by stick or tablet method or both;
(2) Hemoglobin or hematocrit;

(3) Blood sugar;
(4) Examination of stool specimens for occult blood;
(5) Pregnancy tests; and,
(6) Primary culturing for transmittal to a certified laboratory.[13]

Once an RHC satisfies all requirements and has been certified, the RHC maintains certification unless its location changes or the location no longer meets location requirements, i.e., is no longer in an HPSA.[14]

As of January 2019, there were 4,386 certified RHCs in the U.S.; however, approximately 46% of RHCs are operating at a loss, leading to increased risk of closure.[15] From 2010 to February 2019, there have been 98 RHC closures, exacerbating the rural healthcare service shortage.[16] As rural and underserved areas still have an insufficient distribution of the healthcare workforce, they are unable to adequately meet demand and provide timely and appropriate care.[17] As of the end of 2018, there were approximately 7,026 primary care HPSAs,[18] approximately 4,175 (59%) of which were rural areas, and which needed a projected 3,871 providers in order to remove these rural HPSA designations.[19] Limited access to healthcare services negatively affects health status, quality of life, and life expectancies; additionally, the inability to provide timely or appropriate care may lead to unmet health needs of the patient population, leading to preventable and costly hospitalizations.[20]

The market for rural health services is expected to experience increasing demand in the coming years, due to the aging *Baby Boomer* population and an influx of insured individuals through the ACA.[21] Both of these factors may increase the number of those seeking healthcare services. As demand increases, the supply of physicians is anticipated to decrease, due to an imbalance between the number of physicians who are moving toward retirement and the number of residents who are entering the profession.[22] While this may lead to a shortage of primary care services (especially in areas that are already underserved), because RHCs are required to be staffed by NPPs at least 50% of the time, RHCs may not be as strongly affected by the physician manpower shortage.[23]

In most industries, any shortage may lead to rising prices. However, in the healthcare industry, the federal government has some power to set prices through the Medicare program. Further, with respect to Medicare reimbursement, RHCs are reimbursed on an *all-inclusive rate* (AIR), which indicates that even if there is a shortage of primary care services in the next several years, prices (i.e., RHC reimbursement) may not rise to reflect this shortage.[24]

Although RHCs are typically not profitable ventures, as demonstrated by the significant proportion of RHCs operating at a loss,[25] they provide an invaluable service to areas that may not otherwise have access to primary services. Due in part to the relative dearth of RHCs in MUAs, free-standing RHCs may consequently be potential acquisition targets by entities such as *critical access hospitals* or other non-profit healthcare enterprises that are seeking to meet their charitable mission and increase healthcare access and quality of care in their communities. The remaining articles in this five-part series will explore RHCs

in relation to the *Four Pillars* that influence the valuation of healthcare enterprises, assets, services: *competition*, *reimbursement*, *regulation*, and *technology*.

Valuation of Rural Health Clinics: Competition

[This is the second article in a five-part series regarding Valuation of Rural Health Clinics. This installment was published in April 2019.]

As discussed in the first installment of this five-part series regarding *Rural Health Clinics* (RHCs), the significant proportion of RHCs operating at a loss has led to an overall reduction in the number of RHCs.[26] Despite this decrease, the demand for RHCs continues to rise, limiting access to care for patients in rural communities.[27] This second installment will review the *competitive environment* of RHCs.

Supply of RHCs

As of July 2018, there were approximately 4,300 RHCs across the U.S.[28] However, the number of RHC closures is rising, with 98 closures from 2010 to February 2019, and approximately 46% of active RHCs operating at a loss (potentially signaling additional closures in the future).[29] These financial issues typically stem from the disproportionate number of Medicare and Medicaid patients (i.e., patients whose insurance coverage reimburses providers less than commercial insurance) that utilize RHCs.[30] As of 2018, there were 7,026 primary care *Health Professional Shortage Areas* (HPSAs) in the U.S., with 59% of those HPSAs located in rural areas.[31] These statistics indicate an insufficient supply of healthcare organizations such as RHCs for the size of the U.S. population living in rural areas.

Additionally, the overall supply of rural health services is expected to decrease as the number of physicians (especially primary care providers) decrease, with more physicians currently moving toward retirement than the number of residents entering the profession.[32] Further, the primary care physician to patient ratio is 39.8 physicians per 100,000 people in rural areas, compared to 53.3 physicians in urban areas.[33] Due to a lack of primary care physicians entering the field, and the current limited number of primary care physicians practicing in rural areas, the supply of rural health services could further decrease in the future.

Demand Drivers of RHCs

The demand for rural health services is driven by various social and health determinants, as well as by the proximity of a patient to an RHC. As set forth in Table 1, the rate of various social determinants of health are more acute in the rural areas of the U.S. than in the urban areas, potentially indicating a less

healthy population (and thus greater need for healthcare services) in rural locations.

Table 1: Social Determinant Comparisons between Urban/Rural Areas

	A	B	C
	Social Determinant	**Urban Figure**	**Rural Figure**
1	Average Per Capita Income[34]	$59,652	$44,020
2	Poverty Rate[35]	14.3%	17.2%
3	Unemployment Rate[36]	4.8%	5.4%
4	Percent that Lacks a High School Diploma[37]	12%	14%

In addition to these *social* determinants, a number of *health* determinants, such as smoking and obesity, drive demand for rural health services. Across the U.S., those who live in rural areas have higher rates of smoking and smokeless tobacco utilization, as well as an earlier age at which smoking habits develop.[38] Smoking increases the risk of coronary heart disease, stroke, and lung cancer, and diminishes the overall health of an individual, contributing to the increased demand for healthcare resources.[39] Not only do more rural residents smoke than urban residents, they also smoke more frequently – those that live in rural areas are more likely to smoke more than 15 cigarettes a day, compared to those in urban areas, who are more likely to smoke six or fewer cigarettes a day.[40]

In addition to an increased demand for healthcare services, driven in part by the smoking habits of adults in rural areas where RHCs are located, a large number of Americans are considered obese. Approximately 39.6% of U.S. adults are obese (i.e., reported a body mass index $\geq$ 30).[41] Additionally, a majority of adults are physically inactive, with only 51.7% of adults meeting the national Physical Activity Guidelines for aerobic activity.[42] In turn, obesity, which has a greater prevalence among rural adults, contributes to increased chronic conditions and higher utilization of medical services, leading to increased demand for rural health services, driven by complications due to obesity.[43] In addition, obesity rates are higher among rural children and adolescents than in urban children, with rural children having 26% greater odds of becoming obese compared to urban children.[44] Studies have also shown that rural children engage in less physical activity compared to urban children, in which physical activity barriers include: isolation; lack of transportation; climate and terrain; safety concerns; and, lack of access to locations with physical activity opportunities.[45] Further, overweight children are more prone to become overweight adults, exacerbating this health determinant within rural areas.[46] The high rate of obesity in adults and children, as well as the contributing factor of physical inactivity, effectively increases healthcare demand by the rural patient population.

However, according the *U.S. Department of Agriculture* (USDA), population growth rates have been significantly lower in rural counties than in urban counties.[47] Many communities have experienced a net population loss, with a

majority of the Northeast and Midwest rural counties losing population since the 2000s.[48] Many of those individuals leaving rural communities are younger, causing the median age in rural communities to rise, exacerbating the age difference compared to urban or suburban areas.[49] Additionally, the older population is expected to rise significantly as the *Baby Boomer* cohort ages, causing the number of older adults to increase by 18 million by 2030.[50] With the increase in the elderly population in rural communities (who will inevitably utilize a disproportionate amount of care), demand for RHCs will continue to rise despite the rural population out-migration.

Future Outlook

Despite current instability in the RHC market, as well as in rural healthcare generally, the *Centers for Medicaid and Medicaid Services* (CMS) is taking steps to implement new policies that will positively impact rural healthcare. On September 20, 2018, CMS released a proposed rule to reduce unnecessary regulatory burdens within the Medicare program, including several proposals to reduce burdens for RHCs.[51] Reduced regulatory burden may increase the ease of entry into the rural health market or improve the financial status of RHCs, potentially increasing the supply of RHCs in the future. Additionally, the *RHC Modernization Act*, introduced by Senators John Barrasso (R-WY) and Tina Smith (D-MN), aims to ensure that people in rural areas have access to healthcare services, as there is still a shortage of providers.[52] Because many RHCs are heavily dependent on Medicare and Medicaid reimbursement, the Act proposes to increase the RHC *all-inclusive rate* (AIR), i.e., the fixed reimbursement for all RHC visits.[53] An increase to reimbursement could potentially help the 43% of RHCs that are operating at a loss and are at risk for closure.[54] Additionally, an increase in reimbursement could draw more physicians into rural areas, as well as loan forgiveness and repayment options available to physicians practicing in *Health Professional Shortage Areas* (HPSAs).[55] Additionally, *non-physician providers* (NPPs), such as *nurse practitioners* (NPs) or *physician assistants* (PAs), often have extended scope of practice, which can range from autonomous practice to direct physician oversight depending on state regulations.[56] Increased reimbursement, as well as options for loan forgiveness and repayment programs, may draw NPPs to rural communities.[57]

The increase in demand for rural healthcare services is expected to increase due to the aging *Baby Boomer* population and the overall unhealthiness of rural communities, due to both *social* determinants, e.g., the relatively high unemployment and poverty rates, and *health* determinants, e.g., higher rates of smoking and obesity rates, in those areas.[58] However, the decrease in supply of RHCs and primary care providers results in a critical shortage of rural health services that are wholly insufficient to meet the rising demand. The next installment of this series will examine the *reimbursement environment* of RHCs.

Valuation of Rural Health Clinics: Reimbursement

[This is the third article in a five-part series regarding Valuation of Rural Health Clinics. This installment was published in May 2019.]

The U.S. government is the largest payor of medical costs, through Medicare and Medicaid, and has a strong influence on healthcare reimbursement. In 2017, Medicare and Medicaid accounted for an estimated $705.9 billion and $581.9 billion in healthcare spending, respectively.[59] The prevalence of these public payors in the healthcare marketplace often results in their acting as a *price setter*, and being used as a *benchmark for private reimbursement rates*.[60] This is particularly true for *rural health clinics* (RHCs), which tend to serve a disproportionately large Medicare population.[61] This third installment in the five-part *Health Capital Topics* series on RHCs will focus on the RHC reimbursement environment.

Medicare Reimbursement of RHCs

Medicare reimburses RHCs on an *all-inclusive rate* (AIR) for "*medically-necessary primary health services and qualified preventative health services furnished by an RHC practitioner*."[62] The AIR for RHCs is typically calculated by dividing total allowable costs (i.e., costs reasonable and necessary, including practitioner compensation, overhead, and other costs applicable to the delivery of RHC services) by the total number of visits.[63] This AIR calculation (which, of note, only reimburses for professional services, and not for any facility fees) also takes into consideration *productivity*, *payment limits*, and other factors.[64]

Productivity is calculated in terms of visit numbers; a full-time equivalent (FTE) physician's productivity standard is 4,200 visits, while each FTE non-physician (i.e., nurse practitioner, physician assistant, certified nurse-midwife) has a standard of 2,100 visits.[65] For an RHC, physician and non-physician practitioner productivity can be combined,[66] but patient encounters with multiple RHC practitioners or multiple encounters with the same practitioner on the same day only constitute a single visit.[67] Upon the recalculation at the end of the cost reporting year, if there are fewer visits based on these productivity standards, the AIR rate is lowered.[68]

The 2019 RHC payment limit per visit is $84.70, an increase of 1.5% from the 2018 payment.[69] An RHC that is an integral part of a hospital (including critical access hospitals) can receive exemptions to the payment limit (i.e., receive a higher payment) if: the hospital has fewer than 50 beds; or, the hospital's average daily patient census count of those beds does not exceed 40 and meets other additional requirements.[70]

In addition to the services reimbursed under the AIR, RHCs can also bill Medicare for chronic care management services (determined under the *Medicare Physician Fee Schedule* [MPFS]), which rate was approximately $42

in 2017, as well as for the facilitation of telemedicine services.[71] Of note, RHCs may not provide telemedicine services, but they may serve as the *originating site* (which is reimbursable under the MPFS).[72]

It is important to note that the current RHC payment cap is not enough to cover the average cost per visit to an RHC, i.e., the reimbursement that the RHC receives is less than what it cost them to provide the service, as set forth below in Table 1.

Medicaid Reimbursement of RHCs

Medicaid reimburses for RHC visits under a *prospective payment system* (PPS).[73] Under the PPS methodology, the state calculates a per-visit rate based on reasonable costs for an RHC's first two years of operation, increasing the baseline rate each year by the *Medicare Economic Index* (MEI).[74] Alternatively, the RHC may seek an agreement with the state's Medicaid program under which the RHC receives reimbursement through an *alternative payment methodology* (APM), which payments would be at least as much as the PPS rate.[75] Each state has its own method of applying either the PPS or the APM.[76]

Similar to the rest of the U.S. healthcare delivery system, RHCs are moving from *volume-based* to *value-based reimbursement* (VBR). Especially considering that 43% of RHCs that are operating at a loss and are at risk for closure,[77] these entities must be creative in their efforts to stay financially viable in the midst of this rapid sea change resulting from payment reform. In one example, five states (Colorado, Hawaii, Michigan, Nevada, Oklahoma) and Washington, DC were selected to participate in the *National Academy for State Health Policy's* (NASHP) 2016 *Value-Based Payment Reform Academy* for federally qualified health centers (FQHCs) and RHCs in order to transform how care is delivered at these organizations.[78] RHCs are also involved in other VBR initiatives, such as Medicare Shared Savings Program (MSSP) accountable care organizations (ACOs) and APMs under the Quality Payment Program (QPP).[79]

Conclusion

The market for rural health services is expected to experience increasing demand in the coming years, due to an aging U.S. population and a greater number of insured individuals due to the Patient Protection and Affordable Care Act (ACA).[80] Both of these factors may increase the number of people seeking healthcare services. As demand increases, the supply of physicians is anticipated to decrease, due to an imbalance between the number of these physicians who are moving toward retirement and the number of residents that are entering these fields.[81] While this may lead to a shortage of primary care services, especially in areas that are already underserved, because RHCs are required to be staffed by midlevel providers at least 50% of the time, RHCs may be relatively immune to the physician manpower shortage.

In most industries, any shortage may lead to rising prices. However, in the healthcare industry, the federal government has some power to set prices through the Medicare program. Further, with respect to Medicare reimbursement, because RHCs are reimbursed on an AIR, even if there is a

shortage of primary care services in the next several years, prices (i.e., RHC reimbursement) may not rise to reflect this shortage.

Although RHCs are (purposely) not profitable ventures (as illustrated in the above table), they provide an invaluable service to patients in rural areas who may not otherwise have access to primary services. Due in part to the relative dearth of RHCs in medically underserved areas, free-standing RHCs may consequently be potential acquisition targets by entities such as critical access hospitals or other non-profit healthcare enterprises that are seeking to meet their charitable mission and increase access and quality of care in their communities.

RHC Mean Adjusted Cost Per Visit (ACPV)[82]

	A	B	C	D	E	F
	RHC Characteristics (n)		**n**	**Mean ACPV**	**2017 Cap**	**Shortfall**
1	**Independent RHCs**		1,235	$112.12	$82.30	$29.82
2	***Size***	Small (1-4,342 visits)	324	$126.40	$82.30	$44.10
3		Medium (4,343-9,324 visits)	408	$106.83	$82.30	$24.53
4		Large (9,325-28,040 visits)	402	$106.01	$82.30	$23.71
5		Extra-Large (28,041+ visits)	101	$112.03	$82.30	$29.73
6	***Ownership***	Private/for profit	883	$103.96	$82.30	$21.66
7		Non-profit/publicly owned	296	$130.70	$82.30	$48.40
8	**Provider-Based RHCs**		1,904	$176.73	$82.30	$94.93
9	***Size***	Small (1-4,342 visits)	650	$186.64	$82.30	$104.34
10		Medium (4,343-9,324 visits)	571	$170.02	$82.30	$87.72
11		Large (9,325-28,040 visits)	571	$171.02	$82.30	$88.72
12		Extra-Large (28,041+ visits)	112	$182.52	$82.30	$100.22
13	***Subject to Cap?***	Yes	421	$163.38	$82.30	$81.08
14		No	1,254	$181.00	N/A	N/A
15	***Attached to Critical Access Hospital?***	Yes	1,026	$182.06	N/A	N/A
16		No	778	$168.54	Varies	Varies

Valuation of Rural Health Clinics: Regulatory

[This is the fourth article in a five-part series regarding Valuation of Rural Health Clinics. This installment was published in June 2019.]

As discussed in the first installment of this five-part series, *rural health clinics* (RHCs) are statutorily-created entities, established via the *Rural Health Clinic Service Act of 1977*.[83] These providers face a range of federal and state legal and regulatory constraints, which affect their formation, operation, and transactions. This *Health Capital Topics* article will discuss two important regulatory issues affecting RHCs – licensure requirements and fraud and abuse law compliance.

Licensing of RHCs

There are a number of requirements that RHCs must meet in order to become licensed and maintain Medicare certification. First, the RHC must be located in a rural, underserved area (as defined by the *U.S. Census Bureau* and the *Health Resources and Services Administration*).[84] Additionally, the clinic must utilize *non-physician providers* (NPPs) in rendering patient services, including nurse practitioners (NP), physician assistants (PA), and certified nurse midwives (CNM) – in fact, the RHC is required to be staffed with these NPPs a majority of the time.[85] As regards the services to be offered, RHCs must provide outpatient primary care services, as well as basic laboratory and diagnostic services such as:

(1) Chemical examination of urine by stick or tablet method or both;
(2) Hemoglobin or hematocrit;
(3) Blood sugar;
(4) Examination of stool specimens for occult blood;
(5) Pregnancy tests; and,
(6) Primary culturing for transmittal to a certified laboratory.[86]

The advantage to licensing an RHC is that the clinic may then receive (enhanced) Medicare and Medicaid reimbursement, as discussed in the May 2019 issue of *Health Capital Topics*.[87]

Fraud and Abuse Laws

Fraud and abuse laws, specifically those related to the federal *Anti-Kickback Statute* (AKS) and physician self-referral laws (the "*Stark Law*"), may have the greatest impact on the operations of healthcare organizations. The AKS and Stark Law are generally concerned with the same issue – the financial motivation behind patient referrals. However, while the AKS is broadly applied to payments between providers or suppliers in the healthcare industry and relates to any item or service that may be paid for under any federal healthcare program, the Stark Law specifically addresses the referrals from physicians to entities with which the physician has a financial relationship for the provision

of defined services that are paid for by the Medicare program.[88] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[89]

The AKS makes it a felony for any person to "*knowingly and willfully*" solicit or receive, or to offer or pay, any "*remuneration*," directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[90] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[91] Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[92] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to the HHS to protect certain business arrangements by means of promulgating several *safe harbors*.[93] These *safe harbors* set out regulatory criteria that, if met, shield an arrangement from regulatory liability, and are meant to protect transactional arrangements unlikely to result in fraud or abuse.[94]

Two AKS *safe harbors* that are specifically applicable to RHCs include the *practitioner recruitment safe harbor* and the *joint venture safe harbor*. The *practitioner recruitment safe harbor* protects recruitment payments to physicians to convince them to locate to a *health professional shortage area* (HPSA).[95] Additionally, the *joint venture safe harbor* allows for investments in joint ventures that are located in medically underserved areas (provided they meet several requirements). In effect, this safe harbor allows RHCs to attract and obtain needed capital (often from local physicians).[96]

The Stark Law prohibits physicians from referring Medicare patients to entities with which the physicians or their family members have a financial relationship for the provision of *designated health services* (DHS).[97]

The Stark Law contains a large number of *exceptions,* which describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.[98] Similar to the AKS *safe harbors,* without these *exceptions,* the Stark Law may prohibit legitimate business arrangements. However, unlike the AKS safe harbors, an arrangement must fully fall within one of the *exceptions* in order to be shielded from enforcement of the Stark Law.[99]

Two Stark Law exceptions that are of particular importance to RHCs include the "*assistance to compensate a nonphysician practitioner [NPP]*" *exception* and the *Rural Provider exception*. The 2016 *Medicare Physician Fee Schedule* (MPFS) final rule added the NPP exception, which permits "*remuneration provided by a hospital...or RHC to a physician to assist the physician with compensating an NPP to provide primary care services or mental health care services to patients of the physician's practice*."[100] This exception arises out of the need to increase access to primary care services, a central goal of the ACA, in light of projections of a shortage of primary care physicians.[101] Additionally, the *Rural Provider exception* concerns referrals by physicians with an ownership/investment interest in an enterprise, for DHS "*...furnished in a rural*

area... if...substantially all of the [DHS] furnished by the entity are furnished to individuals residing in such a rural area…"[102]

Conclusion

Despite the stance of the current presidential administration toward de-regulating healthcare,[103] the regulatory scrutiny of healthcare entities (especially with regard to fraud and abuse violations) has generally increased in recent years. Therefore, under current regulation, the severe penalties that may be levied against healthcare providers, including RHCs, under these various federal and state fraud and abuse laws are still a risk factor for RHCs, as well as for potential investors in such entities.

Valuation of Rural Health Clinics: Technology

[This is the final article in a five-part series regarding Valuation of Rural Health Clinics. This installment was published in July 2019.]

Over the past decade, there has been a rapid adoption of technological innovations in the U.S., which has fundamentally changed the healthcare delivery system, improving the quality of patient care, as well as the efficiency of healthcare processes and practices.[104] Research indicates that implementation of *healthcare information technology* (HIT) may lead to improved efficiency and quality management,[105] especially in rural areas.[106] This *Health Capital Topics* article will discuss the various technological advancements that may assist *rural health clinics* (RHCs) in providing more tailored and advanced care to a greater number of patients.

HIT "*uses technology to store, secure, retrieve, and transfer protected health information electronically*," and includes a variety of software applications, such as:

(1) *Electronic health records* (EHR);
(2) Digital networks to electronically transmit medical test results and patient records;
(3) Electronic communication between providers, as well as with their patients;
(4) Electronic prescribing/ordering;
(5) Digital support systems;
(6) Billing software; and,
(7) Staffing models.[107]

EHR systems in particular are linked to clinical improvements,[108] and have the ability to ameliorate cost savings, quality, and coordination of care, as well as increase efficiencies,[109] which could financially benefit the operations of RHCs.

Specifically, the *Office of the National Coordinator for Health Information Technology* (ONC) asserts that HIT can help rural areas in the following ways:

(1) Improving access to and coordination of care;
(2) Improving the surveillance of disease;
(3) Improving health education; and,
(4) Helping in the compilation of regional data.[110]

Despite the obvious capabilities of HIT, the technology has a number of drawbacks, especially for smaller facilities with limited resources and expertise (such as RHCs), including capital requirements and the ongoing maintenance.[111] In addition to the prohibitive cost of purchasing and implementing the HIT,[112] the technology (like most software) requires constant maintenance, including updates and optimization to the HIT.[113] However, rural providers have access to a number of resources that may help alleviate these issues, including various grant programs and funding opportunities, as well as toolkits and technical assistance, from the ONC and other governmental entities.[114]

In addition to EHR systems, the utilization of *telehealth* in rural areas has the ability to significantly increase patient access to healthcare. *Telehealth* is broadly defined as "*the use of information and telecommunications technology to provide health care across time and/or distance*," and is often used interchangeably with the term *telemedicine*.[115] Telehealth can take a number of forms, including:

(1) Provider/patient videoconferencing;
(2) Remote patient monitoring (which may be the most common form of telehealth in rural healthcare);
(3) The "*store and forward transmission*" of medical data and information; and,
(4) Mobile health communication (mHealth), such as through various smartphone apps.[116]

Telemedicine has grown significantly over the past fifteen years, with rural Medicare beneficiary visits increasing at an annual growth rate of 28% between 2004 and 2013, with nearly 80% of these telehealth visits for the purpose of treating mental health conditions.[117]

The ONC lists the following as telehealth benefits for rural providers:

(1) "*Give[s] health care clinicians instant access to information to make timely, vital decisions and save lives*
(2) *Decrease[s] travel time for patients and their families*
(3) *Help[s] rural hospitals use remote clinicians, pharmacists, and staff to improve and extend access*
(4) *Simplif[ies] efficient transfer to other facilities for vital services*
(5) *Facilitate[s] post-hospitalization care close to patients' families and primary care clinicians*."[118]

Perhaps most importantly, the technology allows specialists, who are disproportionally located in urban areas, to remotely connect with and consult on patients in rural areas, and improve the access to and quality of care in specialties including, but not limited to:

(1) Audiology;
(2) Cardiology;
(3) Dentistry;
(4) Dermatology;
(5) Obstetrics;
(6) Oncology;
(7) Ophthalmology;
(8) Psychiatry; and,
(9) Radiology.[119]

Much like EHR systems, telemedicine models have certain drawbacks that may restrict rural providers' adoption and implementation of the technology, including:

(1) The restrictions on Medicare reimbursement of telemedicine services (including geographic /originating site, provider, and service type);
(2) Interstate licensure issues; and,
(3) The lack of access to broadband (i.e., internet connection with sufficient upload/download speeds to support the transmission of data) in rural communities – according to the *Federal Communications Commission* (FCC), nearly 40% of Americans in rural areas lack access to adequate broadband.[120]

As regards the last drawback, i.e., inadequate broadband access, the FCC recently announced plans for a $100 million pilot program to promote the provision of telemedicine services.[121] Named the *Connected Care Pilot*, the three-year program would support various projects focused on defraying the costs of broadband to promote the provision of telemedicine services to low-income Americans and veterans.[122]

The market for rural health services is expected to experience increasing demand in the coming years, due to an aging U.S. population and an increasing number of people with insurance through the ACA. Both of these factors may increase the number of people seeking healthcare services. As demand increases, the supply of physicians is anticipated to decrease, due to an imbalance between the number of these physicians who are moving toward retirement and the number of residents that are entering these fields.[123] While this may lead to a shortage of primary care services, especially in areas that are already underserved, RHCs and other rural providers have an opportunity to mitigate this shortage through technology such as EHR systems and telemedicine models, which allow providers to see more patients, and to augment their practices by remotely including specialists in patient care, thereby continuing to provide an invaluable service to areas that may not otherwise have access to primary and specialist services and increase the quality of care in their communities.

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Home Healthcare and Hospice Enterprises: Fair Market Considerations - Part 1

[This is the first article in a two-part series regarding Home Healthcare and Hospice Enterprises. This installment was published in the April 17, 2019 issue of NACVA QuickRead.]

Introduction

Home healthcare enterprises may be classified as those enterprises that coordinate the delivery of healthcare services to patients in their homes. In 2015, there were approximately 386,384 home healthcare agencies (HHAs) in the U.S., over 12,300 of which were Medicare certified; however, in recent years, there has been a slight decline in the number of Medicare-certified HHAs.[1] The home healthcare industry, including Medicare-certified HHAs, generated revenues of approximately $83.9 billion in 2015, with an annual revenue growth rate of 4% between 2010 and 2015.[2]

There are three types of entities that typically fall under the umbrella of home healthcare: (1) *home healthcare enterprises*, which provide medical and supportive care; (2) *home care aide enterprises*, which provide non-medical care or custodial/non-meal care; and (3) *hospice enterprises*, which provide end-of-life care.[3] Additionally, two of the main types of home healthcare services are: (1) *infusion therapy* and (2) *respiratory therapy*.

Integral to the delivery of many home healthcare services is the utilization of *durable medical equipment* (DME), i.e., medical equipment designed for repeated use in order to improve the quality of life for patients with illnesses or injuries, including equipment for *home respiratory therapy*, *home infusion therapy*, and *diabetic care supplies*, as well as for *patient positioning* and *mobility*.[4] Medicare assigns DME into separate categories, based on the nature, price, and maintenance frequency of an item, as follows:

(1) Inexpensive or other routinely purchased equipment;
(2) Frequently serviced items;
(3) Oxygen and oxygen equipment;
(4) Other covered items that are necessary for the effective use of DME; and
(5) Capped rental items.[5]

DME includes not only *physical medical equipment*, but also any *drugs* and *medications* necessary for the equipment to function,[6] e.g., *heparin* (an anticoagulant) administered through a *dialysis machine*. Medicare spending for DME reached $54.4 billion in 2017 and increased at a rate of 6.8%.[7]

Despite the slight decrease in active Medicare-certified HHAs, the number of Medicare beneficiaries using hospice services has been increasing over the last decade – the number of hospice beneficiaries in 2016 exceeded 1.4 million, more than double the number of beneficiaries in 2000.[8] Likewise, the number of hospice providers participating in Medicare almost doubled, from 2,255 in 2000 to 4,382 in 2016, with Medicare payments for hospice services increasing from approximately $3 billion in 2000 to almost $17 billion in 2016.[9] Of note, the number of for-profit hospice providers has also been growing;

approximately 67% of hospice agencies were for-profit enterprises as of 2016, as compared to almost 30% in 2000.[10]

The valuation of home healthcare and hospice enterprises and services are influenced by certain market forces related to the *Four Pillars of Healthcare Valuation*, i.e.: (1) *regulatory*; (2) *reimbursement*; (3) *competition*; and, (4) *technology* – each of which relates to almost all aspects of the U.S. healthcare delivery system. This first part of a two-part series on home health and hospice enterprises will review the unique value drivers that impact the typical valuation approaches, methods, and techniques that are often utilized in determining the value of these enterprises in the current healthcare delivery system.

Current and Future Trends: Regulatory, Reimbursement, Competition, & Technology

Regulatory

In addition to state licensure requirements, HHAs must be certified by Medicare in order to receive reimbursement for services provided to patients who are Medicare or Medicaid beneficiaries. HHAs may meet the requisite Medicare certification requirements by obtaining *accreditation* through an accepted national accreditation organization, i.e.: (1) *The Joint Commission*; (2) the *Accreditation Commission for Home Care, Inc.*; and, (3) the *Community Health Accreditation Program*.[11] In addition, HHAs must also maintain compliance with federal *Health Insurance Portability and Accountability Act* (HIPAA) requirements; applicable state *certificate of need* (CON) laws; and, federal fraud and abuse laws, such as the *Anti-Kickback Statute* and the *Stark Law*.

Fraud and abuse scrutiny has increased across the entire healthcare delivery system in recent years. In 2017 alone, more than 400 defendants were charged with participating in fraudulent activity involving $1.3 billion in false billings to Medicare and Medicaid, over a third of which billings were related to home health and hospice activities.[12] In 2010, the *Medicare Payment Advisory Committee* (MedPAC) recommended curbing fraudulent home health services, calling on the Secretary of the *Department of Health and Human Services* (HHS) to use the Department's authorities to examine providers with utilization patterns consistent with fraud and abuse.[13] In 2017, the *Centers for Medicare & Medicaid Services* (CMS) expanded previously-established local moratoria to statewide moratoria for HHAs in Florida, Illinois, Michigan, and Texas, due to the high incidence of fraud in those areas.[14] Despite the moratoria, there continued to be numerous criminal prosecutions in home health fraud in these areas, despite the large reductions in the numbers of HHAs.[15] CMS did not extend the moratoria on new HHAs in the affected states beyond the expiration date of January 30, 2019, after being extended for several six-month periods since the initial moratorium.[16] Although the moratorium has expired, initiatives continue to emerge to battle fraud concerns related to HHAs.

As relates to hospice, the HHS *Office of Inspector General's* (OIG) active work plan has a significant portion dedicated to hospice investigation, resulting in an

increase in the number of civil cases against hospice providers.[17] Consistent with its work plan, since 2016, the OIG has announced approximately seven hospice-related evaluations or audits.[18] As a result of this increased scrutiny, many hospice providers who allegedly sought false Medicare claims have been subject to whistleblower suits, facing legal and financial repercussions. For example, in 2017, Genesis Healthcare Inc. agreed to pay $53.6 million to the federal government in response to allegations of providing medically unnecessary or substandard rehabilitation therapy and hospice services.[19] As the OIG continues to audit and evaluate both home health and hospice entities, the supply of these agencies may decrease.

Reimbursement

Approximately 3.4 million Medicare beneficiaries received home healthcare services in 2015 and 2016, with Medicare payments for home healthcare services totaling approximately $18.1 billion in 2016 alone.[20] Medicare reimburses for home healthcare services under the home healthcare *prospective payment system* (PPS), which was implemented in 2000.[21] This episode-based PPS relies on a 153-category *case mix adjuster* to establish payment rates based on patient characteristics, including: (1) *clinical severity*, (2) *functional severity*, and (3) *service utilization*.[22] While the PPS is similar to the methodology used for *skilled nursing facility* reimbursement, payment is based on a 60-day *episode of care*, as compared to the *daily unit* of payment utilized for skilled nursing reimbursement.[23] Significantly, respiratory care services are specifically *excluded* from Medicare's home health PPS.[24] However, respiratory care services may be covered under Medicare if they are furnished as part of a "*plan of care*" by a nurse or a physical therapist as a "*skilled care*" visit, rather than as a "*home health episode*."[25]

On October 26, 2018, CMS finalized new case-mix methodology refinements for home health payments for calendar year 2020.[26] In order to promote patient-driven care, CMS will implement the *Patient-Driven Groups Model* (PDGM), which will remove current incentives to overprovide therapy.[27] Rather than paying for the number of therapy visits a patient receives, CMS will rely more on clinical characteristics and patient information to allow payments to reflect patient needs, moving from a *volume*-based model toward a more *value*-based reimbursement (VBR) system.[28] Additionally, the PDGM would cut the home health unit of payment from 60 days to 30 days.[29] Under this model, HHAs are expected to have a net savings of $60 million in annualized costs, with each home health agency projected to save $5,150.[30]

Another (less extensive) Medicare VBR model was implemented for HHAs beginning January 1, 2016.[31] The CMS Innovation Center's *Home Health Value-Based Purchasing Model* (HHVBP) is mandatory for HHAs in nine states, tying payment to quality performance.[32] Payment adjustments (upward and downward) were set at a maximum of 3% in 2018, slowly increasing to an 8% adjustment by 2022.[33] The model is currently undergoing adjustments, which may indicate that the model will expand at the conclusion of the pilot program, affecting payments to HHAs in all states.[34]

Of note, on March 4, 2019, HHS Secretary, Alexander Azar, stated that Medicare will be significantly changing its payment system to move the large majority of dialysis treatments from the facility to the home.[35] The federal government wields extensive influence in kidney disease reimbursement, with over one-fifth of Medicare's spending in 2016 devoted to kidney disease treatments;[36] consequently, it is likely that any changes made by Medicare will be echoed by commercial insurers.

As regards the provision of DME during a home healthcare episode, Medicare reimbursement payments are typically 80% of the lesser of either: (1) the supplier's actual charge; or, (2) the Medicare fee schedule for an item or a service.[37] For certain types of DME (e.g., oxygen and oxygen equipment), the carrier determines the fee schedule.[38] In addition, under the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, HHS established a program under which DME suppliers must participate in a *competitive bidding program* in order to obtain Medicare contracts.[39]

In contrast to reimbursement for home healthcare services, Medicare reimbursement for hospice services is based on an *adjusted per diem rate* for each day a beneficiary is enrolled in the *hospice benefit program*, regardless of the level of services provided in a given day.[40] The payment rate for each day is determined by a fee schedule containing four levels of care: *routine home care* (RHC), *continuous home care* (CHC), *inpatient respite care* (IRC), and *general inpatient care* (GIC).[41] In addition to the *per diem rate*, hospice facilities may bill the patient a coinsurance amount separately for *prescription drugs* or *respite care*.[42] Significantly, Medicare *caps* payments to hospice facilities in two ways: (1) the *inpatient cap* limits the number of days of inpatient care that the hospice may provide, to no more than 20% of the total inpatient care days; and, (2) the *aggregate cap* is an absolute dollar limit on the average annual payment per beneficiary that an agency can receive, which is the cap amount times the number of Medicare patients served.[43] The *aggregate cap* amount for 2019 is equal to the 2018 amount of $29,205.04.[44]

Individuals covered under Medicare Part A can elect to receive hospice care if they:

(1) Have a terminal illness with a prognosis of under six months, if the disease runs its normal course;

(2) Receive treatment in a Medicare-approved hospice center; and,

(3) Sign a statement electing hospice care and waiving all other rights to Medicare payments associated with the terminal illness.[45]

During the first 90 days of hospice care, the beneficiary must receive a signed certification of a terminal illness from both: (1) the medical director of the hospice or the physician member of the hospice group; and, (2) the individual's physician, describing the clinical findings that support a life expectancy of under six months.[46] After the initial 90-day period, a physician must recertify that the patient is still eligible for hospice care.[47]

As noted above, hospice utilization has steadily increased over the years, with Medicare paying $16.7 billion for these services in 2016; however, these programs do not always provide appropriate services, may be of poor quality, and consequently cost Medicare millions of dollars due to fraudulent billing.[48] In light of this trend, HHS and the OIG recommend that CMS strengthen the survey process to promote compliance and ensure quality care and establish additional remedies to tackle poor performance within hospice enterprises.[49] In addition, to reduce fraudulent billing, the agencies recommend that CMS strengthen hospice oversight by analyzing claims and identifying practices that raise concerns.[50] While, to date, no action has been taken to change reimbursement incentives for hospice services, fraud and abuse scrutiny of these facilities will likely continue in their intensity going forward, as the U.S. healthcare delivery system evolves in this new era of healthcare reform. As a result of these recommendations and increasing concerns related to quality and billing, potential modifications to the reimbursement structure may emerge through the introduction of VBR programs, similar to the HHVBP.

Competition

According to a March 2018 MedPAC report, Medicare beneficiary home healthcare utilization has been declining since 2011, in both the demand for, and the supply of, services.[51] The number of HHAs fell by 1.2% in 2016, after a 60% increase from 2004 to 2015.[52] This decline is thought to be due to the decrease in hospital discharges, which are a common source of referrals, and the low growth in the overall U.S. economy;[53] decline was most acute in Texas and Florida, states that had previously seen the greatest amount of concentrated growth, resulting in CMS implementing moratoria to stop the entry of new agencies.[54] As previously mentioned, due to the moratoria expiration at the end of January 2019, more HHAs will likely be established in those areas moving forward; however, these newer entities will face continued challenges in the form of high levels of regulatory scrutiny and the new payment model in 2020.[55] Despite the decline of HHAs in states with high instances of fraud, these decreases have not been experienced in other areas of the U.S., with 44 states experiencing a 2.1% growth, principally in the for-profit sector.[56]

Evidence indicates that home health services decrease costs, improve health outcomes, and reduce hospital stays.[57] Especially as the U.S. population continues to age (with approximately 10,000 individuals turning 65 every day), patient demand for these services will continue to increase as healthcare utilization and prevalence of disease increases with age.[58] Additionally, there has been a shift in government reimbursement (primarily Medicare and Medicaid), toward home health services, as 2015 marked the first year that more money was spent on home care rather than nursing home care.[59] Both payors (as demonstrated by CMS's March 4, 2019 announcement – see above) and patients may continue demanding home health services in attempts to reduce expenditures by avoiding more costly alternatives (e.g., inpatient hospital stays) and improving outcomes (e.g., reducing the potential for facility-acquired infections).[60]

Competition among home healthcare providers is largely variable, due to the wide spectrum in the scope of services that may be provided by a given HHA. For example, HHAs may provide services that require a licensed provider, such as home infusion therapy; respiratory care; physical, occupational, and speech therapy; behavioral care; and, skilled nursing services, or may provide services that do not require a licensed provider, such as those provided by a home healthcare aide.[61] As a result, the home healthcare industry is quite fragmented, with the four largest industry firms only generating one-tenth of total industry revenue in 2015.[62] However, the industry is expected to continue consolidating, as home and hospice enterprises are "*far less fragmented than [they were] just five years ago.*"[63]

Similar to HHAs, *hospice services* vary in scope, but principally provide *palliative services*, which focus on providing patients with relief from the symptoms, pain, and stress of a serious, terminal illness.[64] These services include: (1) skilled nursing services; (2) drugs and biologicals for pain control and symptomatic management; (3) physical, occupational, and speech therapy; (4) counseling services; (5) home healthcare aide services; (6) short-term inpatient care; (7) inpatient respite care; and, (8) such other palliative services as may be required for the management of a terminal illness.[65] Accordingly, hospice providers may compete with short-term acute care hospitals, long-term acute care hospitals, skilled nursing facilities, and HHAs, all of which have the ability to offer certain hospice care services under their continuum of care.[66]

Technology

Technological advancements in DME and other home healthcare supplies, such as those related to infusion therapy, have increasingly allowed patients to receive medical care in their homes, rather than at an inpatient or outpatient facility. In addition, advancements in telemedicine have allowed for remote patient monitoring for conditions such as: (1) active heart monitoring; (2) blood pressure; (3) diabetes; (4) kidney disease; (4) prescription compliance; and, (5) sleep apnea, which have permitted more patients to remain in their homes unless a need for acute healthcare services arises.[67] CMS recently finalized a proposal to allow HHAs to report the cost of remote patient monitoring for Medicare beneficiaries, potentially encouraging more HHAs to adopt the technology.[68]

Additionally, equipment advancements have similarly enabled the provision of home-based treatments. Over the past decade, advances in dialysis techniques and machinery have allowed increasing numbers of *end-stage renal disease* (ESRD) patients to receive, or personally perform, home-based services. *Peritoneal dialysis*, which uses the lining of the patient's abdomen as a filter to clear wastes and extra fluids,[69] allows the ESRD beneficiary the luxury of receiving dialysis treatments at home or at work, without visiting an outpatient dialysis center.[70] Similarly, *hemodialysis*, i.e., the process of purifying the blood of a person whose kidneys are not working through a dialyzer (artificial kidney),[71] machines have evolved such that patients may receive this form of treatment in their homes through a machine similar to that found in outpatient

dialysis centers, but smaller and portable.[72] As home care services have come "*full circle*" as a prominent healthcare delivery avenue, and home healthcare providers are increasingly being viewed as a critical link in the array of patient-centered healthcare services aimed to bring care back into the community, technology will likely play an increasingly prominent role in managing patient populations in need of, and preferring, home healthcare services.

Conclusion

The value of home healthcare and hospice enterprises is significantly tied to the rapidly evolving U.S. healthcare industry, eminent in the modern era of U.S. healthcare reform. The ability of these providers to operate as a part of the *continuum of care* in this new VBR paradigm may determine their viability as an ongoing enterprise in the future. Part 2 of this series will discuss the unique value drivers that impact the typical valuation approaches, methods, and techniques that are often utilized in determining the value of home healthcare and hospice enterprises and providers in the current healthcare delivery system.

Home Healthcare and Hospice Enterprises: Fair Market Considerations - Part 2

[This is the final article in a two-part series regarding Home Healthcare and Hospice Enterprises. This installment was published in the April 25, 2019 issue of NACVA QuickRead.]

Introduction

As discussed in Part I of this two-part series on the *fair market value* (FMV) considerations of home health and hospice enterprises, *home healthcare enterprises* are those enterprises that coordinate the delivery of healthcare services to patients in their homes. There are three types of entities that typically fall under the umbrella of home healthcare: (1) *home healthcare enterprises*, which provide medical and supportive care; (2) *home care aide enterprises*, which provide non-medical care or custodial/non-meal care; and (3) *hospice enterprises*, which provide end-of-life care.[73]

The valuation of home healthcare and hospice enterprises and services are influenced by certain market forces related to the *Four Pillars of Healthcare Valuation*, i.e.: (1) *regulatory*; (2) *reimbursement*; (3) *competition*; and, (4) *technology* – each of which relates to almost all aspects of the U.S. healthcare delivery system. The first part of this two-part series on reviewed the unique value drivers that impact the typical valuation approaches, methods, and techniques that are often utilized in determining the value of these enterprises in the current healthcare delivery system. This second part will discuss the value drivers related to home healthcare and hospice enterprises.

Value Drivers: Home Healthcare Enterprises

Value drivers refer to specific factors that impact the valuation of a business. Similar to those of other outpatient enterprises, the *value drivers* identified for *home healthcare* and *hospice enterprises* are: (1) *Capacity*, (2) *Revenue Stream*, (3) *Payor Mix*, (4) *Operating Expenses*, (5) *Capital Structure*, (6) *Suppliers*, (7) *Market Rivalries and Competitors*, and (8) *Subject Entity Specific/Nonsystematic Risk.* Each of these are discussed in turn below.

Capacity

The *capacity* of a home healthcare enterprise differs from other types of outpatient enterprises, in that home healthcare services are not provided at a specific *facility*, but rather in a *patient's home.* Consequently, the requisite *due diligence* to ensure that the subject enterprise has *sufficient resources* to handle the projected *patient volumes* may require different considerations. Accordingly, capacity, as a *unit of measurement* for home healthcare enterprises, is typically based on labor metrics, e.g., the number of full-time equivalent (FTE) provider staff, and staffing mix (e.g., registered nurses, licensed practical nurses, home care aids, physical therapists, occupational therapists, social workers) to provide quality services efficiently and effectively to meet the available demand.

Revenue Stream

Reimbursement for home healthcare services is significantly limited by: (1) the *type of condition being treated*, (2) the *type of service being performed*, and (3) the source of payment. Accordingly, only certain *patient populations* are likely to generate a steady *revenue stream*, such as those patients who exhibit chronic health conditions. In addition, several services are reimbursed under *episode-based payments*, which use a different *unit of productivity*, i.e., the *episodes of care* (measured in 60-day episodes for Medicare reimbursements), than the metrics used for *other professional practices*, such as *work relative value units* (wRVUs) or *procedure volumes.*[74] Hospice services are available to terminally ill patients with less than six months to live, which may create challenges for the development of patient volume projections. Also, Medicare, which represents over 85% of the payor mix for hospice services, has payment caps in place that may impact the payments of the subject provider.

Although *home healthcare* is declining in certain geographic areas, total industry revenue is expected to rise to $122.6 billion in 2023, with an annual growth rate of 5.7% from 2018 to 2023.[75] The projected growth increase in the HHA industry, along with the current fragmentation in the industry, is expected to continue fueling consolidation within the home healthcare industry.[76] It should be noted that for *hospice enterprises*, for-profit entities typically experience significantly higher profitability than their not-for-profit counterparts (which may be taken into consideration as these entities seek alignment opportunities).[77]

Additionally, hospitals are referring *fee-for-service* (FFS) beneficiaries more frequently to home healthcare rather than to skilled nursing facilities.[78]

Secondly, the rise of value-based care and alternative payment models have reinforced the idea of treating patients in less costly settings.[79] For example, in those areas participating in the *Comprehensive Care for Joint Replacement* (CJR) program, hospitals would be incentivized to work with less costly home agencies in order to maximize the benefits of receiving a bundled payment.[80]

Payor Mix

Similar to that of most healthcare enterprises, the *payor mix* affects the *revenue* (and subsequent *net economic benefit*) generated by an HHA and is often a significant factor driving the *value* of a specific enterprise. Medicare remained the largest single payor of home healthcare services in 2017, paying for 40% of all home healthcare expenditures; Medicaid trailed closely behind, paying for just over 36% of expenditures.[81] Since commercial payors typically pay higher reimbursement rates than public payors, the ability of the subject enterprise to obtain reimbursement from these higher-paying sources may positively affect their revenue generating capabilities. However, because the demand for home healthcare services is typically driven by an older patient demographic, Medicare reimbursement will likely continue to be a major funding source for home healthcare enterprises.

Operating Expenses

Despite the growing demand for home healthcare services, the industry's average profit margin is expected to continue to decline, accounting for 7.2% of revenue in 2018.[82] Typically, the largest operating cost for home healthcare enterprises is staff costs, which include both *skilled labor*, e.g., physicians, nurses, social workers, chaplains, therapists, and counselors, and *unskilled labor*, such as nurse aides and home care aides.[83] Of those staff costs, the skilled labor component is usually the largest single expenditure.[84] Labor costs account for 52% of *home healthcare revenues*, in contrast to labor cost to revenue of 39.8% for the *entire healthcare industry*.[85]

Capital Structure

The implications of the capital structure decision for HHAs are similar to those of physician professional practices. These implications include: (1) the mix of debt and equity financing affects the *risk-adjusted required rate of return* for investment in the subject enterprise; (2) *debt financing* is typically cheaper than *equity financing*; and, (3) financing costs reflect the risks associated with each type of capital provided, e.g., debt financing typically considers the risk of the four Cs: **c**redit risk (default risk) of the borrower, **c**apacity of the borrower to make timely repayments of both principal and interest (short-term liquidity and interest coverage), **c**ollateral to cover the lender in case of borrower default, and an analysis of the **c**ovenants included in the indenture agreement.

HHAs are characterized by low capital needs (exceptions may include those HHAs offering home respiratory therapy services) and the personalized nature of the services provided. Due to the presence of publicly traded companies operating in the home healthcare industry, data and information pertaining to

the most probable capital structure of a home healthcare enterprise can be derived from normative industry benchmark survey data, as well as comparable publicly traded company data (with adjustments for the consideration of the specific enterprise's service offerings and operating characteristics). In addition, the capital structure can be determined through techniques such as the *iterative method*. Further, for the purpose of establishing the FMV of a business enterprise, it is important to use formulas based on *market values* of *equity* and *debt*, rather than *book values*.[86]

Suppliers

The *healthcare industry supply chain* may also have a significant impact on the economic operating cost burden incurred by an HHA, due to the amount of drugs, supplies and durable medical equipment (DME) required by the organization to generate the services provided by the subject home healthcare enterprise. Enterprises in general generate a significant amount of their *bargaining power* from their size, with larger enterprises being more likely to have greater *negotiating power* with vendors and suppliers, which may translate into *lower operating costs* and a greater *value* attributable to the enterprise.

Market Rivalries and Competitors

As discussed above, the home healthcare market is highly fragmented, with 90% of the industry consisting of sole proprietorships.[87] While concentration in the industry is currently low, consolidation has begun increasing, and is anticipated to continue.[88] Home healthcare providers differentiate themselves in the competitive landscape mainly on the basis of price (particularly for Medicare's Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program), quality of services offered and brand/reputation.

Of note, the *home infusion therapy* market is expected to be worth $25 billion by 2024, with a compound annual growth rate (CAGR) of 10% during the forecast period.[89] The industry employment of this industry is steadily declining as well as the number of businesses. Similarly, the *respiratory therapy* market is steadily declining, decreasing to an estimated 4,000 providers from 18,000 in 2008, due to the implementation of Medicare's competitive bidding that year.[90]

Subject Entity Specific/Nonsystematic Risk

In the determination of the adjustment for the specific risk premium for the interest in an HHA, a valuation analyst may, somewhat subjectively, consider the various risk factors that are inherent and specific to the enterprise being valued, as well as the enterprise's operational performance as compared to the industry benchmarks. Specific risk factors may include: (1) diversity of referral sources; (2) depth of management; (3) stability of business; (4) level of competition; (5) operational performance; (6) risk related to future changes in reimbursement, due to the contracting ability of the subject enterprise; (7)

diversity of payor mix and service offerings; and, (8) variance in availability of workforce in the market service area.

Other Pertinent Valuation Considerations

Table 1, below, illustrates some of the other pertinent considerations related to the valuation of HHAs:

Table 1: Other Pertinent Valuation Considerations for HHAs

Pertinent Considerations	Description
Operating Expense Structure	HHAs do not require the development of facilities for the provision of medical services and therefore have significantly different expense structures from other outpatient enterprises. *Human resource–related expenses* represent the greatest portion of a *home healthcare enterprise's* expenses, requiring greater scrutiny as to the *market value* of these services.
Capital Expenditures	HHAs typically have lower capital requirements than other, building-intensive, outpatient enterprises. *Home infusion* and *respiratory therapy* may require *greater* capital expenditures than other HHAs, related to the equipment necessary for the provision of these services.
Regulatory – Market Entrance Barriers	States may restrict or limit new home healthcare and hospice enterprises, or the expansion of service offerings by existing providers, through Certificate of Need (CON) legislation. Enterprises operating in CON States, may be more valuable (all else being equal) than enterprises operating in States that do not have CON, or less restrictive CON thresholds. The CON itself, may be a valuable asset and may be valued separately.

Applicability of Valuation Approaches

Each of the three recognized valuation approaches (i.e., income, market, and asset) may be applicable to the valuation of home healthcare and hospice enterprises. Careful considerations of the scope of the engagement, the level of value desired, and the availability of data and information should determine which approaches and methodologies to employ for the valuation of the enterprise.

Income approach based methods are commonly used and widely accepted for the valuation of home healthcare and hospice providers when the enterprise has achieved sufficient cash flow to provide a reasonable return on its assets. The

Discounted Cash Flow Method, if revenues, expenses and working capital needs can be projected with some degree of certainty, may be the most useful valuation method to employ for is allows the value drivers, specific to the subject provider, to be explicitly identified and modeled. Market approach based methods, while appropriate for the valuation of home healthcare and hospice enterprises, are more challenging to employ due to the difficulty in obtaining sufficient information regarding the comparable companies and transactions to make the necessary considerations and adjustments to apply to the subject provider being valued. Additionally, there are several large publicly traded home healthcare and hospice companies, which may, at a minimum, provide an understanding of the marketplace and value drivers from the perspective of the most likely buyers of HHAs, as well as provide a reasonableness test of other valuation approaches by calculating valuation multiplies of the guideline public companies. Asset approach based methods employed for the valuation of a going-concern home healthcare or hospice enterprise, may be useful, but may also fail to capture the entirety of the intangible asset value of the company, especially if the company is capable of producing significant economic benefits (i.e., profits).

Conclusion

There are unique value drivers that impact the typical valuation approaches, methods, and techniques that are often utilized in determining the value of home healthcare and hospice enterprises and providers in the current healthcare delivery system. The value of home healthcare and hospice enterprises is significantly tied to the rapidly evolving U.S. healthcare industry, eminent in the modern era of U.S. healthcare reform and government regulation. The ability of these providers to operate in a *continuum of care* in the new *value-based reimbursement* paradigm may determine their viability as an ongoing enterprise in the future. It is critical when valuing these enterprises that not only consideration be given to, but an understanding be had, of the *Four Pillars of Healthcare Valuation*, i.e.: (1) *regulatory*; (2) *reimbursement*; (3) *competition*; and, (4) *technology* – and their applicability to home healthcare and hospice enterprises within the U.S. healthcare delivery system.

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II. REIMBURSEMENT TOPICS

Value Based Reimbursement – Does It Work?

[Excerpted from the article published in October 2018.]

The 2010 *Patient Protection and Affordable Care Act* (ACA) accelerated the transition from traditional *fee-for-service* (FFS), *volume-based* reimbursement to *value-based reimbursement* (VBR), by introducing a variety of new initiatives and payment models.[1] Although the volume-to-value transition is now several years old, data regarding the effectiveness of these programs is still minimal, and the analyses of the data that is available often contradict each other. Two recent examples of VBR models include *accountable care organizations* (ACOs) and bundled payment models, such as the *Bundled Payment Care Improvement* (BPCI) *Initiative* and the *Comprehensive Care for Joint Replacement* (CJR) model, both of which models were recently examined as to their effectiveness in reducing healthcare spending.

Federal Accountable Care Organizations (ACOs)

ACOs are organizations which physicians, hospitals, and other providers voluntarily join, that seek to offer quality coordinated care and reduce spending.[2] In most ACO models (federal and commercial), when these entities succeed in both lowering cost growth and meeting quality performance standards, they are able to obtain some amount of shared savings from the payor, e.g., the *Centers for Medicare & Medicaid Services* (CMS).[3] Currently, *Medicare Shared Savings Program* (MSSP) ACOs are the largest type of this value-based model, with 561 organizations to date, serving 10.5 million Medicare beneficiaries.[4]

On August 9, 2018, CMS released a proposed overhaul of the current risk structure of MSSP ACOs, entitled *Pathways to Success Initiative*.[5] This comprehensive initiative would impose more accountability on ACOs, promote patient engagement, and incorporate new technology, among others.[6] Increased ACO accountability would be accomplished by decreasing the amount of time during which an ACO could participate in upside-only risk, from six to two years, and introducing down-side risk (i.e., shared losses) after those two years.[7] Shared savings incentives would also decrease from 50% to a maximum of 25%.[8]

CMS Administrator, Seema Verma, presented an analysis of ACO performance data as a basis for why the ACO risk structure should be overhauled, CMS's snapshot analysis of Track 1 ACOs in 2016 suggests that Medicare costs for these entities increased relative to their target costs,[9] indicating that upside-only ACOs (both physician-led and hospital-based) had a positive net impact, or increased costs for Medicare. In response, Seema Verma stated, "*Medicare cannot afford to support programs with weak incentives that do not deliver value*."[10] Supplementing the poor MSSP ACO outcomes data, CMS conducted projections of the *Pathways to Success*'s financial impact, estimating savings to Medicare of $2.2 billion over 10 years.[11] In contrast to MSSP ACOs, CMS's evaluation of Next Generation ACOs, which share 80-100% of financial risk,

showed a net reduction in Medicare spending, totaling $62.12 million in 2016.[12] This study demonstrates that ACOs can succeed in a downside risk model, providing the foundation for CMS's assertion that MSSP ACOs should increase risk after 2 years.

Reacting to the proposed structural changes to MSSP ACOs and calculations of federal spending by CMS, the *National Association of ACOs* (NAACO) released a study suggesting that there were considerably larger savings to Medicare federal spending than CMS analyses suggested. The NAACO study, conducted by Dobson Davanzo & Associates, found that MSSP ACOs saved Medicare $1.84 billion between 2013 and 2015, rather than the $954 million in savings reported by CMS.[13] After accounting for ACO bonuses, the NAACO study found that MSSP ACOs decreased federal spending by $542 million between 2013 and 2015 – this study stands in direct contrast to the estimated $344.2 million decrease in savings based on CMS's benchmarks.[14] Another peer-reviewed study by Harvard University researchers, similar to the NAACO study, indicated decreases to Medicare spending, wherein ACOs saved more the longer they participated in the MSSP.[15] This Harvard study also reported that the reduction in FFS spending was 39% greater than what was reported by CMS and net savings to Medicare was 2.8 times greater.[16]

While the CMS and NAACO studies both utilized the same set of data, the vast difference in their results is due to the analysis methodology. CMS utilized an administrative formula building off of the benchmarking used to set financial targets of the program,[17] while the NAACO study used the difference-in-differences regression,[18] which compared (a) changes in Medicare spending for ACOs before and after entry into the MSSP to (b) changes in spending by those not participating.[19] It is important to note that CMS used the difference-in-differences methodology in comparing both the Next Generation and Pioneer ACOs, but not the MSSP ACOs, commenting that the reason for using divergent methodologies in evaluating these ACOs and MSSP ACOs was established by the ACA, which contains different evaluation requirements than ACOs established by the CMS Innovation Center.[20]

In response to the CMS proposal, nine stakeholder groups, including the Medical Group Management Association (MGMA), America's Health Insurance Plans (AHIP), American Hospital Association (AHA), and American Medical Association (AMA), support the improvements made to the program, but urged CMS to acknowledge the potential unintended consequences. Most notably, CMS does not recognize the millions of dollars of an organization's own capital that is required to implement an ACO or acknowledge savings presented in other peer-reviewed studies using different methodologies, including the NAACO study. Furthermore, these stakeholders assert that the CMS proposal should be modified to: (a) allow more time for ACOs to be in the shared savings only model; and, (b) keep at least the current shared savings rate of 50%.[21] A separate survey conducted by NAACO found that over 71% of ACOs were more than likely to leave the program if faced with down-side financial risk in 2019.[22]

At this time, CMS has not responded to the results of the conflicting studies or stakeholder comments; however, there is an anticipated response after the 60 day comment period, which closed on October 16, 2018.[23]

Bundled Payments

In addition to the recent scrutiny related to the effectiveness of shared savings models, bundled payments have also been analyzed as to their success in achieving the aims of VBR. Bundled payment models take a different approach from ACOs in lowering costs and increasing value. The voluntary BPCI Initiative is intended to cut costs for an episode of care, by paying organizations a single "*bundled*" payment for that entire episode, encouraging care coordination and unnecessary utilization, because the provider would otherwise effectively lose money on the episode.[24] There are four (4) bundled payment models under the BPCI, each of which include different types of services in the associated bundled payment.[25] Model 1 of the BPCI (currently inactive) included only Medicare Part A inpatient hospital services, rendered during the episode of care, as part of those services to be reimbursed through the model's bundled payment.[26] Model 2 is the most heavily utilized, bundling payment for acute hospitals and up to 90 days of post-acute care.[27] Model 3 bundles payments for post-acute care, excluding acute inpatient hospital stays, and Model 4 is the only prospective payment, bundling acute inpatient hospital stay only.[28]

Early analysis on the BPCI Initiative suggested that bundled payments generate savings, with a 2016 study (which analyzed the first 21 months of the BPCI program) finding that payments declined approximately $1,166 more per *lower extremity joint replacement* (LEJR) episode when compared to non-participating hospitals.[29] The most recent CMS evaluation of BPCI Models 2 through 4 indicates that Medicare payments were reduced relative to the comparison group in BPCI using the difference-in-differences methodology.[30] However, after taking into account the average *net payment reconciliation amount* (NPRA) paid to participants, the Medicare program likely did not achieve savings for a vast majority of the clinical models.[31]

The CJR, another CMS bundled payment model that was originally mandatory in selected markets, was designed in order to determine whether LEJR bundled payments would succeed when implemented in different hospitals with diverse infrastructures and market composition.[32] An early study of the CJR program revealed that joint replacement surgery decreased total spending per episode by as much as 20% between July 2008 and June 2015 for 3,738 episodes of joint replacement without complications.[33] Additionally, a *Journal of the American Medical Association* (JAMA) study on the CJR model found that, in the first year, there were no significant differences in the admission of patients with lower risk; however, they also found that there were no significant changes in Medicare spending after bonus payments.[34] This lack of Medicare savings could be due to the fact that CJR was originally mandatory, incorporating organizations that were not prepared to handle the program, among other reasons.[35]

A major concern of these studies on the effectiveness of bundled payment models (CJR and BPCI) is that the savings are due to organizations by increasing the volume of episodes paid for by Medicare with lower risk patients and deterring higher risk patients[36] to attempt to increase their reimbursement, consequently "*padding the numbers*" of the study. A September 2018 JAMA study addressed this concern by measuring the market-level LEJR volume before and after the BPCI periods for hospitals.[37] Out of the over 1.7 million beneficiaries observed, it was determined that participation in the BPCI did not affect the case mix or case volume when using the adjusted difference-in-differences estimate.[38]

Despite the indeterminate and conflicting results of bundled payment savings, on January 9, 2018, CMS announced the new BCPI Advanced model, which builds upon the apparent successes the original BPCI Models.[39] BPCI Advanced will: (a) have a bundled period of only 90 days, rather than the choice of 30, 60, or 90 days provided in the original BPCI; (b) have a risk adjustment accounting for patient case mix of the benchmark price at which costs are measured; (c) increase risk from the start of the program; and, (d) link payment to quality measures, incorporating a value aspect.[40]

VBR methods have achieved increasing popularity among public and private payors in the healthcare industry, but their effectiveness is still indeterminate, despite both CMS and external studies on the topic. The data on these VBR models vary in relation to methods used and timeframe, rendering difficult any comparisons between the studies and their reliability. Regardless of their effectiveness, both ACOs and bundled payments remain active, new models are being introduced, and current models are being further modified, in an effort to hold healthcare providers accountable for both their spending and their quality of care.

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Drug Pricing Proposal Targets High Pharma Expenditures

[Excerpted from the article published in November 2018.]

On October 25, 2018, the Trump Administration released a proposed plan to modify the *Centers for Medicare & Medicaid Services* (CMS) Medicare Part B payment model in an effort to control pharmaceutical spending, employing an *International Pricing Index* (IPI) model in contrast to the current model (defined below).[1] Major concerns provoking the payment model adjustment include the considerable amount that Medicare spends on drugs, as well as the relatively low costs that other countries pay for the same drugs.[2] A CMS evaluation of Medicare spending from 2011 to 2016 indicated that *fee-for-service* (FFS) drug spending increased from $17.6 billion to $28 billion under Part B, a *compound annual growth rate* (CAGR) of 9.8%.[3] In addition, the *Department of Human and Health Services* (HHS) released a report that revealed drug prices to be approximately 80% higher in the U.S. compared to other nations for 27 of the most expensive physician-administered drugs.[4]

Due to these concerns, CMS released an *Advanced Notice of Proposed Rule Making* (ANPRM) regarding the details of the new model, with the goals of rebalancing the market power between the U.S. and other countries while encouraging manufacturers to cut down on "*foreign freeriding*."[5] This new model will be implemented through a five-year pilot program, projected to start in 2020, and will aim to:

(1) "*Reduce the price Medicare pays for a set of costly drugs to closer to what other countries pay.*
(2) Remove perverse incentives that encourage the prescribing of more expensive drugs.
(3) Reduce physician burden associated with 'buy and bill' by enabling private sector vendors to pay a larger role in the purchase and distribution of these drugs."[6]

This model will be mandatory for participants, incorporating 50% of eligible providers at the start of the pilot and gradually introducing other providers throughout the subsequent five years.[7] Mandatory model participants include physician practices and hospital outpatient departments (HOPDs); CMS is considering also incorporating *durable medical equipment* (DME) suppliers, *ambulatory surgery centers* (ASCs), and other Part B providers and suppliers in the future.[8] The five-year plan intends to test three new measures: the IPI model, a *Competitive Acquisition Program* (CAP), and *average sales price* (ASP) add-ons.[9]

The IPI model would create a Target Price that is 126% of the average price other countries pay for each drug, and this Target Price would be paid to providers that buy and bill for the drug, in contrast to the current payments for physician-administered drugs that are evaluated at the ASP in the U.S. market, with a price-based add-on fee.[10] This change is meant to reduce the high Part B spending compared to other countries and ensure that patients will receive fair

deals on the discounts that pharmaceutical companies voluntarily give other countries.[11]

In addition, the new plan would integrate a CAP that enlists private vendors to buy Part B drugs and supply them to physicians and hospitals.[12] This program intends to eliminate the financial risk under the current system, wherein physicians and hospitals take on the risk associated with buying and supplying drugs themselves.[13] With this program, the contracted private sector vendors would bill Medicare for administered drugs; providers would be able to compete to be a vendor under the program.[14] The intention of this private vendor practice is to create new competition through the vendors seeking volume-based discounts and competing for provider business.[15]

Lastly, in the proposed plan's ASP add-on model, providers would receive a flat fee for provider costs associated with drugs covered by this model in order to remove the current model's financial incentive to administer more expensive drugs, allowing patients to benefit from lower drug costs.[16] Currently, Medicare Part B pays physicians 6% in addition to the ASP, but that percentage is subject to the 2013 Budget Sequestration, which effectively reduces the add-on to 4.3%;[17] the new flat fee would more accurately reflect the 6% mark-up.[18] With the initiation of these measures in the pilot program, the Administration projects a savings of $17.2 billion over five years, and $50 billion over eight years.[19]

However, there are concerns with the strength of this plan due to the lack of effectiveness of, and opposition to, similar programs and proposals. In the *Medicare Modernization Act of 2003*, a similar voluntary (rather than mandatory) CAP was enacted.[20] This program had only a few participating physicians and only one company approved to be a CAP vendor, causing the early cancelation of this program and apprehension toward utilizing the program again.[21] However, HHS believes that the new CAP system will provide more incentives for participation, flexibility, and choice of vendors, due to the previous CAP being a voluntary program.[22] Further, in 2016, the Obama Administration proposed changes to the Medicare Part B payment model, but the proposal did not move forward, and was formally withdrawn by the Trump Administration due to opposition from stakeholders (i.e., physicians, patients, and the pharmaceutical industry).[23] This proposal utilized the current purchasing framework, rather than through private vendors in the Trump Administration's plan, while cutting the ASP add-on from 6% to 2.5% and providing an additional flat fee.[24] Although different from the proposed model, it is unclear whether the new proposal will succeed due to opposition from various stakeholders, mainly pharmaceutical companies and physician advocacy groups,[25] with patient advocacy groups yet to respond.

In the proposed program, pharmaceutical companies would receive lower Medicare Part B drug payments compared to the current model.[26] Stephen Ubl, Pharmaceutical Research and Manufacturers of America (PhRMA) president and CEO, believes that this model will discourage innovation in the pharmaceutical industry (i.e., research and development) and will ultimately be detrimental to patients.[27] The new model will include the shifting of cancer drug

and biologic payments (which take a considerable amount of time and financial resources to develop) to international prices.[28] In 2016, the biopharmaceutical industry invested $90 million in *research and development* (R&D), with biopharmaceutical drugs taking on average 10 to 15 years and $2.6 billion to develop.[29] Upon lowering Medicare prices paid in the U.S., profits for pharmaceutical companies would decrease, potentially reducing the incentive to invest in the considerable cost of R&D for innovative drugs. Despite this concern, R&D spending has stayed relatively the same while profits are continually increasing, suggesting that pharmaceutical companies will still profit even with reduced Part B spending.[30] In addition to reduction in innovation, Ubl also believes that reducing physician reimbursement and utilizing private vendors will limit patient access to medicines.[31]

In addition to concerns regarding the stifling of pharmaceutical innovation, there are also patient access concerns with this model. In the new model, pharmaceutical companies potentially may not sell their products to vendors at the new reference price, causing the drugs to be unavailable to consumers.[32] If pharmaceutical companies are unwilling to reduce prices, vendors may stop providing certain drugs, further exacerbating the access issue.[33] Although patient access could potentially be affected, patients will likely be benefited by reduced spending under this model. Medicare beneficiaries (without other coverage) pay a 20% coinsurance on physician-administered drugs; if drug prices were to be reduced, coinsurance payments will similarly decrease.[34] Consumers will save an estimated $3.4 billion in the first five years of this model through cost sharing.[35]

As mentioned above, the physicians and HOPDs that currently experience financial risk when purchasing, storing, and billing for drugs under Part B will be relieved of this duty and the associated risks in the new model. The current reimbursement (i.e., ASP add-on model) incentivizes physicians for using high cost drugs, contributing to out of control costs, while the new program will remove these incentives with a flat fee tied to storing and handling drugs rather than on drug prices.[36] However, the *Community Oncology Alliance* (COA) asserts that the incentive of reimbursement rates do not change oncologists' prescribing patterns.[37] In addition, the COA believes that the transition to private sector vendors will interfere with Medicare treatment in terms of quality, accuracy, and timeliness.[38] In contrast, the *American Hospital Association* (AHA) commends the model's focus on reducing drug prices that may be detrimental to both patient access and a physician's ability to deliver care.[39]

Overall, the Trump Administration's Medicare Part B proposal seeks to address concerns with the inflated drug expenditures relative to other countries. With the incorporation of the IPI model, the CAP, and the ASP add-on modifications, this proposal aims to decrease the costs of drugs while putting financial risk on private vendors rather than on physicians and HOPDs. Compared to past programs that incorporated similar measures, the success of this proposal remains uncertain. However, the ability of this program to succeed may largely

rely on the input of stakeholders to identify concerns and unintended consequences of the model during the comment period, which ends on Monday, December 31, 2018.[40]

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New State Innovation Waiver Guidance Increases Flexibility, Decreases Coverage

[Excerpted from the article published in November 2018.]

On October 22, 2018, the *Department of Treasury* and the *Department of Health and Human Services* (HHS) released new proposed guidance regarding Section 1332 of the *Patient Protection and Affordable Care Act* (ACA), allowing states more flexibility than previous guidelines to lower premiums and increase choices for their health insurance markets.[1] Section 1332, also known as a *State Innovation Waiver* or *State Relief and Empowerment Waiver*, permits a state to waive certain requirements of the ACA in order to pursue innovative strategies, with approval from the Secretaries of HHS and Treasury (Secretaries).[2] These waivers, under the current 2015 guidelines, must stay within the parameters of four statutory requirements (or "*guardrails*"):

(1) "Must provide coverage that is at least as comprehensive as would be provided absent the waiver;
(2) Must provide coverage and cost sharing protections against excessive out of pocket spending that are at least as affordable as would be provided absent the Waiver;
(3) Must provide coverage to at least a comparable number of residents as would be provided absent a Waiver;
(4) And must not increase the Federal deficit."[3]

While there are certain ACA provisions that may not be waived, those that can be waived include: Part I and Part II of Subtitle D of Title I of the ACA (regarding qualified health plans[4]); Section 1402 of the ACA (regarding cost sharing reductions[5]); and Sections 36B, 4980H, and 5000A of the *Internal Revenue Code* (regarding premium tax credits,[6] the Individual Mandate, and employer mandates).[7] State Innovation Waivers, under the current guidelines, have been available to states since the beginning of 2017, and thus far, eight states have had their waivers approved, the majority being for state-based reinsurance programs.[8] However, the *Centers for Medicare & Medicaid Services* (CMS) believes that the 2015 guidance is too strict to allow states to investigate innovative strategies and limits state waiver options to only one type (i.e., reinsurance waivers).[9]

The CMS Administrator, Seema Verma, asserts that "*state officials are far better positioned to address their state's health care challenges than the federal government*."[10] Verma elaborated that the ACA removed state regulatory power over health insurance and led to negative impacts on state insurance markets.[11] Most notably, according to Verma, once the ACA Exchanges were in full effect, health insurance companies began incurring considerable financial losses, resulting in insurers leaving the individual market and premiums rising for consumers, with average premiums sold through Healthcare.gov rising by 105%.[12] Moving forward, the new proposed guidance aims to increase state power by providing more options for healthcare consumers to receive coverage

and for states to improve their individual insurance markets and provide affordable coverage. The new guidance could allow states to expand options including *Association Health Plans* (AHP), allowing businesses to combine and buy health insurance for members, and *short-term, limited-duration insurance* (STLDI), which could be sold for up to a year or renewed for up to three years.[13] Both of these plans are not subject to the same ACA requirements in terms of eligibility and benefits, such as being able to exclude based on pre-existing conditions and not covering mental health or maternity coverage, contrasting with the previously set guardrails on plan comprehensiveness.[14] In addition to the proposed guidelines, CMS is also preparing Waiver Concepts to help states create ideas for innovative strategies and spur conversations to improve state healthcare markets.[15]

The revised guidance for states establishes five new principles for the state waivers:

(1) "Providing increased access to affordable private market coverage;
(2) Encouraging sustainable spending growth;
(3) Fostering state innovation;
(4) Supporting and empowering those in need;
(5) *And, promoting consumer-driven healthcare."*[16]

Along with these principles, the guidelines expand and differ from the current guardrails. As previously mentioned, a current guardrail is to "*provide coverage that is at least as comprehensive as would be provided absent the waiver*."[17] The new guidelines will allow states to provide options that are less than the "*minimum essential coverage*" under the ACA, including AHP and STLDI plans.[18] State departments will be able to evaluate comprehensiveness of their plans by comparing access to coverage under the waiver to the state-selected *essential health benefits* (EHB) benchmark for the plan year.[19] The Department of Treasury and HHS (Departments) stated that although the innovative coverage in some states might be potentially less comprehensive, the coverage could be better suited for consumer needs and attractive to residents.[20]

The new guidance interpretation will take into account comprehensiveness and affordability together, meaning that it will focus on the aggregate effects of the waiver to offset any detrimental effects on some residents.[21] To evaluate affordability, waivers that make coverage more available for some people while rendering coverage costly for a few will likely be acceptable criteria to meet the new guidance requirement, rather than requiring coverage to be at least as affordable without the waiver for everyone.[22] In addition, waivers will not focus on vulnerable populations as in the current guidelines; rather, they will focus on the comprehensiveness and affordability for the state residents as a whole.[23] However, states will need to include in their plan how they will support low income individuals and those with high expected costs.[24]

Previously, a comparable number of residents would need to purchase insurance under the waiver; however, with the new guidelines, waivers will be evaluated in terms of access to coverage, rather than the actual enrollment numbers.[25] As mentioned by CMS, this change will allow states to incorporate

different price points and benefit levels for health insurance coverage, affirming that this shift will still give state residents the option to retain coverage similar to the coverage the ACA outlines.[26] States will need to forecast for each year the number of those individuals that will have healthcare coverage and compare to those that would have had coverage without the waiver; but the Departments will consider private coverage (e.g., employer-based, individual market) in addition to public coverage.[27]

Although these changes grant states more flexibility, the new guidance still requires that the waiver not increase the federal deficit as stated in the 2015 guidance; however, a state's ten year budget plan can now increase the federal deficit in a given year as long as the overall waiver does not increase the federal deficit.[28] In addition to changes in the interpretation of the guardrails, changes have also been expressed in terms of funding and legislation requirements. Pass through funding by the Secretaries allows states to implement their waiver through federal money that would have been provided to state residents under ACA's financial assistance programs in absence of the waiver.[29] Within an application, a state must provide analysis to support the assistance amount, and the annual amount can now be updated to reflect modifications in state or federal law.[30] There is also increased flexibility on legislation; states will not have to adopt new legislation in order to implement the waiver and can now rely on existing law, duly-enacted state regulations, and state executive orders.[31]

The increased flexibility of the proposed guidelines may have significant implications for state insurance coverage. The ability to have a state waiver approved with less than the "*minimum essential coverage*" as stated in the ACA will likely increase the number of people with coverage, but through offering less comprehensive coverage.[32] Additionally, the lack of emphasis placed on vulnerable populations relative to the old guidelines will likely increase out-of-pocket costs and result in more coverage options that will exclude pre-existing conditions.[33] However, a press release by CMS asserts that people with pre-existing conditions will still be protected, though the method as to the protection remains uncertain.[34] In addition, more states may participate in State Relief and Empowerment Waivers now that new legislation does not need to be adopted to enact the waiver.[35] Although these new guidelines increase state flexibility to modify health insurance offerings, the application process is lengthy, and states will likely need more time to develop their programs.[36]

The new guardrails aim to increase flexibility for states to enact innovative strategies that were largely restricted to reinsurance programs in the previous guidelines. Along with a new set of principles, and a less strict interpretation of the guardrails, more state residents might have access to coverage, but that could mean coverage that is less comprehensive and more expensive for some individuals. The overall hope is that the new guardrails will allow more waivers to be approved and ultimately lower premiums in states; however, it is uncertain how these new guardrails affect the application process and the coverage of state residents.

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CMS Finalizes 2019 Physician & Outpatient Fee Schedules

[Excerpted from the article published in November 2018.]

In the course of twenty-four hours, the *Centers for Medicare & Medicaid Services* (CMS) finalized the calendar year (CY) 2019 *Medicare Physician Fee Schedule* (MPFS), the Hospital *Outpatient Prospective Payment System* (OPPS), and the *Ambulatory Surgical Center* (ASC) *Payment System*.

The finalized rules generally remained unchanged from their proposed versions, with a couple of exceptions. Each finalized rule is reviewed briefly below.

MPFS Final Rule Provisions

On November 1, 2018, CMS finalized the 2019 MPFS rule, which includes a number of changes to the payment system, and one noteworthy proposal that was not implemented.

CMS finalized the 2019 MPFS conversion factor at $36.04 (no change from the proposed rule), which it noted was a "*slight increase above the 2018 [M]PFS conversion factor of $35.99*."[1]

In its July 12, 2018 proposed rule, CMS sought comments on consolidating the current structure of *evaluation and management* (E/M) office visits, from five levels to two levels.[2] In its final rule, CMS delayed this significant change until CY 2021, while, in the interim, implementing a number of smaller changes to the documentation guidelines for E/M office visits. Part of CMS's reason for the delay was the strong negative reactions from industry stakeholders. As CMS admitted, "*Commenters largely objected to our proposal to eliminate payment differences for office/outpatient E/M visit levels 2 through 5 based on the level of visit complexity*."[3] Notably, CMS also did not finalize components of the E/M proposal that would have: "*(1) reduced payment when E/M office/outpatient visits are furnished on the same day as procedures, (2) established separate coding and payment for podiatric E/M visits, or (3) standardized the allocation of practice expense RVUs for the codes that describe these services.*"[4]

Regarding the updates to the *Merit-based Incentive Payment System* (MIPS), one of the ways in which providers can participate in the *Quality Payment Program* (QPP) established by the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA), CMS adjusted the weight of the categories upon which clinicians are scored. Specifically, CMS increased the weight of the MIPS *cost* category to 15% (previously 10%), while lowering the *quality* category weight to 45% (previously 50%).[5]

OPPS Final Rule Provisions

On November 2, 2018, CMS finalized the 2019 OPPS rule, which includes a number of notable changes to the payment system.

CMS finalized the OPPS payment rates by 1.35%, a slight increase from the proposed update of 1.25%,[6] which was based upon the 2% hospital market

basket increase, minus a 0.8 percentage point multifactor productivity (MFP) adjustment, and a statutorily-required 0.75 percentage point adjustment.[7]

One notable provision is the new requirement that payments for clinic visits conducted at off-campus HOPDs (i.e., those allowed to bill under OPPS) be made at the reduced rate applied to non-excepted off-campus HOPDs. CMS asserts that this will "*control unnecessary increases in the volume of covered [HOPD] services by applying [an MPFS] equivalent payment rate for the clinic visit service when provided at an off-campus [HOPD]…*," as well as reduce copayments for Medicare beneficiaries.[8]

As noted in the August issue of *Health Capital Topics*,[9] there is currently 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.[10] The 340B Program allows participating hospitals and providers to purchase certain covered outpatient drugs from the manufacturer at discounted prices.[11] 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.[12] Consequently, CMS finalized its proposal 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.

ASC Payment System Final Rule Provisions

The OPPS final rule also included provisions related to ASCs. Significantly, CMS finalized their proposal to change the index upon which it updates ASC payment rates, with the goal that it "*will help to promote 'site-neutrality' between hospitals and ASCs and encourage the migration of services from the hospital setting to the lower cost ASC setting*." [13] Historically, these rates were annually updated by the percentage increase in the *Consumer Price Index for all urban consumers* (CPI-U). However, starting 2019, CMS will update the ASC payment rates using the hospital market basket (through at least CY 2023), which it has historically used for updating HOPD payments.[14] For CY 2019, this results in an update to a payment rate update of 2.1%, based upon the 2.9% hospital market basket increase, minus the 0.8 percentage point MFP adjustment.[15]

Regarding the ASC Quality Reporting program, CMS had proposed removing eight measures from the program. Ultimately however, only two were removed:

(1) *ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel* (beginning CY 2020); and,
(2) *ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use* (beginning CY 2021).[16]

Forthcoming issues of *Health Capital Topics* will feature coverage of these payment systems, and their impact on the U.S. healthcare industry generally, as well as on the valuation of healthcare enterprises, assets, and services.

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Medicare Part D Proposed Rule Seeks to Lower Drug Spending

[Excerpted from the article published in December 2018.]

On November 26, 2018, the *Centers for Medicare & Medicaid Services* (CMS) issued a proposed rule regarding *Medicare Part D* and *Medicare Advantage* (MA) drug pricing with the intention of lowering high drug costs and reducing out-of-pocket spending for patients.[1] This proposal is consistent with the Trump Administration's *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (Blueprint) released earlier this year,[2] spurring the release of this proposal as well as other drug pricing proposals, such as the Medicare Part B international pricing index model[3] and the 340B prescription discount program (which final rule will take effect January 1, 2019).[4] The utilization of the proposed reform strategies set forth by the Blueprint, along with this proposed Part D and MA drug pricing rule, seeks to: *improve competition*; *increase negotiation*; *incentivize lower list prices*; and, *lower out-of-pocket costs.*[5]

This proposed rule is principally focused granting greater flexibility for plans as regards "*protected class*" drugs, i.e., classes of drugs that Part D plans are required to cover with limited exceptions.[6] This proposal was prompted in part by the challenges related to the rapidly increasing price of drugs in protected drug classes (antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics).[7] For example, Latuda®, a drug that more than 100,000 Medicare beneficiaries utilize, has increased in price by approximately 19% every year between 2013 and 2017, subsequently increasing costs for beneficiaries.[8] In addition, because Part D plans must cover all available products with very few exceptions, the nature of these protected classes results in Part D plans having limited ability to negotiate their pricing, allowing the pharmaceutical industry to raise their prices with minimal plan pushback.[9] For example, drugs in Part D protected classes have discounts of approximately 6%, while discounts for the same drugs in a typical private market are 20 to 30%.[10] These limited discounts result in increased costs for beneficiaries, and the new proposal attempts to mitigate these challenges for both the consumers and the plans. While the proposed rule keeps all six protected drug classes, it aims to increase flexibility for plans to negotiate discounts so that Part D consumers receive lower costs.[11]

In addition, the rule proposes three new exceptions for Part D plans to better manage the protected drug classes to lower drug costs for beneficiaries and payors.[12] The first exception would allow plan sponsors to "*implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indication*."[13] Under this exception, prior authorization would be necessary to determine whether a drug that has more than one intended use is being used for the protected class indication, regardless of its status as a new start or existing therapy.[14] Additionally, the exception utilizes a step therapy requirement (i.e., utilizing less expensive drug therapies

before transitioning into higher cost options), which applies only to new starts of medication, and must receive the approval of the plan's pharmacy and therapeutics committee, which CMS believes is a cost-effective utilization management tool.[15] For example, instead of starting a Medicare beneficiary on an expensive biologic, the beneficiary would start on a lower-cost biosimilar that could potentially be just as effective.[16]

The second exception would "*exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market.*"[17] For example, a manufacturer might introduce a more expensive, enhanced version of a drug while withdrawing the older, less expensive version from the market.[18] Under the current regulations, this leaves Part D plans with no option to add the new (more expensive) drug to their formularies, consequently raising costs for enrollees and Part D plans.[19] However, the exception would allow Part D insurers to remove coverage from new formulation drugs, regardless if the older version is still on the market.[20]

The third exception allows plans to "*exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.*"[21] This exclusion would allow Part D sponsors to exclude a protected class drug whose price increases (relative to the price in a baseline month and year) beyond the rate of inflation, utilizing calculations from the *Consumer Price Index for all Urban Consumers* (CPI-U).[22]

Partnership for Part D Access, which is comprised of patient advocacy groups, has expressed concern about the potential implications of these proposed changes, e.g., it may force beneficiaries to switch to less-costly, but potentially less-effective, drugs.[23] Other advocacy groups believe that utilization management practices already in place limit patient access and employing additional tools such as prior authorization and step therapy could further delay access to care.[24] The *Community Oncology Alliance* (COA) has also commented on the access issue, claiming that navigation through drug hurdles would be an unnecessary burden for beneficiaries and would delay cancer treatment, leading to potentially fatal consequences.[25]

In addition to the above provisions, the proposed rule contains less controversial measures. For example, Part D e-prescribing standards would be updated to increase the utilization of *Real Time Benefit Tools* (RTBT), requiring each Part D plan to implement one RTBT starting before or on January 1, 2020.[26] This tool would help inform prescribers whether there are less expensive therapy alternatives under a beneficiary's prescription drug benefit, potentially resulting in improved medication adherence and lower drug, as well as out-of-pocket, costs.[27] Part D explanations of benefits (EOB) sent to plan members would also be revised to include drug pricing information and lower cost therapeutic alternatives.[28] In addition, Part D sponsors would be restricted from prohibiting or penalizing pharmacies from disclosing a lower cash price to an enrollee to help lower out-of-pocket costs for beneficiaries (i.e., gag clauses).[29]

As currently defined, negotiated drug prices "*must include all pharmacy payment adjustments except those contingent amounts that cannot be 'reasonably be determined' at the point-of-sale*."[30] Due to this definition, negotiated prices often lack performance adjustments, as they typically occur after the point-of-sale.[31] As a result, CMS will potentially implement a policy that would consider the negotiated price "*as the baseline, or lowest possible payment to a pharmacy*."[32] Redefining this term would mean that the price would need to include all price concessions that could possibly flow from network pharmacies, as well as any dispensing fees, but exclude any additional contingent amounts.[33] CMS estimates that beneficiaries would save $7.1 to $9.2 billion over 10 years; however, the cost to the government over this time period would be approximately $13.6 to $16.6 billion due to the expected growth in Medicare's direct subsidies of plan premiums and low income premium subsidies.[34]

Under the proposed rule, MA plans would also implement prior authorization and step therapy for Part B (i.e., physician administered) drugs as a utilization management tool to better ensure low overall, or per unit, payments for Medicare beneficiaries.[35] The intended outcome for the utilization of step therapy would be increased savings, resulting in a decrease in MA premiums. However, similar to Part D step therapy, one concern is that this requirement would restrict access to medications.[36] However, CMS assures that there would be patient protections to guard against discriminatory practices, such as denying approval based on disease, with an expedited appeals process in place for when a physician recommends a medication exception.[37]

This proposed rule, which seeks to lower drug costs and reduce out-of-pocket spending for patients, is consistent with the aims articulated by the Trump Administration in the Blueprint and other drug pricing proposals released this year. This newest effort seeks to allow increased negotiation, mainly in Part D plans, for lower costs and inclusion of alternative therapies to beneficiaries. Although the intent is to lower drug costs, patient advocacy groups have expressed concern that some of the proposed changes could potentially limit patient access to more effective and beneficial drugs. The proposed rule is open for public comment until January 25, 2019.[38]

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Federal Agencies Recommend Policies to Increase Healthcare Competition

[Excerpted from the article published in December 2018.]

On December 3, 2018, the *U.S. Department of Health and Human Services* (HHS), as well as the Departments of *Treasury* and *Labor*, issued a report entitled, "*Reforming America's Healthcare System Through Choice and Competition*," resulting from an executive order that President Donald Trump issued over a year ago.[1] This 119-page report comprises more than 50 policy recommendations in an attempt to increase quality and decrease costs in healthcare.[2] In order to achieve the aims of increased competition and consumer choice, the agencies' recommendations center on free market principles and deregulation of the healthcare industry.[3] As stated in the forward of the report, although there have been numerous efforts to address regulations that limit these aims, there are still areas that largely inhibit choice and competition and thus require modification.[4]

The report asserts that healthcare competition has been suppressed due to the limited supply of providers and the restriction of the scope of services provided by non-physician clinicians.[5] In order to combat this lack of competition, which leads to higher healthcare prices and reduced choices,[6] the report endorses broadening the scope of practice for *advanced practice registered nurses* (APRNs), *physician assistants* (PAs), pharmacists, optometrists, and other highly trained professionals.[7] Recommendations include urging states to change their scope-of practice statutes to allow all healthcare providers to practice to the top of their license (i.e., to the full extent of their abilities, given their education, training, skills, and experience) and consider proposals to allow non-physician (e.g., APRNs and PAs) and non-dentist (e.g., hygienists and dental therapists) providers to independently treat patients.[8] In addition, the 2019 President's Budget proposed streamlining federal government funding toward a single graduate medical education grant program to address physician supply shortages, with the HHS Secretary having the authority to modify amounts to effectively allocate to hospitals based on the proportion of residents training in priority specialties.[9]

Currently, the supply of physicians in the U.S. has not kept pace with the demand for healthcare services. The gap may continue to increase as: the number of new entrants to the physician workforce remain insufficient to replace the number of physicians retiring; and, the drivers of demand (e.g., the aging *Baby Boomer* population) intensify.[10] The impact of broadening the scope of healthcare providers addressing physician supply shortages will impact business of healthcare organizations by increasing competition as more providers enter the market or increase their scope-of-practice, but also allowing these organizations to keep up with demand as the *Baby Boomer* generation ages. In reference to allowing non-physicians to practice independently, the *American Nurses Association* (ANA) commends the broader scope-of-practice statutes as APRNs tend to deliver high quality care with positive patient

outcomes.[11] However, healthcare organizations may want to consider how increased competition and an influx of new providers may affect their service line(s).

In addition to the shortage of providers that may stymy competition, the report also addresses state policies that restrict entry into healthcare provider markets, and create a barrier to choice and competition, leaving few incentives for providers to improve quality.[12] The report's primary recommendation is to encourage entry into markets through the repeal of restrictive *certificate of need* (CON) laws, which would affect the 35 states that currently maintain some form of CON program.[13] State CON laws generally require permission from a state (or state-authorized agency) before healthcare providers may construct new healthcare facilities, expand existing facilities, or offer certain healthcare services.[14] The report urges states to repeal or scale back CON laws, such as ensuring that competitors of CON applicants cannot weigh in or otherwise influence the application process.[15] These changes to CON laws are intended to encourage competition, as these policies: can restrict investments that may potentially benefit consumers and lower costs in the long term;[16] include a lengthy approval process; and, face third-party challenges, all of which increase costs to the government and providers, and serve as a significant barrier to entry in certain healthcare markets.[17] This deregulation would allow greater, and quicker, investments in needed healthcare services.

The *Patient Protection and Affordable Care Act* (ACA) continued restrictions on physician-owned hospitals by closing a loophole in the Stark Law's "*whole hospital*" exception, which had allowed physicians to refer to hospitals in which they had ownership interest as long as it was the whole hospital rather than just one service line or department.[18] In order to address the potential financial conflicts of interest with physicians referring patients to their own hospitals or only referring those who are healthy to their hospitals, the ACA limited the expansion of existing facilities without HHS Secretary approval and prohibited new physician-owned hospitals from participating in Medicare or Medicaid, a major source of revenue.[19] Previous research by Congress's independent *Medicare Payment Advisory Commission* (MedPAC) found evidence that physician-owned hospitals tend to take lower acuity and higher revenue cases.[20] However, a more recent study by the *British Medical Journal* contradicts that initial research, finding that "*although [physician-owned hospitals] POHs may treat slightly healthier patients, they do not seem to systematically select more profitable or less disadvantaged patients or provide lower value care*."[21] Supplementing this conclusion, a study by the *Journal of the American College of Surgeons* found that many physician-owned hospitals actually provide higher quality care.[22] Additionally, the *Centers for Medicare and Medicaid Services* (CMS) reported that approximately 40% of physician-owned hospitals as of 2015 had a 5-star rating on the *Five-Star Quality Rating System*, which is a tool to help consumers select and compare the quality of healthcare organizations.[23] As a recommendation, through the support of these studies, the report urges Congress to consider repealing ACA changes to the Stark Law that limited

physician-owned hospitals in order to increase choice for consumers and introduce more competition.[24]

As discussed in the October 2018 *Health Capital Topics* article entitled, "*DOJ Approves CVS-Aetna Merger*," healthcare consolidation is an ongoing trend and is changing the healthcare competitive landscape.[25] The agencies' report calls for improvements to the current *value-based reimbursement* (VBR) payment system, which system tends to increase consolidation within the industry.[26] *Accountable care organizations* (ACOs) and other *alternative payment models* (APMs) often encourage provider consolidation, as hospitals acquire physician practices (or merge with other hospitals) in order to amass the requisite resources to provide a full continuum of care, consequently raising healthcare prices and decreasing competition.[27] Increased consolidation is partly thought to be a response to the threat of new payment models in which larger health systems are better able to resist payor pressures to enter into risk-based contracts.[28] In addition, small practices or solo practitioners may accept buy-outs by hospitals and health systems in order to alleviate the financial and administrative demands of delivery reform, thereby limiting competition.[29] In May 2018, the *National Bureau of Economic Research* found that healthcare prices were 12.5% higher at hospitals without local competition than at those hospitals that have four or more competitors.[30] As a result, the report urges the delivery system to not harm smaller practices that often consolidate due to financial pressures of VBR models.[31] Further, the report recommends that these delivery system models foster collaboration (not consolidation), which could affect the future of some delivery models such as ACOs.[32]

The report also made certain recommendations related to health insurance, including measures to shift toward consumer-driven healthcare through the expanded utilization of *health savings accounts* (HSAs) and *health reimbursement arrangements* (HRAs). The expansion of HSAs and HRAs, according to the report, would improve consumer control and enable patients to shop for lower-cost healthcare.[33] The *Employers Council on Flexible Compensation* (ECFC), a nonprofit organization that promotes choice and benefit solutions, notes that it is a "*positive step for employers and American workers and advances healthcare consumerism offering additional choices*,"[34] and the *Council for Affordable Health Coverage* (CAHC) believes that HSA and HRA flexibility will improve cost transparency.[35] To supplement more consumer-driven healthcare, the report calls for an increase in price and quality transparency in order for consumers to make well-informed decisions.[36] Recommendations for facilitating price transparency include eliminating any federal policies that create unnecessary barriers to sector initiatives at various levels that provide price transparency.[37] The report elaborates that Congress, federal agencies, and state governments should be incentivizing providers to compete on price through reference pricing models in order to facilitate price transparency for consumers.[38]

In addition to these above recommendations, the report made a number of other policy suggestions, including:

(1) Loosening insurance rules and mandates;
(2) Reimbursing for telehealth services;
(3) Permitting interstate medical licenses;
(4) Implementing site-neutral payment policies;
(5) Facilitating price transparency;
(6) Standardizing and streamlining quality measures across programs;
(7) Relaxing network adequacy standards for Medicare Advantage; and,
(8) Scrutinizing any willing provider (AWP) laws.[39]

Overall, this report focuses on improving the U.S. healthcare delivery system by increasing healthcare competition and choice, which recommendations would have a significant impact on the operation of healthcare organizations. These recommendations address the physician manpower shortage, the impact of certain laws, and the purported harmful effects of consolidation. In addition, the report pushes consumer-driven healthcare through the employment of HRAs and HSAs. Although these recommendations could significantly change the healthcare landscape, when these recommendations might take effect, or if they will at all, remains unclear.

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National Healthcare Spending Slows for Second Straight Year

[Excerpted from the article published in January 2019.]

A recent analysis conducted by the Office of the Actuary at the *Centers for Medicare & Medicaid Services* (CMS) has found that, although healthcare spending rose to $3.5 trillion in 2017, the U.S. *national health expenditure* (NHE) growth rate slowed, declining from 4.8% in 2016 to 3.9% in 2017.[1] Of note, this is the second consecutive year that healthcare spending has slowed, reaching its lowest increase in growth since 2013.[2] This growth has been somewhat slower than the growth rate of the overall economy, which was 4.2% in 2017; however, healthcare spending was still a large percentage of the U.S. *gross domestic product* (GDP), at 17.9%.[3] According to the *CMS Forecast Summary*, from 2017 to 2026, growth rates are projected to rise at an increasing rate, effectively increasing the percent of GDP and total expenditures, and resulting in the U.S. continuing to be the highest spender on healthcare, compared to other high-income countries.[4] This *Health Capital Topics* article will review this CMS analysis, as well as the various healthcare spending components examined by the agency.

From 2009 to 2013, the NHE had record low rates, with 2013 seeing a 3.6% growth rate (often attributed to the poor economy during the *Great Recession*).[5] Transitioning into 2014, healthcare spending rose dramatically, largely due to retail prescription drugs, rising from a growth rate of 2.4% in 2013 to 12.2% in 2014.[6] The leading source of the high prescription expenditures was the introduction of *Sovaldi* and *Harvoni*, expensive treatments for Hepatitis C (a viral, chronic disease of the liver, affecting approximately 3 million Americans).[7] To quantify the effect of these treatments on NHE growth, sales of these treatments were approximately $12.3 billion higher in 2014 than in the previous year.[8] Additionally, the large hike in healthcare expenditures that occurred in 2014 was partly due to the impact of *Medicaid Expansion*, in those states that chose to expand Medicaid coverage, and the introduction of private health insurance Marketplace plans.[9] This expanded coverage effectively increased utilization of healthcare goods and services as those newly insured individuals sought out treatment that they had forgone when they were not covered by healthcare insurance.[10] Despite this high period of increased healthcare expenditures, the impacts of *Medicaid Expansion* and increase in Marketplace enrollment eventually started to slow after 2015, as the amount of newly enrolled individuals utilizing medical goods and services started to decline.[11] In addition, the considerable spending on Hepatitis C drugs declined in 2015, as those who took the new medications were cured (and thus ceased purchasing the drugs), effectively reducing the NHE rate back down to 4.8% in 2016.[12]

In 2017, growth rates stagnated more quickly than expected, as CMS initially projected a 4.6% growth rate of NHE for the year, rather than the 3.9% growth that was experienced.[13] The deceleration in spending growth was fundamentally due to a decrease in the use of hospital care, physician and

clinical services, and retail prescription drugs (the three largest categories for healthcare goods and services spending).[14] In 2017, there was a decrease in the residual use and intensity (i.e., utilization) of these goods and services, effectively decreasing from 2.1% in 2016 to 1.1% in 2017.[15] Likewise, both hospital care and physician and clinical services cost growth fell from 5.6% in 2016 to 4.6% and 4.2%, respectively.[16] A factor that likely contributed to the lower utilization and growth rate of services was the increase in the number of high-deductible health plans, which often shifts additional financial strain onto healthcare consumers, leading to a reduction in preventative and clinical visits.[17] In 2017, approximately 40% of Americans had high-deductible plans, compared to only 25% in 2010.[18] In addition, spending on retail prescription drugs dropped from 2.3% to 0.4% from 2016 to 2017.[19] This was the slowest rate of growth in retail prescription drugs since 2012,[20] and is due to the shift to lower-cost generic drugs and the decline in the volume of high-cost drugs.[21] Another significant factor in the decreased growth in retail prescriptions was the tightening of prescriptions written and dispensed, likely as a result of concern regarding the opioid epidemic.[22]

The two largest payors of total healthcare spending, the federal government (e.g., Medicare) and households (together responsible for 56% of total spending), had a decrease in expenditure growth in 2017.[23] Federal spending slowed for the third consecutive year, after an increase of 10.9% in 2014, to 3.2% in 2017, due to (as noted above) 10.2 million people gaining coverage through Medicaid and 8.7 million people gaining coverage through private health insurance as a result of the *Patient Protection and Affordable Care Act* (ACA).[24] Medicare spending grew 4.2% in 2017, minimally lower than the 4.3% growth rate in 2016; however, Medicaid spending decelerated more significantly in 2017 to 2.9% from 4.2% in 2016.[25] In previous years, Medicaid Expansion was funded entirely by the federal government; however, beginning in 2017, states were required to fund 5% of the associated costs, effectively lowering Medicaid expenditures for the federal government while increasing costs for the state and local governments.[26] In addition to federal spending, there was a deceleration in household spending, from a 4.8% growth in 2016 to an only 3.8% increase in 2017,[27] likely driven by the decreased growth in out-of-pocket spending.[28]

Under the current healthcare structure, spending is forecasted to grow at a rate of 5.5% each year, from 2017 to 2026, a more rapid rate than is currently occurring.[29] Healthcare spending is projected to grow 1% faster than the GDP per year during this period, rising from 17.9% in 2017 to 19.7% in 2026.[30] Under this projected growth model, NHE will total approximately $5.7 trillion by 2026.[31] This projected growth is based on economic and demographic factors such as the increase in prices for healthcare goods and services, and expenditures due to the aging population switching from commercial insurance to Medicare. In addition, this growth reflects the rise of incentive payments to physicians beginning in 2019 through the *Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015* (MACRA).[32] Further,

Medicaid will contribute to this expected growth due to an increasing projected rise in aged and disabled individuals.[33]

Despite this notable decrease in spending growth, the U.S. still spends significantly more per person on healthcare-related expenses compared to other countries, and approximately 31% more than the next highest per capita spender – Switzerland.[34] In addition, healthcare accounts for almost 18% of the U.S. GDP, while in other developed countries healthcare spending is 9.6% to 12.4% of GDP, indicating that the U.S. spends more on healthcare than other comparable income nations.[35] Despite the outsized spending of the U.S., health outcomes are lower than comparable countries, indicating deficiencies within the U.S. healthcare system.[36]

For the second straight year, the growth rate of NHE has slowed, dropping considerably from the large growth rate in 2014 and 2015 with the enactment of the ACA and introduction of Hepatitis C drugs. The decrease in NHE is largely due to an adjustment from the initial impact of the ACA, as well as a decrease in services utilized. However, in the future, projections expect total healthcare expenditures to continue to increase as prices increase, reaching approximately $5.7 trillion in 2026.[37] Although expenditures are projected to increase, the combination of various healthcare reforms may help to reduce NHE in the future. For example, the continued effort to lower pharmaceutical spending could reduce NHE, such as the proposed Medicare Part B payment model that would utilize an *International Pricing Index* (IPI).[38] Additionally, the increased implementation and modification of certain *value-based reimbursement* (VBR) initiatives could also play an impact in reducing NHE such as *accountable care organizations* (ACOs) and *bundled payment models*, moving away from traditional volume-based reimbursement. Nevertheless, healthcare spending may also be dependent on the state of the economy and healthcare advancements, which can effectively increase or decrease NHE, neutralizing the predictability of healthcare expenditures.

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Hospital Prices Drive Healthcare Spending

[Excerpted from the article published in February 2019.]

According to a newly-released *Health Affairs* article analyzing *Health Care Cost Institute* (HCCI) claims data between 2007 and 2014, hospital prices grew substantially faster than physician prices for total inpatient care and hospital-based outpatient care, as well as for four high-volume services: cesarean section, vaginal delivery, hospital-based outpatient colonoscopy, and knee replacement.[1] A recent *Health Capital Topics* article discussed the latest release of the *Centers for Medicare & Medicaid Services* (CMS) national health expenditures (NHE) growth analysis, which stated that spending for hospital care and physician and clinical services has slowed in 2017 compared to recent years.[2] The overall decrease in growth for hospital care was attributed to decreased utilization, largely due to the high costs of hospital care that put financial strain on healthcare consumers.[3] Although the overall spending growth rate has declined, hospitals will encounter policy measures seeking to tackle the high prices that decrease the utilization of hospital services. This *Health Capital Topics* article will examine the *Health Affairs* study, as well as the potential and already implemented policies addressing high healthcare prices.

During the 2007-2014 period, physician prices for inpatient care increased by 18%, faster than the 6% rate at which outpatient hospital care grew.[4] However, hospital prices grew significantly more than physician prices, increasing by 42% and 25% for inpatient and outpatient hospital care, respectively, over the same timeframe.[5] To quantify the difference, hospital prices increased more than twice as much for inpatient care than physician prices, and increased approximately four times as much for outpatient care.[6] For the high-volume services evaluated, physician prices rose from a range of 4.1% to 34.1%, while hospital facility prices rose from a range of 27.4% to 46.8%.[7] Additionally, the growth in facility prices (i.e., both hospital and physician fees) ranged from 77% for a colonoscopy to 97% for a knee replacement.[8] Further, physician prices have grown roughly at the pace of inflation, indicating that hospital prices are the true driver of healthcare costs.[9] This data suggest that physicians may not have as much bargaining leverage with insurers as hospitals.[10]

However, there has been backlash regarding the limitations of the *Health Affairs* study from the *American Hospital Association* (AHA). The AHA asserts that the study uses "*limited data to draw broad conclusions*."[11] These limitations include the HCCI data being restricted to individuals under the age of 65 whom are insured through *employer-sponsored insurance* (ESI), and only includes claims from three large insurers, representing only 27.6% of individuals with ESI coverage.[12] The AHA statement recalls the most recent analysis of NHE, which illustrates that price growth for hospital care services was just 1.7% in 2017.[13] Additionally, according to the Altarum Center for Value in Healthcare,[14] year-over-year hospital price growth was 1.7% during 2018.[15] The AHA notes that a major drawback to this study is the lack of regard

for costs that hospitals and health systems manage, and physicians do not occur, such as regulatory requirements.[16] These regulatory requirements often increase administrative and staffing expenses, with the average-sized community hospital spending $7.6 million per year to support compliance with federal regulations.[17]

Despite the limitations identified by the AHA, the *Health Affairs* study outlines possible causes and potential policies to address these causes. According to a recent PricewaterhouseCoopers report, healthcare mergers and acquisitions increased 14.4% in 2018 over 2017.[18] This trend is likely to continue through 2019, with *Catholic Health Initiatives* (CHI) and *Dignity Health* recently finalizing a merger that creates the largest nonprofit health system by revenue at approximately $29 billion, spanning 21 states.[19] Regardless of claims that consolidated organizations have larger economies of scale, and thus are able to offer better care and at lower costs, studies have indicated that consolidations lead to increased pricing due to more negotiation leverage,[20] as well as poorer healthcare outcomes (higher rates of mortality, higher readmission rates, etc.).[21] Because of the increasing the number of mergers and acquisitions, the *Health Affairs* article suggests that increased antitrust enforcement may address the growth in spending by preventing harmful consolidations that would dominate the market.[22]

In terms of vertical integration (i.e., the combination of separate sections in the supply chain of an industry),[23] recent studies have found that referring physicians have influence on where their patients receive care, and vertically integrated physicians often refer their patients to more expensive locations.[24] Therefore, payors should incentivize physicians to refer patients to hospitals that deliver the most efficient care.[25] Finally, the study suggests policies that would regulate hospital payments in markets that are already highly concentrated or practice reference pricing to lower rates.[26] An example of this type of regulation would be instituting a policy that would set inpatient prices at 120% of Medicare rates, which is estimated to lower private spending by 20% if implemented.[27]

Some states have already taken unilateral measures to decrease hospital prices. In California, a bill introduced in February of 2018 proposes to allow state officials to regulate hospital and physician prices in the commercial healthcare market.[28] This bill would "*establish a commission that would set rates for healthcare services based off what the government pays for such services under Medicare.*"[29] This proposal is similar to the Maryland model, wherein the state sets the prices paid by all payors for hospital services.[30]

The Trump Administration has also implemented policies that may curb this growth through price transparency, which has the potential to drive consumers to lower priced care, subsequently forcing hospitals to reduce their prices in order to compete. Effective January 1, 2019, hospitals are required to post their charge master online, in a machine-readable format, as a first step in CMS's price transparency effort.[31] From a *Kaiser Health News* analysis, prices varied greatly on basic procedures, even when comparing hospitals close in proximity;

some hospital procedure prices were seven times as much as other hospitals in the area.[32] As the hospital industry becomes more transparent, patients will be able to more efficiently "*shop*" for healthcare, and drive prices down.

However, this transparency policy, in its current format, is difficult to understand for shopping patients, as the charge master has codes and medical terms that may be hard to interpret for the consumer and does not account for any amounts that may be paid by the patient's respective insurance coverage.[33] Additionally, these lists may be difficult to find on a hospital's website, hindering a patient's ability to research and compare prices.[34] To mitigate patient confusion, some hospitals have calculators to estimate healthcare costs by inserting patient information (e.g., insurance policy number, demographics) to receive a more accurate estimate based on the hospital's charge master list.[35] The Trump Administration will likely continue to address this price transparency policy's inefficiencies through supplementary changes, in order to achieve the level of transparency needed for a patient to make an informed decision.

As demonstrated in the *Health Affairs* study, hospital prices have increased rapidly over the years, faster than the rate of physician prices, causing various policy changes with the aim of targeting high healthcare prices. As a result, hospitals will be under increased pressure to accommodate these new policies and undertake further efforts to decrease prices. Further, hospitals seeking to merge may be under increased scrutiny, as studies continue to show that highly concentrated markets lead to increased spending and poorer outcomes. Although there is debate on whether or not hospital prices are the true driver in the growth of spending, hospitals should expect increased regulation in the future in attempts to lower the cost of care.

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MedPAC Recommends Raising Hospital Payments

[Excerpted from the article published in March 2019.]

On March 15, 2019, the *Medicare Payment Advisory Commission* (MedPAC), an entity established by the *Balanced Budget Act of 1997* to assist the U.S. Congress in evaluating various Medicare program issues, released the 2019 edition of its annual *Report to Congress: Medicare Payment Policy*.[1] The report identifies issues and presents recommendations to Congress that are aimed at providing high-quality care to Medicare beneficiaries while helping to control Medicare spending.[2] The majority of these recommendations involve reimbursement rate changes for providers paid under *fee-for-service* (FFS) Medicare, in which modifications are expressed as a percentage change in base payment relative to the prior year.[3] For 2020, MedPAC recommends positive payment updates for hospitals, *long-term care hospitals* (LTCHs), and dialysis centers; zero updates for physicians, *skilled nursing facilities* (SNFs), and *ambulatory surgical centers* (ASCs); and, negative updates for *home health agencies* (HHAs), *inpatient rehabilitation facilities* (IRFs), and hospice agencies.[4]

Hospital Medicare margins for both inpatient and outpatient services tend to be negative (i.e., costs are greater than reimbursement); margins were approximately -9.9% in 2017, and industry experts project these margins to decrease to -11.0% in 2019.[5] Historically, MedPAC has not recommended a positive payment update for hospitals; however, in light of high-quality hospitals losing money under Medicare, MedPAC is recommending a payment increase.[6] In 2017, there were 291 highly-efficient hospitals, i.e., low cost and high quality, with Medicare margins that were negative (-2.0%), despite their efficiency.[7] As a result, MedPAC recommends increasing payments to hospitals by 2.0%, to counteract the negative margins.[8]

MedPAC also recommends an additional 0.8% payment increase to hospitals (resulting in a total payment increase of 2.8%) to fund a new proposed quality program, the *Hospital Value Incentive Program* (HVIP), which would consolidate four exiting programs.[9] The proposed quality program that MedPAC Commissioners approved in January 2019 would merge: the *Hospital Inpatient Quality Reporting Program* (IQRP), the *Hospital Readmissions Reduction Program* (HRRP), the *Hospital-Acquired Condition Reduction Program* (HACRP), and the *Hospital Value-Based Purchasing* Program (VBP).[10]

Through the elimination of two penalty-only programs, i.e., HRRP and HACRP, the proposed quality program would eradicate approximately $1 billion in overall hospital penalties per year.[11] The proposed quality program considers the overlapping reporting measures that hospitals currently face through the four payment programs, and the belief that some of the reported measures in these programs are not appropriate to assess hospital performance.[12] The HVIP would set standards to assess hospital performance in order to determine incentive payments or penalties upon comparing a

hospital to its respective peer group.[13] This proposed program would be patient-centric, focus on population-based outcomes, and encourage coordination of care, measuring five domains administered by the *Centers for Medicare and Medicaid Services* (CMS), including mortality, readmissions, *Medicare spending per beneficiary* (MSPB), patient experience, and hospital acquired conditions.[14] Further, MedPAC believes that HVIP would reduce the administrative burden for hospitals and would be easier to administer.[15]

Beyond the 2.8% hospital inpatient and outpatient services payment adjustment, for year 2020, MedPAC recommends that Congress:

(1) Increase the LTCH base payment rate by 2.0%;
(2) Increase outpatient dialysis services *prospective payment system* (PPS) base rate by the amount determined under current law (1.9%);
(3) Maintain the current base rate for SNFs (MedPAC also recommends that Congress revise the entire SNF PPS);
(4) Maintain the current base rate for physician and other health professional services;
(5) Maintain the current payment rate for ASCs, as well as urge the Secretary of *Health and Human Services* (HHS) to collect cost data from ASCs – without this data, MedPAC cannot adequately calculate a Medicare margin as they do for other provider types in order to assess payment adequacy;
(6) Reduce the HHA PPS base payment rate by 5.0%;
(7) Reduce the IRF PPS base payment rate by 5.0%; and,
(8) Reduce hospice payment rates by 2.0%.[16]

Additionally, in order to "*cross-cut*" issues in *post-acute care* (PAC) providers, i.e., SNFs, HHAs, IRFs, and LTCHs, MedPAC has long promoted a uniform payment system for all PAC providers to increase equity of payments in these settings.[17] MedPAC believes that the current separate FFS payment systems for different PAC providers may not align costs and payments, reducing payment accuracy.[18] In three of the four PAC settings (SNF, HHA, and IRF), Medicare payments are extremely high relative to the costs of treating beneficiaries, and has created inequities among patients with different healthcare needs.[19] There are currently overpayments to these facilities, and MedPAC has expressed concern about the accuracy and reliability of the information given on provider-reported quality measures.[20] Unifying the PAC payment system is projected to mitigate these overpayment concerns and increase the equity of payments across PAC settings.

Overall, MedPAC's recommendations have a significant influence on Medicare updates and changes.[21] However, it is important to note that these are only recommendations; MedPAC's analysis has to be sufficiently compelling for Congress to move forward with the recommendations.[22] For example, MedPAC has recommended reductions in HHA payment in the past, calling for a 5.0% reduction to HHA payments in 2020, which would lower home health spending by $750 million to $2 billion in 2020.[23] However, CMS has instead increased funding for these services, finalizing a 2.2% increase in payment to HHAs in

2019.[24] Although it is unclear whether these recommended reductions will occur in 2020, the HHA payment increase in 2019 indicates that CMS and HHS may choose to proceed in contradiction to MedPAC recommendations.

As healthcare spending keeps increasing, MedPAC will continue to scrutinize Medicare spending inefficiencies, in order for the Medicare program to have greater fiscal sustainability.[25] Going forward, the aging *Baby Boomer* generation will continue to influence the Medicare program, as well as the taxpayers who finance it.[26] Over the next 15 years, Medicare enrollment will surge; however, the number of tax paying workers is projected to decline over the same timeframe.[27] These forces create a critical financing challenge for Medicare, the entire federal budget, and, in turn, healthcare organizations, which may potentially face further reductions in Medicare payments as the federal government seeks to decrease federal spending and implements initiatives to combat current incentives to provide high-cost care.[28] In response, healthcare entities may pursue precautionary steps to ensure that their services are not only high-quality, but highly-efficient, in order to survive (and thrive) in this most recent era of healthcare reform.

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CMS Releases ET3 Pilot Model

[Excerpted from the article published in March 2019.]

On February 14, 2019, the *Centers for Medicare & Medicaid Services* (CMS) announced a new voluntary *Emergency Triage, Treat, and Transport* (ET3) payment pilot model, granting ambulance teams greater flexibility when addressing 911 initiated emergency calls for Medicare *fee-for-service* (FFS) beneficiaries.[1] The number of costly *emergency department* (ED) visits has been gradually increasing for decades, causing healthcare spending concerns;[2] in 2015, there were approximately 136.9 million ED visits, 15.6% of which visits were by those aged 65 and older.[3] As a response to the high ED utilization, most private insurance plans and select Medicaid programs discourage costly ED use through methods such as imposing higher copays or refusing to pay if the condition does not meet the definition of an "*emergency*."[4] However, under current policies, Medicare only pays for emergency ground ambulance services to hospitals, critical access hospitals, skilled nursing facilities, and dialysis centers, with no incentive for transporting non-emergent patients to lower cost care.[5] Due to this payment constraint, ambulances are funneling patients to high cost settings, i.e., hospital EDs, even when a less expensive, more appropriate alternative may be available, effectively increasing Medicare (and overall healthcare) expenditures.[6] This *Health Capital Topics* article will discuss the various aspects of the ET3 model, as well as the implications for the *emergency medical services* (EMS) system and other healthcare organizations.

The ET3 model aims to limit the incentive for emergency ambulance teams to transport Medicare FFS beneficiaries only to covered Medicare facilities, e.g., hospital EDs, by making it possible for the participating ambulance suppliers and providers to partner with qualified healthcare practitioners, i.e., individuals qualified by education, training, etc. to perform a healthcare service within their scope of practice,[7] and be reimbursed for that treatment through two new types of ambulance payments.[8] In addition to the traditional hospital ED transport payment, the ambulance team would also receive payment for transporting beneficiaries to alternative destination sites (e.g., primary care physician offices or urgent care clinics) and for treatment with a qualified healthcare practitioner in place (for services either rendered on the scene or through telehealth services).[9] In addition to allowing payment to these alternative destinations/treatments, the model will enable participating ambulance suppliers and providers to earn up to a 5% positive payment adjustment based on the achievement of certain quality measures in later years.[10] Although there is limited information regarding the quality component, the quality measurements strategy intends to minimize new reporting requirements to reduce participant burden.[11] However, both qualified healthcare practitioners and alternative site destinations will receive their usual Medicare payment for services provided.[12]

Additionally, this model seeks to develop triage lines for low-acuity 911 calls wherein the dispatch system would screen patients based on their needs.[13]

Either an ambulance ride would be initiated, to triage the individual through ET3 interventions based on their condition, or the individual would stay on the phone, and be transferred to discuss their health concerns with a healthcare professional via a medical triage line.[14] Of note, a beneficiary is still able to override a first responder's decision and choose to be brought to an ED.[15] While the ET3 system is limited to Medicare FFS beneficiaries, CMS encourages a multi-payor alignment strategy, supporting model participants in their partnerships with additional payors to provide similar interventions to all patients (and not just Medicare beneficiaries) within the locality.[16] CMS intends to issue 40 two-year cooperative agreements, available to local governments or other relevant entities, in the participating geographic areas in order to establish medical triage lines; this would allow 911 dispatch to evaluate whether a patient's condition is appropriate for a medical triage line instead of an ambulance transport.[17]

Through the ET3 model's aim of engaging healthcare providers across the continuum of care to meet beneficiaries' needs, overall spending is projected to decrease, as a result of avoiding unnecessary transports and additional downstream costs. A whitepaper released by the U.S. Departments of *Health and Human Services* (HHS*)* and Transportation reported that Medicare could save approximately $560 million per year by transporting patients to physician offices, rather than always transferring individuals to a hospital ED.[18] In addition, avoided hospitalizations from unnecessary ED transports may provide further savings and quality improvements.[19] CMS estimates that up to 19% of FFS beneficiaries could be treated at the alternative destinations, allowing beneficiaries to decrease their out-of-pocket costs, rather than paying for expensive ED visits.[20] Beneficiaries choosing these alternative destinations will be able to avoid hours spent waiting in the ED, avoid the costs associated with unnecessary hospitalization, and mitigate exposure to hospital acquired conditions.[21]

CMS Administrator, Seema Verma, believes that "*[t]his model will help make how we pay for care more patient-centric by supporting care in more appropriate settings while saving emergency medical services providers precious time and resources to respond to more serious cases*." CMS estimates that average treatment time per patient would be reduced by 45 minutes through the utilization of this model, saving first responders approximately 50 million minutes per year.[22] As a result, this system will enable EMS to more quickly respond to higher acuity cases, e.g., heart attacks, as a few minutes may make a significant difference in patient outcomes.[23]

General healthcare and EMS industry leaders, including leaders those of the *American Medical Association* (AMA) and the *National Association of EMS Physicians* (NAEMSP), are in strong support of the ET3 model.[24] EMS leaders are especially supportive, due to the model's potential to increase patient quality and optimize outcomes; however, they recognize that the EMS system will need to forge new relationships and change the structure of their current relationships, in order for the program to be successful.[25] EMS leaders in

participating areas will need to effectively locate alternative treatment destinations to which they will direct patients, as well as establish effective triage systems.[26] Currently, many EMS jurisdictions do not allow ambulances to transport from an uncontrolled environment to anywhere except an approved ED.[27] State and local EMS authorities will need to alter protocol and policy in order to allow providers to transport to alternative destinations or provide non-transport services in order to guard against liability.[28] In addition, leaders will need to inform *emergency medical technicians* (EMTs) on the new protocol and methods on how to appropriately *triage, treat, and transport* patients to alternative destinations in order to ensure success of the system.[29]

The ET3 model reflects the ongoing push toward value-based care. Because the model does not seem to carry any downside financial risk, participation may increase in areas across the U.S., expanding the overall impact of the model. However, because the model is voluntary, local governments and other entities that have authority over the EMS system,[30] particularly those without strong infrastructures, may choose to not participate, limiting the overall assessment of this model in different areas. Regardless, with the implementation of the ET3 model, especially with the inclusion of the multi-payor strategy, hospitals may experience decreased ED revenues, but gain more efficiency. With fewer low-acuity patients, more hospital beds will be available for high-acuity patients, offering faster treatment and improved outcomes. In addition, there may be decreased ED wait times, which will likely increase patient satisfaction and reduce the number of those left without being seen in the ED. Other alternative destination organizations may also benefit from the ET3 model, as they would receive a greater influx of patients and higher utilization of their services. Ultimately, healthcare costs will likely decrease as a result of reducing of unnecessary ED visits, providing benefits to healthcare organizations, e.g., the ability to more efficiently utilize resources.

The ET3 pilot is expected to run from January 1, 2020 to December 31, 2024, with staggered performance start dates in order to maximize participation in different U.S. localities.[31] This model aims to improve healthcare quality and lower cost by reducing avoidable transports to the ED, and, consequently, unnecessary hospitalizations. However, despite the focus on FFS Medicare beneficiaries, this model may serve to change the U.S. healthcare delivery system through multi-payor participation, ultimately reducing healthcare expenditures across the board.

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CMS Announces New Primary Care Reimbursement Model

[Excerpted from the article published in May 2019.]

On April 22, 2019, the Secretary of the *U.S. Department of Health and Human Services* (HHS), Alex Azar, and the Administrator for the *Centers of Medicare and Medicaid Services* (CMS), Seema Verma, announced a new system of payment models related to primary care reimbursement.[1] The purpose of this new payment model system is to shift the focus of patient care from *volume*-based to *value*-based care, and to emphasize the importance of primary care's role in the U.S. healthcare system. This new primary care initiative consists of two paths: *Primary Care First* (PCF) and *Direct Contracting* (DC). PCF, which will begin in 2020, consists of two payment models, i.e., PCF and PCF for high need populations.[2] DC, which will begin a year later, in 2021, consists of three payment models, i.e., Global, Professional, and Geographic.[3]

Currently, most primary care providers who provide services to Medicare beneficiaries are paid through the *Medicare Physician Fee Schedule* (MPFS).[4] The MPFS provides payment for more than 10,000 physician services.[5] The fee schedule gives the fee maximums used by Medicare to pay physicians and other enrolled healthcare professionals on a *fee-for-service* (FFS) basis.[6] Medicare bases its payment on the *relative value units* (RVUs) of the specific procedure, which encompasses the work, practice expense, and malpractice RVUs.[7] The pricing amounts for each provider are then modified based on a physician's location, under the *geographic practice cost index* (GPCI).[8] Ultimately, Medicare's payment amount for a given procedure is either the charge for the procedure or the MPFS amount, whichever is less.[9]

While the MPFS is used generally as the primary method of reimbursing primary care physicians, it has been utilized in newer payment models as well, including the *Comprehensive Primary Care Plus* (CPC+) program, which was commenced in January 2017.[10] This model was used as a basis for the new PCF and DC models. [11] The CPC+ program is a national primary care medical home model with the main purpose of bolstering the primary care field through a regionally-based multi-payor payment reform and care delivery transformation.[12] CPC+ includes three payment models: *Care Management Fee* (CMF); *Performance-Based Incentive Payment*; and, payment under the MPFS.[13] The program is comprised of two tracks, both of which are based on a practice's readiness for transformation, a key element of such newer primary care payment models.[14] Track 1 focuses on the shift to value-based care and supports comprehensive care.[15] Track 2 focuses on advanced care and the patients' needs.[16] Between Track 1 and Track 2, the requirements for Track 2 illustrate the goals of CMS to strengthen the primary care field, as it requires a practice to develop and record care plans, follow up with patients after hospital discharge, and implement a process to link patients to community-based resources.[17]

The first annual report regarding the results of CPC+ was released on April 22, 2019.[18] Results indicate that since CPC+ began in 2017, there have been more

than 15 million patients served.[19] In the first year, the median practices enrolled in CPC+ received significant financial support.[20] During 2018, Track 1 practices received a total of $88,000 ($32,000 per practitioner on average) in care management fees, and Track 2 practices received a total of $195,000 ($53,000 per practitioner on average) in care management fees.[21] The *care management fee* is a non-visit based fee paid per beneficiary per month.[22] However, CPC+ did not have a profound effect on Medicare FFS beneficiaries.[23] Even with the enhanced CPC+ payments, there were insignificant differences in service use and quality-of-care outcomes between the practices that did not participate in CPC+ and the practices that did participate in CPC+.[24] In fact, there was an actual 2-3% increase in expenditures for Medicare FFS beneficiaries in CPC+ practices that included the enhanced payments.[25]

The PCF Model and DC Model seek to build upon the benefits and drawbacks indicated in the CPC+ first year results. The PCF Model seeks to transform current primary care models and continue to push the system toward a regionally-based, multi-payor approach to care delivery and payment. Specific regions are designated for the PCF Model, which allows it to be considered more regionally-based.[26] This program will reward physicians for higher performance and alleviates administrative burdens that might affect quality of care.[27] The voluntary PCF Model is geared toward advanced primary care practices and seeks to remove from clinicians the financial risks that they face from administrative drains and provide more performance-based payments.[28] As noted above, there will be two PCF payment model options (five years in length), which will be offered in 26 regions for the first performance year.[29] The first model will be for physicians treating general populations, and the second model will be for physicians treating high need populations.[30] With both PCF payment model options, Medicare will pay a risk-adjusted professional population-based payment with a flat primary care fee visit.[31] In the first model, those practices that achieve high performance based on relative actionable outcomes such as high blood pressure, maintaining diabetes, and prevention screenings will be rewarded.[32] The second model is more focused on *Seriously Ill Populations* (SIPs) and will encourage clinicians to provide hospice and palliative care to those seriously ill Medicare beneficiaries who do not have a primary care provider; the payments under this model "*will be set to reflect the high need, high risk nature of the population as well as include an increase or decrease in payment based on quality*."[33]

In contrast to PCF, the DC Model has three payment models, with the main aims of reducing expenditures and preserving or enhancing the quality of care for Medicare beneficiaries.[34] The three payment models include: *Global*, *Professional*, and *Geographic*.[35] The *Global Model* offers the highest risk sharing arrangement (100% savings/losses) and offers two payment options:

(1) *Primary Care Capitation* – A capitated, risk-adjusted monthly payment for enhanced primary care services; or,

(2) *Total Care Capitation* – A capitated, risk-adjusted monthly payment for all services provided by the program participants and preferred providers.[36]

The *Professional Model* offers a lower risk-sharing arrangement (50% savings/losses) and provides *Primary Care Capitation*, a capitated, risk-adjusted monthly payment for enhanced primary care services equal to 7% of the total cost of care for enhanced primary care services.[37]

CMS is still seeking input for the *Geographic Model*, which will provide a similar risk level as the *Global Model*, but its potential participants will take responsibility for total cost of care of all Medicare FFS beneficiaries in a defined target region.[38]

These PCF and DC models will seek to transform the current risk-sharing agreements in place and expedite the transition away from the traditional FFS payments and toward *value-based reimbursement*. The main goals for this these models are to help empower beneficiaries and reduce provider burden.[39] This is yet another step in the ongoing transformation of the U.S. healthcare delivery system, from a *volume-based* system to a *value-based* system, and is not likely to be the last. While CMS's payment model initiatives have largely been voluntary for providers to date, CMS Administrator Verma has affirmed that CMS plans to establish mandatory payment models in order to "*help[CMS] understand the impact of our models on a variety of provider types, so the data resulting from the model will be more broadly representative*."[40]

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CMS Proposes IPPS Updates for 2020

[Excerpted from the article published in May 2019.]

On April 23, 2019, 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) 2020.[1] Other than the increase in IPPS and LTCH payments, the most notable portion of the proposed rule is the changes proposed by CMS to Medicare's reimbursement of rural hospitals.[2] This *Health Capital Topics* article discusses the various provisions set forth in the CMS proposed rule.

The proposed rule includes an estimated 3.7% total 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,[3] increasing overall Medicare spending by approximately $4.7 billion. Additionally, LTCH PPS payments are projected to increase by 0.9%.[4] Both of these projected increases are greater than last year's projections, in which hospital payments were estimated to increase by 1.75%, and LTCH PPS payments were projected to decrease by approximately 0.1%.[5] In addition, payments for uncompensated care to *disproportionate share hospitals* (DSH) are expected to increase by $216 million from FY 2019 amounts, totaling $8.5 billion for FY 2020.[6]

Regarding payment for rural hospitals, CMS solicited comments during the 2018 rulemaking process related to the Medicare wage index, which adjusts a hospital's overall reimbursement depending on the hospital's location (as hospitals in different areas will have differing labor costs).[7] Commentators noted that the disparities between those (typically urban) hospitals with a higher wage index (that are thus receiving higher reimbursement), and those with (typically rural) hospital with a lower wage index were exacerbating labor issues in rural areas, as those hospitals are consequently unable to pay their staff higher wages because they are being reimbursed relatively less. In turn, this discrepancy self-perpetuates, exacerbating the gap between high-wage hospitals and low-wage hospitals. To address this discrepancy, CMS proposes increasing the wage index of low-wage index hospitals, i.e., "*with a wage index value below the 25th percentile*," by half of the difference between the hospital's current wage index value, and the 25th percentile wage index value.[8] The proposed program would commence in 2020 and be in effect for a minimum of four years, so that employee wages have an opportunity to rise in response to the increased wage index value received.[9] In order to keep this change budget neutral, CMS proposes decreasing the wage index of high-wage index hospitals, i.e., "*with a wage index value above the 75th percentile*," by the same formula.[10]

In addition, CMS proposes instituting both a floor and a decrease cap to the hospital wage index. The "*rural floor*" will provide that "*the IPPS wage index value for an urban hospital cannot be less than the wage index value applicable*

to hospitals located in rural areas in the state."[11] Further, the decrease of any hospital's wage index between 2019 and 2020 will be capped at 5%.[12]

CMS Administrator, Seema Verma, asserts that:

> "*Rural Americans face many obstacles as the result of our fragmented healthcare system, including living in communities with disproportionally higher poverty rates, more chronic conditions, and more uninsured or underinsured individuals. The Trump administration is committed to addressing inequities in health care, which is why we are proposing historic Medicare payment changes that will help bring stability to rural hospitals and improve patients' access to quality healthcare*."[13]

The CMS proposed rule includes a variety of other suggested actions, including, but not limited to, the following:

(1) Increasing the amount of uncompensated care payments distributed to *disproportionate share hospitals* (DSHs) by $216 million;

(2) Revisions related to new technology add-on payments, including an increase in payment rates and streamlining access to those payments; and,

(3) The introduction of some new policies related to the *Promoting Interoperability Programs* (f/k/a *Medicare and Medicaid EHR Incentive Programs*).[14]

The changes proposed by CMS would affect approximately 3,300 acute care hospitals and approximately 390 LTCHs.[15] According to CMS, the goal of the IPPS proposed rule is to achieve a "*singular objective: transforming the healthcare delivery system through competition and innovation to provide patients with better value and results.*"[16] Specific to rural hospitals, the agency asserts that the proposals outlined above "*would represent historic changes to the way rural hospitals are paid...and [would] help guarantee [that] people living in rural America have access to high quality, affordable healthcare*."[17] Comments from industry stakeholders regarding the proposed rule are due by June 24, 2019.[18]

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Widening Payment Gap between Medicare and Commercial Insurance

[Excerpted from the article published in June 2019.]

On May 9, 2019, the nonprofit Research and Development (RAND) Corporation published a research report, which found that private insurance companies pay approximately four times more for hospital services than Medicare.[1]

The report reviewed data from self-insured employers, state-based all-payor claims databases from Colorado and New Hampshire, and health plans during the period of 2015 to 2017.[2] In total, these sources included approximately 4 million beneficiaries and 1,598 Medicare-certified acute care hospitals across 25 states, representing $13 billion in allowed amounts.[3] RAND examined both the charges and the allowed amounts per service (including payments from the health plan and the patient), and compared those to the Medicare reimbursement rates for those same procedures and facilities.[4]

The purpose of the report's review was to "*describe hospital price levels, variation, and trends*."[5] The publication notes that "*[t]his is the first broad-based study that reports prices paid by private health plans to hospitals [and hospital systems] identified by name...*"[6]

Specifically, the report found that *relative prices* (i.e., "*the ratio of the actual private allowed amount divided by the Medicare allowed amount for the same services provided by the same hospital*") increased from 236% of Medicare in 2015 to 241% of Medicare in 2017, with a wide distribution among states.[7] The states with the largest increase in relative prices were Colorado, Montana, Wisconsin, Maine, Wyoming, and Indiana, with relative prices ranging from 250-300% of Medicare.[8] Relative prices ranged even more broadly among health systems, from 150% of Medicare to over 400% of Medicare.[9] In addition to the variation among states and systems, relative prices also varied between inpatient and outpatient services. Relative prices for outpatient services were 293% of Medicare, compared to 204% of Medicare for inpatient care.[10]

RAND also reviewed the relative prices for these hospitals and health systems in the context of quality. Comparing the hospital/system's relative price to its Hospital Compare rating (which is based on a five-star system), the report found that while higher-priced hospitals generally had higher quality rating than lower-priced hospitals, there were low-priced hospitals that were highly rated.[11] This finding indicates that providing high-quality services at a lower cost is possible, and this data transparency may allow employers to seek out those options.[12]

These findings are significant due to the large proportion of the U.S. population who receive insurance through their employer and the amount of total personal healthcare spending attributable to hospital services. As of 2017, 56% of the U.S. population had insurance coverage through their employer, and 17.2% were covered through Medicare.[13] Further, in 2017, hospital care expenditures

were 44% of total personal spending for privately-insured individuals, and 33% of total expenditures for Medicare beneficiaries.[14] Any change to private insurance prices in the hospital sector would almost certainly have a significant effect on overall healthcare costs.

As the RAND report points out, the relatively high prices charged to private insurers by hospitals, and the wide variations in those charged prices, indicate that there is room for employer health plans to negotiate lower prices with these providers. With the increasing transparency of data such as that examined by RAND, health plans will likely have a better negotiating position, as these plans can move away from the hospitals and health systems that are found to be more expensive.[15] However, as the RAND report notes, transparency alone will likely not serve as the panacea for this complex problem, and may require further regulatory intervention, such as limiting out-of-network hospital payments or providing a public option that pays via the Medicare fee schedule – an avenue that is likely to further intensify the rhetoric surrounding Medicare-For-All.[16]

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New Data Questions Viability of CMS Oncology Model

[Excerpted from the article published in June 2019.]

On May 21, 2019, Avalere Health released a report analyzing the viability of a compulsory two-sided risk arrangement within the *Oncology Care Model* (OCM), a Medicare payment model commenced in July 2016.[1] Significantly, the analysis found that should practices be forced to switch to a two-sided risk arrangement, more than half of them would be forced to pay recoupments back to the *Centers for Medicare and Medicaid Services* (CMS), meaning that participation in the OCM would no longer be justifiable for these practices.[2]

The OCM was established by the *Center for Medicare and Medicaid Innovation* (CMMI), a division of CMS. The 5-year (10-performance period), voluntary model runs through June 30, 2021, and includes almost 200 participants, comprised of 176 practices and 11 payors (including CMS).[3] The goal of the bundled payment program is "*to examine the impact of the OCM on primary outcomes such as reduction in total cost of care as well as improvements in key utilization quality metrics (risk-adjusted hospital admissions, risk-adjusted emergency department visits and hospice visits) and achievement of performance-based payments*."[4] The OCM is a fairly unique CMS payment model, as it includes not just Medicare fee-for-service (FFS), but also commercial payors.[5]

As part of their participation requirements, practices enrolled in the OCM must furnish a number of "*enhanced services*," including:

(1) "*The core functions of patient navigation;*

(2) *A care plan that contains the 13 components in the Institute of Medicine Care Management Plan outlined in the Institute of Medicine report, "Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis";*

(3) *Patient access 24 hours a day, 7 days a week to an appropriate clinician who has real-time access to practice's medical records; and*

(4) *Treatment with therapies consistent with nationally recognized clinical guidelines*."[6]

The participants are reimbursed via regular payments throughout the six-month episode, which commences with chemotherapy. There are two forms of payment involved, including:

(1) A *Monthly Enhanced Oncology Services* (MEOS) payment of $160 per beneficiary per month (for a total of $960 for the entire episode) for the delivery of the aforementioned "*enhanced services*"; and,

(2) The potential for a *performance-based payment* (PBP) for each episode, which is meant to "*incentivize[] practices to lower the total cost of care and improve care for beneficiaries during treatment episodes*."[7]

In order to obtain a PBP, a participant must meet the following requirements:

(1) The OCM practice must expend less than their target amount;
(2) The OCM practice must achieve an *Aggregate Quality Score* (AQS) of at least 30%;
(3) The OCM practice must report all of the required quality data to the OCM Data Registry; and,
(4) The OCM practice must implement all "*Practice Redesign Activities,*" which activities include the "*enhanced services*."[8]

OCM currently offers three risk arrangement options for participating practices:

(1) A one-sided risk arrangement with a 4% discount;
(2) A two-sided risk arrangement with a 2.75% discount (termed "*original two-sided risk*"); and,
(3) A two-sided risk arrangement with a 2.5% discount (termed "*alternative two-sided risk*").[9]

Only those practices participating in the *two-sided* risk arrangements are eligible for the PBP.[10]

For the first performance period of the model, all practices participated in one-sided risk only.[11] Then, beginning in Performance Period 2 (i.e., January 12, 2017), practices could participate in either one-sided risk or *original* two-sided risk.[12] Starting in Performance Period 7 (i.e., July 2, 2019), practices may participate in one-sided risk, *original* two-sided risk, or *alternative* two-sided risk.[13] Of note, all OCM practices are currently participating in the *one-sided* risk arrangement.[14] However, effective January 1, 2020, CMS will require those practices that did not achieve a PBP in any of the first four performance periods to switch to a *two-sided* risk arrangement (either the *original* or the *alterative*), or leave the payment program altogether.[15]

As noted above, Avalere's report found that should OCM practices be forced to switch to a *two-sided* risk arrangement, most of them would owe money, through repayments, back to the government.[16] Specifically, Avalere's analysis of "*Medicare Part A/B FFS claims and Part D prescription drug event data*" found that, under the *original* two-sided risk arrangement, 70% of those practices would owe recoupments (i.e., payments) to CMS, and under the *alternative* two-sided risk arrangement, approximately 50% would owe recoupments.[17]

For either of the two-sided risk arrangements, Avalere found that more participants would likely earn PBPs than they currently are in the one-sided risk arrangement (because they would have smaller discounts for their spending targets).[18] Additionally, because the OCM is an *alternative payment model* (APM), as established by the *Medicare and CHIP Reauthorization Act* (MACRA), those practices would potentially obtain the 5% bonus payment due to their participation in an APM.[19] However, it is unclear whether these positive payment adjustments would be enough to convince current OCM practices to remain in the voluntary program.[20]

These issues with the OCM are similar to those with the *Medicare Shared Savings Program* (MSSP), wherein CMS is similarly forcing *accountable care organizations* (ACOs) to transition to two-sided risk models, effective July 1, 2019.[21] A subsequent survey conducted by the *National Association of ACOs* (NAACOS) found that 71% of those survey respondents are likely to leave the MSSP (a voluntary program) as a result of being forced to assume two-sided risk.[22] This may indicate that either CMS is forcing participants into two-sided risk arrangements too quickly, or that participants do not wish to voluntarily participate in a program wherein the rules are changed mid-program. However, this latter issue may become a moot point, as HHS Secretary Alex Azar has previously stated that CMS would be launching a mandatory payment model for Medicare cancer patients.[23]

Despite these program drawbacks, private payors are modeling value-based payment programs after CMS, indicating that CMS may be on the right path to value-based reimbursement, despite their programs' various issues. For example, in January 2019, Humana launched a new payment model for both Medicare Advantage and commercial beneficiaries undergoing cancer treatment.[24] The similarly-named *Oncology Model of Care* will seek to coordinate cancer care by offering "*additional payment to [the 16] participating cancer practices for improved performance on certain metrics over a one-year period*."[25] Unlike the OCM, this payment model is not episode based, but quality based.[26] Humana pays each practice a *care coordination fee*, which is used to help participating practices "*implement the reporting requirements and infrastructure for the model*;" those practices that improve performance from one year to the next will see that fee increased.[27] Such payment plans seek to control the costs of one of the most expensive service lines in healthcare (due in part to the cost of chemotherapy drugs),[28] and it appears that more tweaks will need to be made in order to determine a payment plan that is mutually beneficial for providers, payors, and patients, and then scale it to the rest of the oncology providers in the U.S. healthcare system.

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Newly-Announced Program Shifts Dialysis Services to the Home

[Excerpted from the article published in July 2019.]

On July 10, 2019, President Donald Trump signed an executive order launching "*Advancing American Kidney Health*," an initiative that seeks to move the majority of dialysis services away from dialysis centers, and into patients' homes, as well as double the availability of kidneys for transplants.[1] The initiative generally seeks to achieve three goals: "*fewer patients developing kidney failure, fewer Americans receiving dialysis in dialysis centers, and more kidneys available for transplant*."[2]

Specifically, the initiative seeks to reduce the incidence of *end-stage renal disease* (ESRD) by 25% by the year 2030 through HHS's establishment of five proposed payment models – one of which will be mandatory, and four of which will be voluntary[3] – to "*adjust payment incentives to encourage preventative kidney care, home dialysis, and kidney transplants*."[4] The mandatory *ESRD Treatment Choices (ETC) Model* would randomly select approximately 50% of all ESRD facilities and *managing clinicians*, from randomly selected geographic areas, to participate in the pilot; those that serve low volumes of ESRD patients would not be selected.[5] The providers would be subject to two types of adjustments to payments under the *ESRD Prospective Payment System* (ESRD PPS). First, a uniformly positive adjustment would be applied to home dialysis claims (i.e., an additional payment would be rendered to facilities/clinicians that support that beneficiary dialyzing at home).[6] Second, per-treatment adjustments would be applied to "*both home and in-center dialysis and related claims, and could be either positive [up to 3%[7]] or negative*."[8] The model is slated to run from January 1, 2020 through June 30, 2026.[9]

In addition to the mandatory *ETC Model*, the four voluntary payment models, i.e., the *Kidney Care First* (KCF) and *Comprehensive Kidney Care Contracting* (CKCC) Models (which includes CKCC Graduated, CKCC Professional, and Global Models) will test new Medicare payment options that aim to improve the quality of care for patients with kidney disease, delay the need for dialysis, and encourage kidney transplants.[10] Under the KCF Model, nephrology practices that choose to participate "*will receive adjusted fixed payments [based on utilization and outcomes, utilizing historical benchmarks] on a per-patient basis for managing the care of patients with late-stage chronic kidney disease and...ESRD*."[11] The three CKCC models will also reimburse utilizing capitated payments, wherein the *Kidney Contract Entities* (nephrologists, transplant providers and other providers, including dialysis centers) will be responsible for the total cost and quality of the patient care, but can share in any savings achieved.[12] Both the KCF and the CKCC models will run from January 1, 2020 through December 31, 2023, with the option for additional performance years.[13]

The *Advancing American Kidney Health* initiative, which established these five payment models, will work to increase the proportion of dialysis patients receiving dialysis at home (or receiving a transplant), from the current 12% (a rate far lower than other countries) to 80% by 2025.[14] As noted by the *Department of Health and Human Services* (HHS), "*[s]tudies have shown that...dialyzing at home is often preferred by patients and physicians*," as the home setting is more comfortable and allows for more independence and a better quality of life.[15] The initiative also plans to double the number of kidneys available for transplants by 2030 through increasing public awareness for the need, and expanding the coverage for donors. Currently, donors' medical costs are covered; the initiative would also include financial assistance for child care and missed time from work.[16]

This initiative could have a large impact on the U.S. healthcare industry, as kidney disease and ESRD affect a significant number of Americans. Approximately 37 million Americans have chronic kidney disease (which is the ninth leading cause of death in the U.S.), and over 726,000 have ESRD (which incidence is increasing by 5% annually).[17] Of this patient contingent, almost 100,000 patients are on the kidney transplant waiting list (although only "*21,000 donor organs were available for transplant*" in 2012).[18]

ESRD treatment has been covered, for all patients, by Medicare since 1973.[19] Although ESRD patients are only 1% of the overall Medicare population, they account for 7% of overall Medicare spending.[20] In 2016, Medicare served as the primary or secondary payor for approximately 67% of all ESRD patients,[21] and total Medicare expenditures for ESRD totaled approximately $35.4 billion, of which approximately $11.4 billion were spent on outpatient dialysis services.[22] More broadly, kidney disease accounts for approximately 20% of Medicare spending.[23]

The Trump Administration anticipates that the initiative will result in 17,000 additional patients receiving kidney transplants each year by 2030, which they hope will meet the rising need for donor kidneys (that need is rising at a rate of 8% annually).[24] Additionally, the administration believes that this program would also motivate the transplant of other organs, and anticipates that 11,000 additional patients would receive hearts, lungs, and livers each year.[25] Because kidney transplant costs are less than dialysis, the administration anticipates the plan would save $4.2 billion per year.[26]

Reactions from industry stakeholders regarding this new initiative have been generally supportive. The *National Kidney Foundation's* CEO stated that "*The administration's commitment to charting a new course for kidney health will help revolutionize transplantation and dialysis and advance new innovations, therapies and treatments, which patients everywhere have been waiting on for far too long*."[27] Additionally, the *American Society of Nephrology* noted that the initiative has "*only 'upside' potential for doctors*," who, currently, are only reimbursed for seeing patients in dialysis centers, and thus are not incentivized to promote a home dialysis option.[28] DaVita, the country's largest home dialysis

provider, simply stated that it looked forward to working with the administration.[29]

Ironically, the new payment models were established by HHS under its *Center for Medicare and Medicaid Innovation* (CMMI), which was created by the *Patient Protection and Affordable Care Act* (ACA), the landmark legislation that is currently being disputed by the presidential administration in federal court.[30] Should the courts find the ACA to be unconstitutional, the CMMI, and likely any program within CMMI (including these five new models), would be canceled.[31] Therefore, while this new program could radically change the dialysis and nephrology industries, its long-term viability may be subject to outside political and legal forces. The proposed rule was published in the Federal Register on July 18, and will be open to comments until September 16, 2019.[32]

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Hospitals to See Big Changes in Reimbursement in 2020 & 2021

[Excerpted from the article published in August 2019.]

Hospitals are likely to see some significant changes in the way that Medicare reimburses for inpatient services in the next couple of years, according to the calendar year (CY) 2020 *Inpatient Prospective Payment System* (IPPS) final rule that was published on August 16, 2019,[1] and the announcement by the *Centers for Medicare & Medicaid Services* (CMS) on August 19, 2019 that it would change the quality "*star ratings*" system on Hospital Compare, beginning in 2021.

Hospitals that provide care to Medicare Part A beneficiaries are paid by CMS under the IPPS, which reimburses according to predetermined payment rates; these rates are determined by the patient's needs, through Medicare severity diagnosis related groups (MS-DRGs), which classify patients based on the average per discharge cost of caring for their particular diagnosis.[2] The 2020 IPPS final rule, which will apply to discharges on or after October 1, 2019, will impact approximately 3,300 acute care hospitals, and increase payments to hospitals by $3.8 billion (a 3% increase from 2019).[3]

Most importantly, the 2020 IPPS changes the rules by which "*low wage*" hospitals (most of which are rural) will be paid.[4] CMS utilizes the wage index in adjusting standardized amounts "*for area differences in hospital wage levels by a factor...reflecting the relative hospital wage in the geographic area of the hospital compared to the national average hospital wage level*."[5] In response to the comments submitted last year by industry stakeholders, which signaled a shared concern that the current hospital wage index system "*perpetuates and exacerbates the disparities between high and low wage index hospitals*," CMS is finalizing its proposal to increase the wage index for those hospitals below the 25th percentile.[6] These indices will be increased by half the amount between the hospital's current index, and the 25th percentile index.[7] This change will commence in 2020, and continue for a length of four years, so that employee compensation (i.e., wages) has time to increase in response to this change, which will ultimately be reflected in the hospital's wage index calculation.[8]

In its proposed rule, CMS suggested decreasing the wage index for hospitals above the 75th percentile, as a way to keep the program budget neutral. However, CMS ultimately revised this proposal, keeping the program's overall budget neutrality, but through an adjustment to the standardized amount applied to all hospitals.[9] Additionally, CMS is implementing changes to the calculation of the wage index "*rural floor*" (i.e., the wage index value for an urban hospital cannot be less than that of the rural hospitals in the same state).[10] Addressing concerns that some urban hospitals have inappropriately swayed the index via urban/rural reclassifications, CMS will remove such reclassifications from the calculation of the wage index rural floor going forward.[11]

In order to guard against any major decreases in any one hospital's wage index in 2020, CMS is instituting a one-year 5% cap on the decrease of hospitals' wage indices, so that no hospital's final wage index for 2020 will be less than 95% of its 2019 wage index.[12]

Other notable changes to the IPPS for 2020 include:

(1) An increase in the add-on payment for "*new technology*," i.e., "*medical services or technologies found to be 1) new; 2) disproportionately costly to the existing MS-DRG, and 3) a substantial clinical improvement*."[13] There are currently nine technologies that meet these requirements, and an additional nine were approved with the 2020 IPPS final rule.[14] The add-on payment for these technologies will be the lesser of either 50% of the cost of the new technology/service or 50% of the amount in excess of the MS-DRG payment.[15]

(2) Clarifications and updates to the metrics included in the various quality programs, including the:

   (a) Hospital-Acquired Conditions (HAC) Reduction Program;
   (b) Hospital Readmissions Reduction Program (HRRP);
   (c) Hospital Inpatient Quality Reporting (IQR) Program;
   (d) Hospital Value-Based Purchasing (VBP) Program; and,
   (e) PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.[16]

(3) Changes to the three factors included in the calculation of *Disproportionate Share Hospital* (DSH) payments.[17]

In addition to the announced payment updates and other changes, CMS announced on August 19, 2019 that it would be overhauling the methodology by which it determines hospital quality star ratings for the Hospital Compare website.[18] The Hospital Compare website allows patients to "*[c]ompare hospitals based on their star rating, which summarizes a variety of quality measures...*"[19] that are based upon "*common conditions that hospitals treat, such as heart attacks or pneumonia*."[20] Based upon the over 800 comments received in response to CMS's February 2019 public input request on this topic, CMS will revise the current methodology in early 2021 (for 2020, CMS will simply refresh the data utilizing current methodology).[21] Although exact details regarding the overhaul were not shared, the questions asked by CMS in its public input request are illuminating. The CMS request sought feedback on nine potential changes, including abandoning the latent variable model that assigns hospital ratings.[22] Most commenters expressed opposition to the current model, stating that the model is too opaque in its approach, making it impossible for hospitals to predict their rating (and any impact that implemented quality-improvement activities may have on that rating).[23]

In its dual push toward transparency and value-based care, CMS is enacting a myriad of extensive reforms, in every sector of the healthcare delivery system. However, the reforms related to hospitals may be the most significant, as IPPS payments account for approximately 25% of Medicare spending, and these

Medicare payments account for approximately 20% of hospital revenues.[24] This may mean that any change in hospital payments (or the strings attached thereto) may result in a paradigm shift in the healthcare industry, affecting insurers, providers, and patients.

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22 Castellucci, August 19, 2019.
23 *Ibid.*
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CMS Publishes 2020 OPPS/ASC PPS Proposed Rule

[Excerpted from the article published in August 2019.]

The *Centers for Medicare & Medicaid Services* (CMS), in response to President Donald Trump's June 24, 2019 executive order entitled, "*Improving Price and Quality Transparency in American Healthcare to Put Patients First*,"[1] has proposed "*historic changes to various healthcare payment systems in an effort to "lay[] the foundation for a patient-driven healthcare system*."[2] On August 9, 2019, CMS released the proposed rule for the *Calendar Year (CY) 2020 Medicare Hospital Outpatient Prospective Payment System (OPPS)* and *Ambulatory Surgical Center (ASC) Payment Systems*,[3] which includes significant changes to both payment systems. This proposed rule would update Medicare outpatient payment rates by 2.7% in CY 2020,[4] a substantial increase from the 1.25% rate adjustment in 2019.[5] Three proposed changes are expected to significantly impact *hospital outpatient provider-based departments* (HOPDs), specifically as regard: (1) price transparency of hospital standard charges; (2) site-neutral payments for clinic visits in all off-campus HOPDs; and, (3) payments for separately payable, covered outpatient drugs and biologicals acquired through the 340B Program. These proposed changes, their potential effect on the current healthcare delivery system, and relevant stakeholder reactions, are discussed below.

Price Transparency

Perhaps the most contested proposed change requires hospitals to disclose their "*standard charges*," i.e., their "*gross charges and payer-specific negotiated charges*,"[6] including for 300+ "*shoppable services*," i.e., "*those [services] that are routinely provided in non-urgent situations that do not require immediate action or attention to the patient, thus allowing patients to price shop and schedule a service at a time that is convenient for them*,"[7] such as lab tests, outpatient visits, and some procedures.[8] Under this proposal, hospitals will be required to publicly disclose, and annually update, these charges.[9] The penalty for not complying with this rule would be (after a written warning) a civil monetary penalty of up to $300 per day, which penalties would be publicly recorded on CMS's website.[10]

Regarding this new requirement, CMS reasons that "*healthcare markets work more efficiently and provide consumers with higher-value healthcare if...policies that encourage choice and competition*" are promoted.[11] However, provider trade groups, such as the American Hospital Association (AHA), assert that such requirements could, in fact, limit patient choices, as these revealed prices may set a floor for rates, and not a ceiling as intended, ultimately resulting in higher rates.[12]

Site-Neutral Payments

CMS proposes completing the two-year phase-in of site-neutral payments for clinic visits in grandfathered off-campus HOPDs.[13] Established in the CY 2019 final rule, this policy is currently at issue in a number of lawsuits brought by

the AHA and the Association of American Medical Colleges (AAMC).[14] However, CMS believes that these site-neutral payments will address the payment incentives that shift services from physician offices to HOPDs, as well as the beneficiary financial burden caused by this shift, i.e., higher copayments and coinsurance, ultimately saving Medicare and patients $810 million in 2020.[15]

340B Program Payments

CMS also proposes to continue the steep payment cuts to participants in the 340B Drug Discount Program. The 340B Program allows participating hospitals and providers (including nonexcepted off-campus HOPDs[16]) to purchase certain covered outpatient drugs from the manufacturer at discounted prices.[17] However in 2017, CMS finalized a payment policy 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* 6%,[18] resulting in both large cuts to the 340B Program and significantly higher drug expenditures for program participants. Consequently, the AHA (and other hospital association groups) filed a lawsuit in the District of Columbia, claiming that the cuts exceeded the statutory authority of the *U.S. Department of Health and Human Services* (HHS); the court has previously found that the 340B reimbursement rates in 2018 and 2019 were unlawful, and remanded those rules back to HHS for the purpose of "*crafting appropriate remedial measures*."[19]

Changes to ASC Payment Rates

The proposed rule seeks to increase payment rates by 2.7% for ASCs (note that this is the same percent increase as payment rates for HOPDs), provided that they meet the quality reporting requirements under the *Ambulatory Surgical Center Quality Reporting* (ASCQR) *Program*.[20] Additionally, CMS proposes using the CY 2020 hospital *Inpatient Prospective Payment System* (IPPS) post-reclassified wage index for urban and rural areas as the OPPS wage index.[21] The wage index helps to account for local differences in wages for hospital labor; tying the OPPS wage index to the IPPS wage index would standardize those adjustments.

Regarding the procedures for which Medicare will pay under the OPPS, CMS proposes removing total hip arthroplasty from the Inpatient Only (IPO) list, so that going forward, providers may be reimbursed for performing that procedure at an ASC or HOPD.[22] CMS also proposes adding several services to the *ASC Covered Procedures List*, "*a list of covered surgical procedures that are eligible for payment under Medicare when furnished in an ASC*," including Total Knee Arthroplasty (TKA), Knee Mosaicplasty, and three additional coronary intervention procedures.[23]

Conclusion

Overall, CMS estimates that outpatient hospital payments for 2020 will increase by approximately $6 billion from 2019 with the total payments to OPPS providers estimated to be $79 billion, while ASC payments will increase

by approximately $200 million from 2019, to $4.89 billion.[24] Although a number of these proposals offered by CMS are being strongly contested by providers, including in the courts, CMS and the Trump Administration continue to push forward their agenda to "*Improv[e] Price and Quality Transparency in American Healthcare to Put Patients First*"; the consequential impact of this agenda on providers is yet to be determined. Stakeholder comments related to the proposed rule are due September 27, 2019.

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CMS Proposes Updates to Physician Fee Schedule for 2020

[Excerpted from the article published in August 2019.]

On July 29, 2019, the *Centers for Medicare & Medicaid Services* (CMS) proposed significant changes to both fulfill the Trump Administration's "*Patients over Paperwork*" initiative[1] and continue the paradigm shift in the healthcare reimbursement environment from a *volume*-based to a *value*-based system.[2] The 1,704-page *Medicare Physician Fee Schedule* (MPFS) proposed rule, which was published on August 14, 2019,[3] includes proposed updates to payment policies, payment rates, and quality provisions for services rendered under the MPFS, as well as the proposed changes to the *Quality Payment Program* (QPP) established by the 2015 *Medicare Access and CHIP Reauthorization Act* (MACRA).

The QPP is currently comprised of two tracks: (1) the *Merit-based Incentive Payment System* (MIPS); and, (2) advanced *Alternative Payment Models* (APMs).[4] CMS estimates that 818,000 clinicians will be MIPS-eligible for the 2020 performance period, while between 175,000 and 225,000 clinicians will be Qualifying APM Participants.[5] Additionally, CMS anticipates that MPS payment adjustments for 2020 will equal $584 million (which will be equally distributed between negative and positive payment adjustments), and APM payments will approximate $500-600 million.[6] CMS's proposed rule includes various updates to the MIPS and APM tracks, as well as a proposed new framework.

The most significant proposed changes to MIPS include the establishment of *MIPS Value Pathways* (MVPs). Commencing in 2021, this "*conception participation framework*" would seek "*to align and connect measures and activities across the Quality, Cost, Promoting Interoperability, and Improvement Activities performance categories of MIPS for different specialties or conditions*."[7] Currently, MIPS participating clinicians must report on a variety of metrics – under this new program, clinicians will report fewer (although more specialty-specific) measures.[8]

In addition to the introduction of MVPs, CMS is proposing to update MIPS by increasing the performance threshold for participants, as well as to change the weights for some of the MIPS performance categories (in a move toward equally weighting all performance categories by 2022), including:

(1) Quality – Reducing the weight from the current 45% to 40% for 2020, 35% for 2021, and 30% for 2022; and,

(2) Cost – Increasing the weight from the current 15% to 20% for 2020, 25% for 2021, and 30% for 2022.[9]

The proposed changes to the APM policies principally include changes to the APM quality scoring standards.[10]

Of interest, based on the amount of anticipated payments to eligible clinicians, and the estimated number of participants, the maximum positive payment adjustment under MIPS would be only $1,428 per clinician; because the

program is budget neutral, this would also be maximum negative payment adjustment (i.e., -$1,428).[11] For APM participants, the amount is slightly larger, at approximately $2,500 per participant.[12] These amounts have left some industry stakeholders questioning whether the payment adjustments are sufficient incentive for providers to comply.[13]

Regarding the proposed payment updates, a positive adjustment of 0.14% has been proposed to be applied to the MPFS *conversion factor* (CF) used to calculate payments for physician services; this adjustment is slightly higher than the 2019 CF adjustment of 0.13% and like last year, the CF used to calculate payments for anesthesia services includes a separate adjustment based on practice expense and malpractice.[14] The 2020 CF includes a statutory update factor of 0% and a Relative Value Unit (RVU) Budget Neutrality Adjustment of 0.14% to the CF, resulting in the 2020 CF of 36.0896.[15]

Some of the more significant CMS proposed changes to the MPFS include:

(1) Creating new evaluation and management (E/M) codes beginning 2021, which will retain the current five levels of physician office visits for established patients, but reduce the number of levels from five to four for new patient visits. This proposal is a deviation from last year's proposed rule, wherein CMS suggested reducing the number of visit levels from five to two;

(2) Adding three codes to the telehealth services reimbursable by Medicare, all of which concern office-based treatment of opioid use disorder;

(3) Creating six new face-to-face codes for the purpose of describing and reimbursing for "*patient-initiated digital communications that require a clinical decision that otherwise typically would have been provided in the office*";

(4) Allowing providers (including physicians, teaching physicians, physician assistants, and advanced practice registered nurses) to simply review, sign, and date medical records, instead of re-documenting (as currently required) medical record notes created by other clinicians on the medical team, when furnishing and billing for professional services; and,

(5) Allowing the remote patient monitoring codes (which became effective in 2019) to be delivered under general supervision (rather than under direct supervision), and creating a code for those remote monitoring sessions that surpass the initial 20 minutes.[16]

In addition to these myriad changes, CMS is seeking review of, and comments related to, a number of other topics. For example, as a follow up to the comments received in response to its request for information issued in June 2018,[17] CMS is soliciting comments on potential changes to the Advisory Opinion process, as regards the Stark Law.[18] Additionally CMS is soliciting comments related to the quality scoring for the *Medicare Shared Savings Program* (MSSP) and how it might align that scoring with the scoring already used for MIPS.[19]

CMS has made clear in its MPFS and QPP proposed rule for 2020 that many of these proposals and initiatives are aimed at reducing the administrative burden of providers, and estimates that this rule alone will save providers 2.3 million hours per year.[20] At the same time, CMS's proposals, as they relate to the QPP, focus on continuing the shift from volume-based to value-based care. Whether the final rule differs from CMS's original proposals, after the receipt of comments (which are due by September 27, 2019[21]), will be determined when it is released in late 2019.

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5 *Ibid*, p. 40732, 40893.

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III. REGULATORY TOPICS

Community Health Systems Settles with OIG for $262 Million

[Excerpted from the article published in October 2018.]

On September 25, 2018, the *U.S. Department of Justice* (DOJ) announced a $262 million settlement with *Health Management Associates, LLC* (HMA), over fraud and abuse allegations.[1] The former U.S. hospital chain (which is now owned by *Community Health Systems* [CHS]) agreed to the settlement, and to transmit payment in October 2018.[2] The settlement resolves criminal and civil claims (which civil claims arose from eight separate whistleblower suits) that "*HMA knowingly billed government health care programs for inpatient services that should have been billed as outpatient or observation services, paid remuneration to physicians in return for patient referrals, and submitted inflated claims for emergency department facility fees*."[3]

Specifically, HMA pled guilty to criminal charges that, from 2008 to 2012, it was "*pressuring and inducing*" physicians to increase hospital admissions through the *emergency department* (ED), whether or not those admissions were medically necessary, so that HMA could then bill for inpatient hospital care, rather than observation/outpatient care (for which the hospital is reimbursed less than if the patient is admitted).[4] In addition to a financial penalty of $35 million, HMA entered into a three-year *non-prosecution agreement* (NPA)[5] and extended a *corporate integrity agreement* (CIA) to which the CHS and the *Office of Inspector General* (OIG) of the *U.S. Department of Health and Human Services* (HHS) were already party.[6] As part of the settlement, Pennsylvania-based Carlisle HMA, LLC (formerly d/b/a Carlisle Regional Medical Center), an HMA subsidiary, also pled guilty to one count of conspiracy to commit healthcare fraud; under the aforementioned ED admission scheme, HMA "*set mandatory company-wide admission rate benchmarks for patients presenting to HMA hospital [EDs]– a range of 15 to 20 percent for all patients presenting to the [ED], depending on the HMA hospital, and 50 percent for patients 65 and older (i.e. Medicare beneficiaries)*."[7] In addition to the criminal charges stemming from these allegations, HMA also settled civil claims (arising from these same facts) with the DOJ for $62.5 million.[8]

HMA settled four additional civil claims – some claims were alleged of HMA as a whole, and the rest were alleged of a number of its subsidiary hospitals, as follows:

(1) From 2003 to 2011, two HMA hospitals in Florida, Charlotte Regional Medical Center & Peace River Medical Center, allegedly induced patient referrals from: (a) a physician group, through the provision of free office space and staff, as well as by giving money to the group for overhead and administrative costs; and, (b) a surgeon, through free rent and leasehold improvements (for which HMA and the DOJ settled for $93.5 million);[9]

(2) From 2005 to 2007, an HMA subsidiary in Mississippi, Crossgates Hospital, allegedly leased office space to a physician, but only required him to pay for half of the rented space, in return for the physician's referrals (for which HMA and the DOJ settled for $425,000);[10]

(3) From 2009 to 2012, two HMA hospitals in Pennsylvania, Lancaster Regional Medical Center and Heart of Lancaster Medical Center, allegedly paid excessive amounts of money to: (a) a physician group, "*in return for two businesses owned by the group and for services allegedly performed by the group*"; and, (b) a surgeon (for which HMA and the DOJ settled for $55 million);[11] and,

(4) From 2009 to 2011, "*certain HMA hospitals*" allegedly sought Medicare and Medicaid reimbursement for "*falsely inflated*" ED facility charges (for which HMA and the DOJ settled for $12 million).[12]

As noted by the government in the settlement announcement, HMA was bought out by CHS in 2014, after the alleged incidents.[13] However, CHS will still bear the brunt of the settlement arising from these alleged illegal activities. Among these consequences is CHS's potential "*cash crisis*," as a result of paying the $262 million settlement amount. Credit rating company Moody's advised that this settlement will "*severely weaken*" CHS and "*has already constrained [its] liquidity*."[14] Although CHS's stock price stayed steady, and even increased slightly, after the announcement, prices subsequently dropped (perhaps due to unrelated issues such as Hurricane Michael[15] or the October Wall Street "*rout*"[16]), from $3.41 as of the close of September 25, 2018 (the date of the announcement) to $2.64 as of the close of October 10, 2018.[17] Whether this massive settlement will create more long-term problems for CHS remains to be seen.

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7 The information was filed against Carlisle HMA, LLC on September 25, 2018, the same day that the settlement was announced, and the settlement agreement is pending the court's acceptance. "Hospital Chain Will Pay Over $260 Million to Resolve False Billing and Kickback Allegations; One Subsidiary Agrees to Plead Guilty" U.S. Department of Justice, Press Release, September 25, 2018, https://www.justice.gov/opa/pr/hospital-chain-will-pay-over-260-million-resolve-false-billing-and-kickback-allegations-one (Accessed 10/15/18).
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The State of Medicaid Expansion Post-Midterms

[Excerpted from the article published in November 2018.]

By most accounts, the biggest winner of the U.S. midterm elections was Medicaid Expansion. On November 6, 2018, three states passed ballot measures to expand Medicaid, while the residents of two other non-expansion states voted in Democratic governors in favor of expanding Medicaid. This recent overt display of support for expansion comes on the heels of a number of additional states that have reconsidered, and expanded, Medicaid.

The ballot measures passed in three Republican majority states, i.e., Idaho, Nebraska, and Utah, will increase the number of Medicaid Expansion states to 37.[1] For Idaho, expanding Medicaid had become more favorable over the past couple of years.[2] The ballot initiative passed easily, with 61% of residents voting for expansion, and 39% voting against it.[3] However, the ballot did not include any plan for paying for the expansion, which task will now be the responsibility of the state legislature.[4] Upon expansion, an estimated additional 69,000 residents will be covered (reducing Idaho's uninsured rate from 14.6% to 9.9%).[5]

In Nebraska, the expansion ballot initiative passed by a relatively tighter margin (53% in favor to 47% opposed).[6] Of note, Nebraska's governor has stated that while he would "*follow the will of the voters*," he would not sign any bill that financed Medicaid Expansion through a tax increase – no financing plan is currently in place for the expansion.[7] Upon expansion, an estimated additional 45,000 Nebraskans will be covered (reducing the uninsured rate from 12.4% to 9.6%).[8]

Utah's expansion initiative margin of victory was the same as in Nebraska – 53% in favor to 47% opposed.[9] Unlike Nebraska and Idaho, however, voters agreed upon a partial financing plan for the expansion, by adding 0.15% to the state sales tax (which is expected to generate approximately $90 million in revenue).[10] This passage is expected to expand Medicaid eligibility to approximately 150,000 Utahans, lowering the state's uninsured rate from 13.3% to 10.5%.[11]

The state of Montana, on the other hand, voted to reject a plan to preserve the funding for their current Medicaid Expansion program through 2019.[12] The initiative, the "*single most expensive ballot measure in Montana history*," with over $17 million alone coming from tobacco companies,[13] was shot down, with 53% of votes against the measure, and 47% of votes in favor.[14]

A significant reason for the opposition was that, attached to the expansion extension measure was the $2-per-cigarette-pack tax hike, as well as additional taxes on other tobacco products, such as e-cigarettes (which are not currently taxed), which would have helped to fund expansion going forward.[15] If the state legislature does not find an avenue to continue funding Medicaid Expansion in Montana, it will expire in 2019, leaving almost 100,000 individuals without health insurance,[16] and making it the first state to un-expand Medicaid.[17]

In addition to the three states expanding Medicaid through ballot initiatives, two states, Kansas and Wisconsin, voted in Democrats who made Medicaid Expansion a campaign priority, replacing Republican governors who had previously stonewalled expansion efforts in those states. In the Kansas gubernatorial race, Democrat Laura Kelly defeated Kansas Secretary of State Kris Kobach.[18] The former governor, Sam Brownback, vetoed a 2017 expansion bill presented to him by the Kansas legislature, denying extending coverage to approximately 150,000 Kansans.[19] In Wisconsin, Democrat Tony Evers narrowly defeated incumbent Governor Scott Walker.[20] Although Evers has stated his intent to work with the state legislature to pass an expansion bill, the legislature has explicitly opposed expanding Medicaid.[21] Any potential development in the state will be unique, as Wisconsin's application to add work requirements to its current Medicaid program was recently approved by CMS, adding a novel wrinkle to any potential expansion.[22]

The recent wave of voter decisions regarding Medicaid Expansion builds upon the development of another two states over the course of 2018. As discussed in the June 2018 *Health Capital Topics* article,[23] Virginia and Maine have recently taken steps to expand Medicaid in their respective states. In May 2018, Virginia's Republican-controlled Senate voted to expand Medicaid to cover "*an additional 400,000 low-income adults*" starting in 2019,[24] but is seeking a work requirement amendment that non-disabled adults must either work or volunteer to be eligible for the expanded program.[25] In the fall of 2017, Maine voters became the first in the nation to approve *Medicaid Expansion* through a public referendum, but Maine's Governor, Paul LePage, refused to move ahead with the expansion.[26] The newly-elected Democratic governor, however, has stated that one of her first acts, upon the commencement of her term in January 2019, will be to implement the expanded program.[27]

Despite the ebb and flow of public support over the past seven years related to the *Patient Protection and Affordable Care Act* (ACA), which instituted the Medicaid Expansion program, Medicaid Expansion support appears to be gaining steam. In states where elected leaders would not adhere to the will of their constituents, residents nevertheless largely either voted to expand Medicaid through popular referendums or ousted leaders who would not expand the program. Whether the remaining 14 states that have not voted to expand Medicaid will now follow suit before they lose out on more federal government funding through the program (which funding will be reduced to 90% in 2020[28]) remains to be seen.

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Judge Rules Entire ACA Unconstitutional

[Excerpted from the article published in December 2018.]

On December 14, 2018, Texas Federal District Court Judge Reed O'Connor deemed the *Patient Protection and Affordable Care Act* (ACA) to be unconstitutional in its entirety, resulting in mass uncertainty for the millions of Americans who gained coverage through ACA provisions.[1] The lawsuit was commenced in February 2018 when Texas Attorney General Ken Paxton and a coalition of 20 Republican state attorneys general and governors sued the federal government on the foundation that they had been harmed by the increase in the number of individuals on state-supported insurance.[2] Although the judge has rendered his decision, the law remains in place for now because the court did not enjoin the ACA,[3] likely because the ruling is expected to be appealed, and eventually reach the *Supreme Court of the United States* (SCOTUS).[4]

After the congressional Republicans' unsuccessful efforts to wholesale repeal and replace the ACA, the ACA's *Individual Mandate* penalty for those who did not maintain health insurance was at the forefront of the 2017 overhaul of the tax code.[5] Through the enactment of the *Tax Cuts and Jobs Act* (TCJA) in December 2017, this penalty was reduced to $0, effective beginning in 2019.[6] Furthermore, in the previous 2012 SCOTUS case, *National Federation of Independent Business* (NFIB) *v. Sebelius*, Chief Justice Roberts concluded that the Individual Mandate penalty was a tax, with an essential feature being that it produced "*at least some revenue for the Government.*"[7] In this case, the Individual Mandate's penalty tax was valid under Congress' authority to tax and spend and the ACA was, therefore, deemed constitutional.[8]

However, under the same grounds as *NFIB v. Sebelius*, Judge O'Connor concluded that the Individual Mandate is no longer permissible under Congress's taxing power as a result of the TCJA reducing the Individual Mandate's tax to $0 (i.e., it no longer produces revenue, which is an essential feature of a tax), rendering the ACA unconstitutional.[9] Further, the court ruled that the Individual Mandate could not be severed from the ACA because the Mandate was "*the keystone*" of the law, essential to the regulation of the health insurance market, rendering the entirety of the ACA invalid.[10] Contributing to the federal court decision was the *Department of Justice's* (DOJ) position, in which the agency agreed with the plaintiffs that the Individual Mandate is unconstitutional, and asserted that other provisions such as the "*guaranteed issue*" (requiring health insurance companies to accept all applicants regardless of pre-existing conditions) are inseverable from the Mandate.[11] As a result, the DOJ did not defend the constitutionality of the Individual Mandate during the case.[12]

In an effort to avoid widespread confusion in the healthcare market, on December 17, 2018, 17 states filed a motion seeking clarity of the decision to help clarify whether the law becomes unconstitutional on January 1, 2018, and whether the ACA will stay in effect as the case moves through the courts.[13] Representative Nancy Pelosi (D-CA), who is expected to become House

Speaker in January 2019, stated that once the Democrats take control of the U.S. House of Representatives in January 2019, they will "*swiftly intervene in the appeals process*."[14] Further, California Attorney General Xavir Becerra is leading a coalition of Democratic state officials in an attempt to defend the ACA,[15] indicating their intent to appeal.[16] Additionally, some states, such as Texas, are seeking to pass their own state healthcare law to replace the ACA through a "*work around*," should the ACA be struck down, to ensure that popular provisions, such as protecting those with pre-existing conditions, continue.[17]

Numerous healthcare provider associations have condemned Judge O'Connor's ruling. The *American Medical Association* (AMA) stated that this decision is "*an unfortunate step backward for our health system*."[18] The AMA also predicted a regression to pre-ACA insurance coverage, where 20% of the U.S. population was uninsured and there were fewer patient protections.[19] The *American Psychological Association* (APA) added that, especially with the Opioid Crisis, more healthcare services are needed, and there should be an expansion of access to healthcare coverage rather than a limitation of access for Americans. [20]

Repealing the entirety of the ACA will undoubtedly affect the millions of people that received healthcare coverage upon the enactment of the ACA. This includes over 133 million individuals with pre-existing conditions (who were previously unable to obtain insurance);[21] the 12 million individuals who gained coverage through *Medicaid Expansion*, who would lose their insurance coverage if the decision survives appeal;[22] and, the 10 million individuals who received private insurance through the online marketplaces, who would also lose their insurance coverage, limiting the access of healthcare services to this population.[23] In total, the *Kaiser Family Foundation* (KFF) estimates that 52 million adults under the age of 65 (27% of the U.S. population) would be rejected for healthcare coverage by insurers, which will, ultimately, negatively affect healthcare access, which the ACA sought to remedy.[24]

Other popular ACA provisions that would be rescinded should this ruling stand include the requirements that insurers cover those under age 26 on their parents' plans, and that certain employers offer coverage to their employees.[25] With a complete overhaul, healthcare costs would likely increase for individuals, leading to additional financial strain. For example, annual and lifetime limits on coverage would again be permitted and there would no longer be a cap placed on out-of-pocket costs.[26] Without these provisions, out-of-pocket expenditures will likely rise for individuals and further limit access to services due to cost.

However, even though many Americans would lose insurance and bear a greater financial burden as a result of deeming the ACA unconstitutional, there is likely a "*long legal road to travel before that is an immediate threat*."[27] As there have been more than 70 unsuccessful ACA-repeal attempts, many legal experts conclude that this decision will not hold upon appeal.[28] Notably, this could potentially be the third time since 2012 that SCOTUS contemplates a

challenge to the ACA.[29] In the previous two decisions, SCOTUS ruled to uphold the ACA, further indicating that Judge O'Connor's decision might not be upheld.[30]

The December 14th decision was revealed just hours before the end of 2019 Open Enrollment period through the marketplace insurance exchange on HealthCare.gov.[31] In response, the *Centers for Medicare & Medicaid Services* (CMS) Administrator, Seema Verma, made an announcement that open enrollment would continue as planned and that the case would not impact current insurance coverage or coverage in 2019 plans.[32] However, the confusion caused by this decision could result in lower enrollment numbers for 2019, which are down from last year by approximately 12%.[33] However, this low enrollment is also partly due to the excise of the tax penalty of the Individual Mandate that sparked this lawsuit, as well as the increased number of individuals utilizing Medicaid Expansion in states that have recently expanded.[34] Additionally, it is hypothesized that this low enrollment could be as a result from unawareness of the enrollment period as funding for marketing and outreach was decreased by 90% last year.[35] Arguments have also been made that the thriving U.S. economy has contributed to low enrollment, as more people are employed and thus receiving insurance from their employer.[36]

Should the *Texas v. United States* decision survive appeal, it would have major consequences for a large number of healthcare consumers. The decision would force people off of Medicaid in states that have expanded and restrict reasonable and affordable insurance options for those that currently obtain health insurance through the online marketplace. In addition, the decision would eliminate popular ACA provisions that both political parties support, such as covering those with pre-existing conditions. Although the decision has been rendered at the District Court level, the case will inevitably be appealed, eventually to SCOTUS. Until then, it appears that the ACA will remain in place and coverage will not be affected for individuals impacted by ACA provisions at this time.

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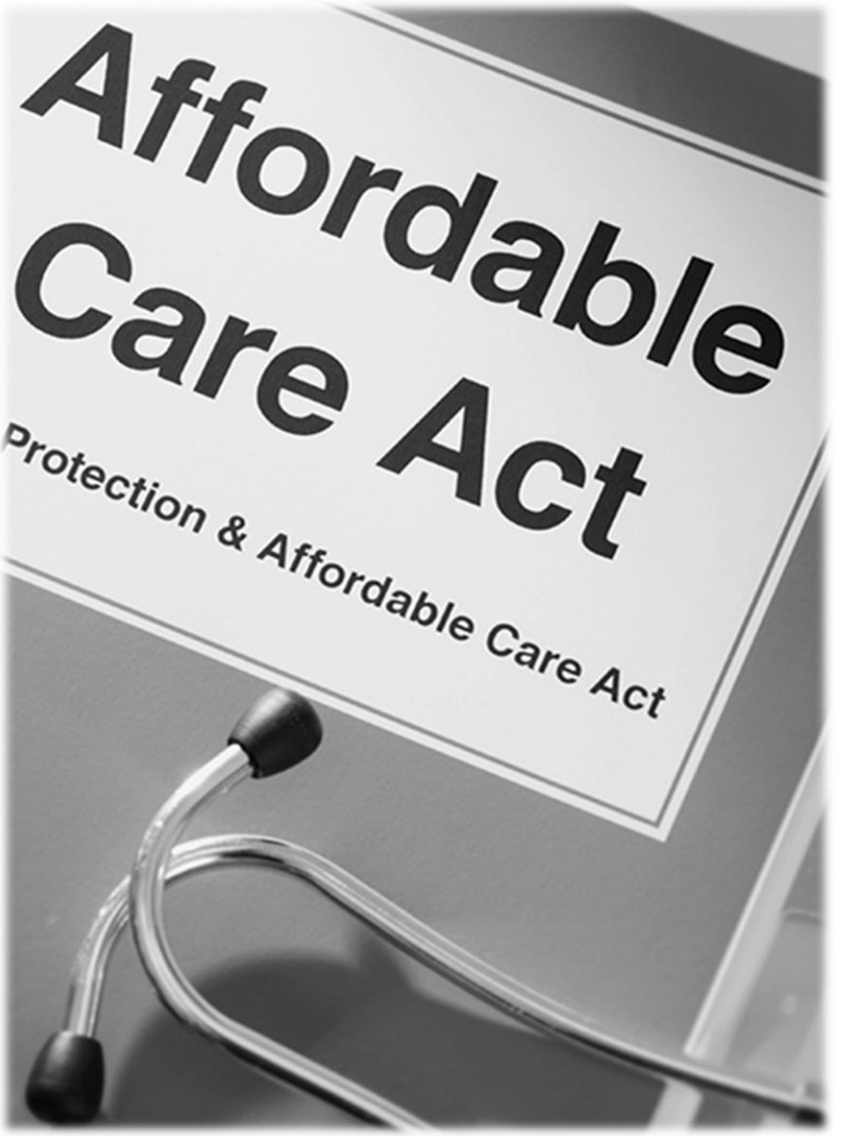

DOJ Agrees that Entire ACA Should Be Struck Down

[Excerpted from the Special Alert published in March 2019.]

In response to a Texas Federal District Court ruling that deemed the *Patient Protection and Affordable Care Act* (ACA) unconstitutional in its entirety, the *U.S. Department of Justice* (DOJ), which had previously asserted that most of the ACA should stand (despite the nullification of the *Individual Mandate* tax penalty),[1] has reversed their position, agreeing with the District Court that the entire ACA should be struck down.[2] This change in direction occurred approximately six weeks after William Barr was sworn in as 85th Attorney General of the U.S.,[3] following through on Barr's mention during his confirmation hearing that he would reconsider the original DOJ position on this matter.[4] In addition, this reversal was announced right after the California-led coalition released their brief that Congress's zeroing out of the *Individual Mandate* penalty did not make the provision unconstitutional, and that the *Individual Mandate* can still be read as part of Congress's taxing authority.[5] Additionally, the coalition argues that even if the *Individual Mandate* is found unconstitutional, it is severable from the rest of the ACA.[6]

The case is anticipated to be ultimately appealed to the U.S. Supreme Court. If the lower court's is upheld, the millions of individuals that gained insurance through the enactment of the ACA (including through Medicaid Expansion) will effectively lose their coverage, among other detrimental implications.[7] Currently, the Fifth Circuit, on which the DOJ called to affirm the lower court's ruling, has not scheduled oral arguments, but the federal government has proposed a hearing date of July 8, 2019.[8]

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1 For more information, see "Judge Rules Entire ACA Unconstitutional" Health Capital Topics, Vol. 11, Issue 12 (December 2018), https://www.healthcapital.com/hcc/newsletter/12_18/HTML/TEXAS/convert_hc_topics_tx_v_us_cite_chked_cataloged_12.20.18_hba.php (Accessed 3.28.19).

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Parties Argue Constitutionality of ACA before 5th Circuit

[Excerpted from the article published in July 2019.]

On July 9, 2019, the parties in the *Texas v. U.S.* lawsuit presented their oral arguments before a three-judge panel at the 5th Circuit Court of Appeals in New Orleans regarding the constitutionality of the *Patient Protection and Affordable Care Act* (ACA). The various questions posed to the attorneys by the judges (two of whom are Republican appointees, and one of whom is a Democratic-appointee)[1] indicated that the (two Republican-appointed) judges may uphold the lower court's ruling – at least as regards the Individual Mandate constitutionality issue.

During the 90-minute hearing, the judges (note that, the Democratic-appointed judge did not ask any questions during oral arguments) focused on a number of issues in the case, including whether the parties have standing to bring and/or defend the case; the constitutionality of the Individual Mandate (given that the tax penalty for violating the mandate is now $0); and, the severability of the Individual Mandate portion of the ACA from the remainder of the law.[2] The Republican-appointed judges seemed partial to the arguments of the Republican plaintiff states and the Department of Justice (DOJ) regrinding the Individual Mandate's constitutionality – with one of the judges bluntly asking: "*If you no longer have the tax, why isn't it unconstitutional?*"[3] However, the panel appeared less certain on the issue of the Mandate's severability from the entirety of the ACA, and uncomfortable with the prospect of being the body responsible for making the decision as to which ACA provisions should stay in effect and which should be voided.[4] However, one of the judges noted that Congress could pass a new law(s) to remedy this issue, although the attorney for the U.S. House of Representatives (an ACA proponent) pointed out that the law would also require the signature of President Trump, which action is extremely unlikely.[5] The judges also listed a number of ACA provisions that have nothing to do with the Individual Mandate, such as the requirement that certain restaurants post calorie counts on their menus,[6] potentially indicating their hesitance to declare the entire law invalid.

This appeal came before the 5th Circuit as a result of the December 14, 2018 ruling in Texas Federal District Court, in which Judge Reed O'Connor deemed the ACA to be unconstitutional in its entirety.[7]

As explained more fully in a December 2018 issue of *Health Capital Topics*, Judge O'Connor concluded that the Individual Mandate was no longer permissible under Congress's taxing power (under the same grounds as the 2012 *NFIB v. Sebelius* case, in which the U.S. Supreme Court found the ACA to be legal under Congress's taxing power) as a result of the 2017 tax reform law, which reduced the Individual Mandate's tax to $0 (i.e., it no longer produces revenue, which is an essential feature of a tax), rendering the ACA unconstitutional.[8] Further, the court ruled that the Individual Mandate could not be severed from the remainder of the ACA because the Mandate was "*the keystone*" of the law, essential to the regulation of the health insurance market,

thereby rendering the entirety of the ACA invalid.[9] Contributing to the federal court decision was the DOJ's position – the agency agreed with the plaintiffs that the Individual Mandate is unconstitutional, and asserted that other provisions such as the "*guaranteed issue*" (requiring health insurance companies to accept all applicants regardless of pre-existing conditions) are inseverable from the Mandate.[10] As a result, the DOJ did not (and will not) defend the constitutionality of the Individual Mandate during the case.[11]

While many ACA opponents believed that the questions posed by the judges indicated a receptiveness to the idea that the ACA is now unconstitutional in its entirety, but noted that the judges also expressed doubt as to whether the courtroom is the correct venue for this debate (in contrast to Congress).[12] On the other hand, legal scholars agree that there is little likelihood of the 5th Circuit affirming the lower court's ruling in its totality, considering the breadth of the law, and the severability option available to the court, as well as the strength of the Republican states' arguments.[13]

The next step in this ongoing saga will be for the appellate court to publish a ruling, which may take several months.[14] Regardless of the outcome, the case is anticipated to be ultimately appealed to the U.S. Supreme Court.[15] If the lower court's ruling is upheld, the millions of individuals that gained insurance through the enactment of the ACA (including through Medicaid Expansion) will effectively lose their coverage, among numerous other detrimental implications.[16]

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DOJ Recovers Over $2.8 Billion in False Claims Act Cases in 2018

[Excerpted from the article published in January 2019.]

On December 21, 2018, the *U.S. Department of Justice* (DOJ) announced their recovery of more than $2.8 billion in settlements and judgments from civil cases involving fraud and false claims for *fiscal year* (FY) 2018.[1] While 2018 marks the ninth consecutive year in which healthcare fraud settlements exceeded $2 billion, this year's amount was the lowest recovery since 2009.[2] Approximately $2.5 billion was recouped from the healthcare industry for federal losses alone, and included recoveries from drug and medical device companies, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians.[3] This figure, over 87% of the total recovery amount, far outstripped the $107.5 million recovered from defense contractor companies and the $259.6 million obtained from other industries such as banking.[4] In addition to the $2.5 billion recovered for federal losses, the DOJ recovered millions of dollars for state and Medicaid programs for FY 2018.[5]

Once again this year, the greatest proportion of healthcare recoveries was obtained from the drug and medical device industry. One of the largest settlements within this sector involved AmerisourceBergen Corporation, which paid $625 million to resolve allegations that the company (and some of its subsidiaries) "*sought to circumvent important safeguards intended to preserve the integrity of the nation's drug supply and profit from the repackaging of certain drugs supplied to cancer-stricken patients*."[6]

Additionally, in two separate settlements, pharmaceutical company United Therapeutics Corporation paid $210 million, and drug manufacturer Pfizer paid approximately $23.85 million, to resolve allegations that they set up foundations to pay the copays of thousands of Medicare patients as a way to raise the prices of their drugs.[7]

Additional legal actions were brought by the DOJ against several other provider sectors within the healthcare industry during FY 2018, including *Medicare Advantage Organizations* (MAOs) and health systems, resulting in large recoupments. The most noteworthy of these actions included the $270 million settlement between the DOJ and HealthCare Partners Holdings (d/b/a DaVita Medical Holdings), to resolve liability for "*providing inaccurate information that caused... [MAOs] to receive inflated Medicare payments*."[8] The other most noteworthy action involved the Health Management Associates (HMA) settlement payment of over $216 million to resolve allegations, arising from eight separate whistleblower actions, that HMA hospitals (which are now owned by *Community Health Systems*) "*knowingly billed government health care programs for inpatient services that should have been billed as outpatient or observation services, paid remuneration to physicians in return for patient referrals, and submitted inflated claims for emergency department facility*

fees."[9] One of HMA's subsidiaries, Carlisle HMA, also pled guilty to conspiracy to commit healthcare fraud "*arising from illegal conduct designed to aggressively increase admissions to the hospital*," which plea included a $35 million financial penalty.[10]

Of note, the DOJ's press release included an additional section entitled, "*Holding Individuals Accountable*," wherein it reviewed several cases in which the DOJ obtained substantial judgments from individuals, illustrating its continued commitment to the 2015 memorandum authored by then-Deputy Attorney General Sally Yates regarding holding individuals accountable for corporate wrongdoing (often referred to as the "Yates Memo").[11]

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.[12] According to the DOJ's press release, the recoveries made in 2018 are "*a message that fraud and dishonesty will not be tolerated*," and "*the Department's vigorous pursuit of health care fraud prevents billions more in losses by deterring those who might otherwise try to cheat the system for their own gain*."[13]

Since 1986, recoveries made under civil FCA suits total more than $59 billion.[14] 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 645 qui tam cases and 122 non qui tam cases initiated in FY 2018 alone (both of which numbers are substantially similar to FY 2017 figures).[15] Despite the Trump Administration's actions to deregulate the healthcare industry during the last two years, and the lower amount of monetary recoveries in FY 2018, the number of new cases in 2018 enforcing healthcare fraud and abuse laws appears to be on par with figures from previous years,[16] suggesting that FCA enforcement will remain high going forward.

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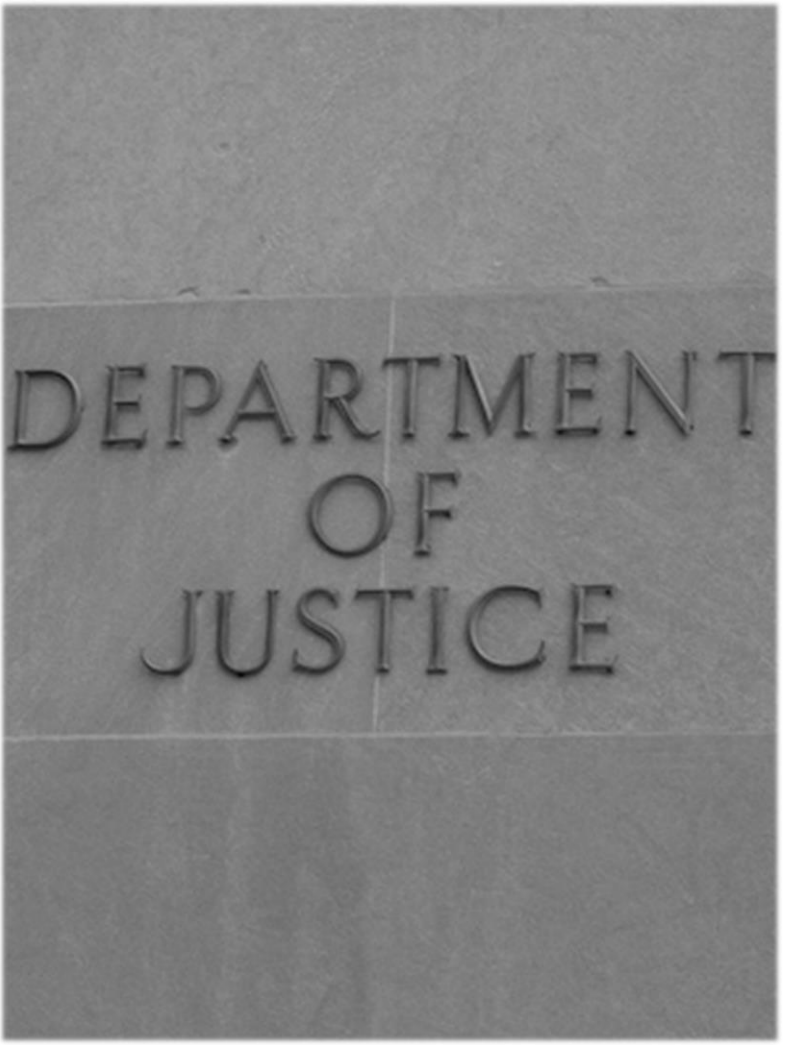

HHS Proposes Removal of Safe Harbor Protection for PBMs

[Excerpted from the article published in February 2019.]

On January 31, 2019, the *Department of Health and Human Services* (HHS) released a proposed rule that would eliminate safe harbor protection under the *Anti-Kickback Statute* (AKS) for rebates that prescription drug manufacturers grant to *pharmacy benefit managers* (PBMs), Medicare Part D plans, and Medicaid *managed care organizations* (MCOs).[1] This proposal carries out Congress's directive under the *Medicare and Medicaid Patient and Program Protection Act of 1987*, requiring the HHS Secretary, Alex Azar, to identify payment practices that should not be subject to prosecution under the AKS and to periodically evaluate safe harbor rules in order "*to reflect changing business practices and technologies in the health care industry*."[2] This proposed rule addresses the changes of the "*modern prescription drug distribution model*" to ensure arrangements benefit federal healthcare program beneficiaries.[3]

PBMs administer prescription programs to Americans who have health insurance through commercial health plans, Medicare Part D plans, managed Medicaid plans, and others, but are experiencing increased scrutiny within the healthcare industry.[4] Historically, PBMs have been "*middlemen*" entities that process medication claims for insurance companies and plan sponsors for a small fee per claim.[5] PBMs have since evolved to manage drug benefits for approximately 95% of the U.S. population, providing drug utilization review and drug plan formulary development, among other services.[6] Because PBMs make formularies for plan sponsors, they are able to negotiate better prices; however, only a portion of the rebates they receive are shared with the plan sponsor, causing concern within the healthcare industry as patients are paying cost shares that do not reflect the actual, lower cost of the drug.[7]

Drug prices and rebate payments to PBMs have grown substantially in recent years, prompting the revision to the AKS safe harbor.[8] The *Office of Inspector General* (OIG) released a report indicating that reimbursement for brand-name Part D drugs increased by 77% from 2011 to 2015, despite a 17% decrease in prescriptions of these drugs.[9] Recently, drug manufacturers announced drug increases at an average of approximately 6.3%.[10] Despite the increase in drug prices that lead to higher rebates, HHS states that many rebates are not seen at the pharmacy counter in the form of price reductions; rather, the rebates are applied as reduced premiums for all enrollees.[11]

Consistent with the Trump Administration's promise to reduce prescription drug prices and out-of-pocket costs, this proposed rule attempts to encourage manufacturers to pass on discounts directly to patients at the point of sale for products payable under Medicare Part D or by Medicaid MCOs, as well as increase transparency within the overall prescription drug industry.[12] Additionally, the proposed rule outlines new safe harbors for the point-of-sale discounts offered to patients and for fixed service fees that drug manufacturers give PBMs for services that meet specific criteria.[13] If the rule is finalized, the prescription drug rebates, which are, on average, 26% to 30% of a drug's list

price, would be passed on directly to patients, particularly benefiting older Americans and those with chronic conditions who have high drug expenditures.[14]

Azar believes that, under the existing structure, Americans often pay more for prescriptions "*because of a hidden system of kickbacks to middlemen [i.e., PBMs]*."[15] Currently, PBMs and Part D plans favor drugs with higher prices, such as brand-name and biologic prescriptions, rather than lower-cost generics and biosimilars, as rebates tend to be a percentage of the list price.[16] The *Pharmaceutical Research and Manufacturers of America* (PhRMA) supports the proposed rule because it focuses on patients and reduces the incentives for insurers and PBMs to favor drugs with high list prices, ensuring "*that the $150 billion in negotiated rebates and discounts are used to lower costs for patients at the pharmacy*."[17] Particularly with insurer-PBM market consolidation, such as the CVS-Aetna and Cigna-Express Scripts deals, drug manufacturers have minimal ability to push back on rebate demand from PBMs.[18]

However, the *Pharmaceutical Care Management Association* (PCMA), a PBM lobbying group, emphasizes that this proposed rule would increase drug costs and force Medicare beneficiaries to pay higher premiums and out-of-pocket expenses.[19] PCMA states that drug manufacturers set and raise prices, independent of rebates, and PBMs are part of the solution to these high costs, as they negotiate on behalf of beneficiaries.[20] A study by Oliver Wyman Consulting found that rebates have reduced costs by approximately $35 billion, and without these rebates, premiums would have increased by 52% in 2018.[21] Further, another study concluded that the price of popular Part D drugs were increasing, but there was no change in rebate levels to PBMs, from 2012 to 2017, supporting the PCMA statement that drug manufacturers are the entities that set and raise prices.[22]

An IHS Markit analysis projects that with negotiated discounts at the point of sale, Medicare beneficiaries with diabetes could save approximately $350 annually.[23] However, despite the intent to lower out-of-pocket costs, there is a possibility of unintended consequences stemming from the proposed rule, such as beneficiaries paying more in cost-sharing at the pharmacy.[24] In addition, according to HHS's analysis, Part D premiums in 2020 could be subject to an increase of $3.20 to $5.64 per beneficiary per month (PBPM); however, total cost sharing would decrease, indicating a net decrease in beneficiary spending PBPM.[25]

Excluding PBMs, Part D plans, and Medicaid MCOs from safe harbor protections, and including safe harbor protection for discounts offered directly to patients, intend to lower drug prices and out-of-pocket costs, increasing transparency in the pharmaceutical industry. Although the proposal only applies to federal plans, it may prompt a similar change in commercial plans. Azar believes that insurers that offer both Medicare and commercial plans may eliminate rebates for their commercial plans, as it may be difficult to "*segregate*" systems.[26] Additionally, Azar mentions that states may eventually

adopt safe harbor protections and outlaw rebates to private plans similar to the proposed rule.[27]

The proposal was published in the Federal Register on February 6, 2019 and will include a 60-day comment period.[28]

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MedStar Pays $35 Million to Settle Kickback Allegations

[Excerpted from the article published in March 2019.]

On March 21, 2019, Maryland's *MedStar Health, Inc.* and its two affiliate hospitals, *MedStar Union Memorial Hospital* and *MedStar Franklin Square Medical Center*, agreed to pay $35 million to the federal government to resolve allegations of *False Claims Act* (FCA) violations.[1] The government relators alleged that the hospitals made kickback payments, "*under the guise of professional services agreements*," for more than five years to a cardiology practice, *Midatlantic Cardiovascular Associates, P.A.* (MACVA), in exchange for MACVA referring Medicare patients to the hospitals for cardiac surgery and other cardiology services.[2]

The FCA imposes civil monetary penalties upon violators in an amount between $5,000 to $10,000 per claim, as well as treble damages if a person performs any of the following actions:

(1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(3) Conspires to commit a violation of the FCA; or,

(4) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government.[3]

The FCA is a potent fraud and abuse enforcement tool, as it allows private individuals, also known as *qui tam* relators or *whistleblowers*, to bring suits on behalf of the government. The MedStar settlement resolves two *qui tam* lawsuits, originating in 2010 and 2012, as well as federal allegations of financial misconduct.[4]

The 2010 lawsuit was brought in the District of Maryland by three physician shareholders of *Cardiac Surgery Associates* (CSA), competitors of MACVA.[5] MACVA was originally solely comprised of cardiologists, who do not perform surgery; through consolidation, MACVA became the largest cardiology practice in Maryland, making over 2,100 referrals per year to independent cardiac surgeons (such as CSA).[6] In efforts to allegedly assert their recently-acquired, significant leverage, and to capitalize on the capture of cardiac surgical revenue, MACVA allegedly sought to merge with CSA, structuring the deal such that MACVA would receive from CSA a one-time kickback payment for their referrals to CSA via an $800,000 assessment under the guise of covering "*overhead costs*," which money would, in reality, be distributed to MACVA cardiologists.[7]

In a subsequent attempt at merger discussions (after the first round of merger talks failed), MACVA then allegedly proposed that, post-merger, each CSA senior surgeon would be subject to an annual $500,000 reduction in earnings, in the form of an "*overhead assessment*," which amounts would be redistributed to MACVA cardiologists.[8] In both sets of merger discussions, MACVA allegedly threatened that if CSA did not agree to merge (and to their payment demands), MACVA would "*put CSA out of business*."[9] After the cessation of the MACVA/CSA merger negotiations, MACVA hired their own cardiac surgeons, and shortly thereafter, followed through on their claim of discontinuing all referrals to CSA.[10] Subsequently, CSA experienced a nearly 100% decline in referrals from MACVA, all of which referrals were, instead, allegedly going to the newly-hired MACVA surgeons or hospitals with which MACVA had relationships.[11] MACVA allegedly also asserted their leverage on the hospitals similar to CSA – for example, MACVA allegedly "*forced*" Saint Joseph's Hospital to (among other things) pay CTVS kickbacks for referrals, under the guise of "*managed care guidance*" and "*outcomes data research*" fees paid to CTVS for helping St. Joseph's streamline their operations and thus maximize reimbursement from managed care organizations, as well as conduct research regarding outcomes emanating from hospital-wide inpatient therapies and treatments (i.e., not just cardiology).[12] As a result, in 2010, CSA filed a lawsuit against MACVA and the associated community hospitals in the Baltimore metropolitan region where the MACVA physicians practiced.[13]

Of note, this MedStar settlement also resolves a 2012 lawsuit, alleging the performance of unnecessary cardiac stent procedures by John Wang, M.D. (who was employed by MACVA and, later, MedStar), and the subsequent false claims submitted to Medicare for those procedures.[14]

While MedStar denies any wrongdoing in both cases, the entity determined that it was in their best interest to settle with the government in order to avoid further litigation.[15] MedStar has emphasized that "*the two cases have been settled without any findings of liability*," and that "*MedStar has full confidence in our quality assurance and compliance programs, and we remain fully focused on advancing our patient care mission*."[16]

As mentioned in the January 2019 Health Capital Topics article entitled, "*DOJ Recovers Over $2.8 Billion in False Claims Act Cases in 2018*," there has been a significant number of FCA suits brought by whistleblowers, as well as by the *Department of Justice* (DOJ), over the past five years.[17] Despite the Trump Administration's actions to deregulate the healthcare industry during the last two years, the number of new cases enforcing healthcare fraud and abuse laws suggest that FCA enforcement will remain high going forward.

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Florida Legislature Votes to Repeal Hospital CON Program

[Excerpted from the article published in June 2019.]

On April 29, 2019, the Florida Legislature passed House Bill 21 (largely along party lines), which repeals the state's *certificate of need* (CON) laws with respect to general hospitals, specialty hospitals, and tertiary services.[1] Pursuant to the bill, general hospitals and providers of tertiary services will be free of this requirement beginning in July 2019, while specialty hospitals will no longer be subject to the CON law starting in 2021.[2] As of now, hospices, nursing homes, and intermediate care facilities for persons with developmental disabilities (ICF/DD) would still be subject to the CON regulations.[3] While Governor Ron DeSantis has not yet signed the bill, he is expected to do so, and the law would subsequently become effective July 1, 2019.[4]

State CON laws generally require healthcare providers to obtain authorization from a state to construct new healthcare facilities, expand/renovate existing ones, or offer certain healthcare services.[5] Most states adopted CON programs in response to the *National Health Planning and Resources Development Act of 1974*, which offered states financial incentives to adopt CON programs;[6] this law was repealed in 1986.[7] These programs were supposed to "*control...costs by restricting provider capital expenditures*," but these outcomes never ensued, leading to the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ) suggesting, approximately 15 years ago, that states repeal or retrench their CON laws.[8] To date, 15 states have eliminated their CON programs, although three of them still have some variation of a CON program.[9] As of July 2019, it appears that Florida will join that group.

Notably, the passage of this Florida legislation comes after the publication of a federal government report that aggressively pushed states to repeal their CON laws. In December 2018, the Department of Health & Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury, issued a report entitled "*Reforming America's Healthcare System through Choice and Competition*," which argued in part that the existence of CON laws has been a significant cause of escalating healthcare costs.[10]

Florida's CON deregulation may spur other states that have also been considering CON repeals (or some variation thereof), including Georgia, Alaska, South Carolina, and North Carolina. In April 2019, the Georgia House passed a bill that (among other provisions), effective July 1, 2019, limits the healthcare providers that could object to a CON application from any hospital, to only those within a 35-mile radius of the proposed project; allows for the establishment of freestanding emergency departments (FSEDs); and, increases the capital expenditure thresholds for new healthcare services from $2.5 million to $10 million.[11] This bill was the culmination of a number of influencing events, including the failure of a previous (more restrictive) bill, strong lobbying efforts against the measure by Georgia hospitals, and public support for the measure from Governor Brian Kemp.[12]

On the other side of the country, Alaska legislators are seeking to repeal the state's CON law for the third straight year. Identical bills in the state house and senate (House Bill 17 and Senate Bill 1, respectively), seek a wholesale repeal of the law, and are currently in their respective committees for consideration.[13] Similarly, South Carolina legislators introduced a bill to wholesale repeal its CON laws in January 2019. House Bill 3823 has since been referred to committee for consideration.[14] In April 2019, North Carolina legislators introduced multiple bills to: (1) repeal the entirety of the CON law (Senate Bill 539); and, (2) absolve ASCs from CON requirements (Senate Bill 646 and House Bill 857).[15] All three bills have passed their first reading and have also been referred to the respective committees.[16]

In addition, a number of states (including Missouri, Montana, Oregon, and West Virginia) have recently repealed CON requirements related to transportation, and Kansas is currently considering such a repeal.[17] Of note, most of these states are considered to be conservatively leaning, from a political standpoint, which may indicate that the Trump Administration report advocating for the repeal of these laws has resonated with states, and motivated this newest wave of CON law repeals.

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Emboldened Antitrust Scrutiny of Healthcare Transactions

[Excerpted from the article published in July 2019.]

While healthcare transactions involving physicians have continued to accelerate over the past several years, these alignments have been fraught with regulatory concerns stemming from the federal government's significant scrutiny of transactions from a fraud and abuse perspective. More recently, government agencies have been increasing their antitrust scrutiny of these deals as well, further complicating the healthcare transactional arena. This intensifying scrutiny has been exemplified through a number of recent actions taken by government agencies, as well as the courts, to stifle physician practice purchases by hospitals and payors. This *Health Capital Topics* article will briefly review these actions, as well as the state of antitrust enforcement generally, and discuss potential implications for future healthcare transactions.

Antitrust law aims to combat anticompetitive behavior conducted by businesses. The *Sherman Antitrust Act* (Sherman Act), which prohibits any "*contract, combination...or conspiracy, in restraint of trade or commerce*;"[1] Section 5 of the *Federal Trade Commission Act* (FTCA), which prohibits "*unfair methods of competition in or affecting commerce*;"[2] and, Section 7 of the *Clayton Act*, which prohibits acquisitions that are likely to "*substantially lessen competition, or tend to create a monopoly*,"[3] are the federal government's three primary means of combating unfair competition and abuse of monopolistic power, through two principal government agencies, *the Federal Trade Commission* (FTC) and the *U.S. Department of Justice* (DOJ). In the healthcare context, these statutes have also been used to combat kickbacks and self-referral joint ventures, which have been recognized as an impediment to competition by providers outside the self-referral or kickback network,[4] as well as other anticompetitive healthcare arrangements including: physician integration under physician hospital organization models, *independent practice associations* (IPAs), and healthcare organizations negotiating on behalf of their physician members.[5]

The most recent wave of healthcare antitrust enforcement is comprised of four (4) actions by the FTC and the DOJ, all of which occurred over a two-month period:

(1) In June 2019, the FTC settled with UnitedHealth Group (UHG) and DeVita Medical Group to unwind UHG's acquisition of DaVita's Las Vegas operations;

(2) In June 2019, Colorado's Attorney General imposed conditions on UHG's acquisition of DaVita's Colorado Springs physician groups;

(3) In June 2019, the Eighth Circuit upheld a lower court ruling that blocked Sanford Health's proposal to acquire a multispecialty physician practice in Bismarck, ND, granting the FTC and North Dakota Attorney General's antitrust lawsuit to block the acquisition; and,

(4) In May 2019, Washington's Attorney General settled an antitrust lawsuit against CHI Franciscan, which imposed conditions on both CHI's affiliation with a multispecialty physician group and its purchase of an orthopedics group.[6]

Of note, the UHG deals were both challenged under the FTC's *vertical merger review*, a seldom-utilized theory (employed to challenge only 22 mergers since 2000) that focuses on the question of whether "*the vertically integrated firm is likely to exclude or collude*."[7] This theory includes three "*theories of vertical harm the FTC has used to challenge a vertical merger*," i.e.:

(1) "*A vertical merger may reduce the likelihood of beneficial entry*," meaning that, post-merger, it may be difficult for new firms to enter the market, because they would have to enter in post segments of the market to compete with the vertically-merged firm;[8]

(2) "*A vertical merger may result in anticompetitive foreclosure*," that is, whether the merger may result in increased costs for their competition, or otherwise negatively impact market entry;[9] and,

(3) "*A vertical merger may lead to anticompetitive behavior due to information sharing about a rival*," wherein two previously competing firms now have access to the other firm's competitor information (upstream or downstream) that it did not have prior to the merger.[10]

This recent uptick in antitrust scrutiny of healthcare transactions may be the result of a number of factors. First, recent research indicates that healthcare consolidation results in higher prices for patients. For example, a 2018 study found that hospital purchases of physician groups resulted in a 35-63% increase in outpatient physician prices in highly-concentrated markets in California, as compared to less-concentrated markets.[11] Other studies have indicated that consolidations lead to increased pricing due to more negotiation leverage,[12] as well as poorer healthcare outcomes (higher rates of mortality, higher readmission rates, etc.).[13]

Second, antitrust scrutiny may have increased in an attempt to repress further consolidation in the already-concentrated healthcare markets in parts of the urban/suburban U.S. As of 2018, 65% of metropolitan statistical areas (MSAs) were considered to have high concentrations of specialists, while 39% of MSAs were considered to have high concentrations of primary care physicians; additionally, most urban areas are now dominated by one to two large hospital systems.[14] Further, the average size of physician practices has grown, with 61% of physicians in practices of 10 doctors or fewer in 2014 (down from 80% in 1983), which concentration was found to have occurred through numerous small acquisitions that did not warrant the attention (or scrutiny) of federal regulators.[15]

Third, perhaps in response to the first two factors, the government's renewed interest in antitrust enforcement may be a manifestation of the Trump Administration's efforts to increase competition and drive down healthcare industry prices. On December 3, 2018, the departments of *Health and Human*

Services (HHS), *Treasury*, and *Labor*, issued a report entitled, "*Reforming America's Healthcare System Through Choice and Competition*," resulting from an executive order that President Donald Trump issued over a year prior.[16] The 119-page report, comprised of over 50 policy recommendations to increase quality and decrease costs in healthcare, included a summary of the research related to competition and pricing (some of which is also noted above), and stated that "*[t]hese studies lend support for vigorous antitrust enforcement to prevent the accumulation of market power in healthcare markets.*"[17] Specifically, the report recommended that the Trump Administration continue to monitor competition in the healthcare market, "*especially in areas that may be less competitive*," and "*ascertain the impact of horizontal and vertical integration among provider practices on competition and prices*." [18]

In the midst of the current shift in the U.S. healthcare market from volume-based to value-based care, providers are likely to continue consolidating as needed (and required) to amass the requisite economies of scope and scale to provide efficient, high-quality patient care in order to survive. At the same time, however, the government is beginning to ramp up its opposition to this growing consolidation, as it is resulting in increased prices, but also poorer outcomes.[19] In fact, the FTC and the DOJ stated in March 2019 that they are updating the current vertical merger guidelines, "*which outline how antitrust enforcers assess the impact of deals between companies that compete in different markets*," and which were last revised in 1984.[20] This may indicate even more intense antitrust scrutiny related to healthcare transactions going forward, and further complicate potential healthcare transactions.

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IV. COMPETITION TOPICS

DOJ Approves CVS-Aetna Merger

[Excerpted from the article published in October 2018.]

On October 10, 2018, the *U.S. Department of Justice* (DOJ) approved the proposed merger of CVS Health Corporation and Aetna, Inc.[1] CVS publicly announced their intent to acquire Aetna in December of 2017 upon unanimous approval by the boards of directors of each company, combining the largest *retail pharmacy chain* and the third largest health insurance company in the U.S., respectively.[2] This $69 billion merger, financed by CVS, was initiated on their belief that the transaction would fulfill an unmet need of consumers (i.e., patients) in the healthcare system, providing low cost, high quality care through the integration of Aetna's analytical capabilities and CVS's vast market presence.[3] Larry Merlo, President and CEO of CVS, envisions that this merger will *combine capabilities in technology, data and analytics to develop new ways to engage patients in their total health and wellness*.[4] Merlo asserts that consumers will benefit from the integrated, community-based healthcare experience with more "*personalized care*" by combining Aetna's providers and consumer access through CVS's 9,800+ pharmacy locations and 1,100+ *MinuteClinics*.[5] Shareholders of the companies are also projected to benefit in terms of the new competitive positioning and the long-term added value of the merger, potentially generating $750 million in savings after two years and $2.4 billion annually by the fifth year.[6]

The likelihood of the DOJ approval of the CVS-Aetna merger was anticipated by the greenlight of the Cigna-Express Scripts merger last month, considering that both mergers involved vertical integration (defined as the combination of separate sections in the supply chain of an industry[7]), i.e., a major health insurer and a *pharmacy benefit manager* (PBM).[8] However, the CVS-Aetna merger, under the proposed structure, also incorporated aspects of horizontal consolidation, i.e., a combination of similar entities in the same industry.[9] Both CVS and Aetna provide a Medicare Part D plan to consumers, if combined would have served approximately 6.8 million beneficiaries.[10] Currently, the three largest providers of Medicare Part D plans (by enrollment numbers) include CVS Health Corporation, UnitedHealth Group, Inc., and Humana, Inc., with Aetna close behind, posing a potential domination of the market with the merger, considering CVS already serves the greatest number of enrollees.[11] The DOJ antitrust division and five state attorneys general (California, Florida, Hawaii, Mississippi, and Washington) filed a federal lawsuit against the horizontal aspect of this merger, while simultaneously proposing a settlement wherein Aetna would divest of its Medicare Part D program to resolve the DOJ's anticompetitive concerns associated with the merger.[12]

According to the DOJ, a merger without this divestiture of the Medicare Part D plans would have resulted in major market domination concerns; reduction of competition; increased prices for Medicare beneficiaries and taxpayers; reduced quality; and, less innovation.[13] An expert testimony report was one source that set forth the reasoning behind the *American Medical Association*'s

(AMA) opposition of the merger with the Medicare Part D plans, and support of the divestiture. The study analyzed market share effects if the Part D plan was included in the merger, and concluded that this merger would indeed enhance the market power of CVS-Aetna and would be anticompetitive for a majority of the states, with the market being moderately to highly concentrated.[14] To alleviate these anticompetitive concerns, Aetna announced that WellCare Health Plans would buy Aetna's Medicare Part D business for an undisclosed amount, transferring approximately 2.2 million members; however, this sale will not affect Aetna's individual or group Medicare Advantage, Medicare Advantage Part D, or Medicare Supplement plans.[15] WellCare, predominantly serving Medicaid consumers, will be assisted by Aetna in the transition of its Medicare Part D business into 2019.[16] This purchase will triple WellCare's Medicare Part D membership from 1.1 million to 3.3 million consumers upon federal regulatory approval.[17]

Although the horizontal consolidation portion of the merger posed a problem for the DOJ, the vertical integration portion did not trigger anti-competitive concerns (as foreseen by the approval of the Cigna-Express Scripts merger).[18] However, vertical integration can create tension within an industry if the seller owns the supplier, potentially making it difficult for other sellers to use the supplier.[19] *CVS-Caremark*, the PBM subsidiary of CVS, negotiates prices with drug companies, and may use its already considerable leverage to offer Aetna larger rebates and discounts post-merger, so that Aetna can attract healthcare insurance consumers.[20] However, this could potentially increase the market share of an already large insurer, resulting in anticompetitive effects.[21] With the vertical integration, CVS's *MinuteClinics* may also benefit because more Aetna beneficiaries will be driven to their sites of service, causing a shift to retail clinics that are providing services that traditional providers once exclusively covered.[22] However, consolidation up and down the supply chain may actually serve to heighten competition, rather than eliminate it, by expanding the scope of services in the *MinuteClinics*, as it may put pressure on more traditional healthcare providers (e.g., hospitals and medical groups) to become more cost effective.[23]

Even with DOJ approval upon divestiture, the CVS-Aetna merger is awaiting state approvals, which may be difficult to obtain due to the concerns of the vertical integration effects on the healthcare industry and consumers. Maria Vullo, New York State Superintendent of Financial Services, led a public hearing on the merger on October 18, 2018, explaining the agency's concerns with both the merger's promise of financial cost savings, and the lack of commitment expressed by the companies to pass on any realized savings to consumers (e.g., lower premiums).[24] In addition, CVS will borrow $40 billion to fund the merger, which could potentially raise insurance premiums, by CVS-Aetna passing on this debt to consumers.[25] This merger could also incentivize Aetna to create cost-sharing structures to ensure that consumers are driven to CVS rather than other competitors, leading to increased drug prices.[26]

The preliminary approval by the DOJ supports the continuing of major mergers up and down the supply chain in the healthcare industry, potentially representing a future trend. More PBMs may consequently merge with insurance companies to match the scale of the two PBM/insurer mergers that have been approved this year.[27] In addition, various healthcare entities up and down the supply chain may combine (rather than only PBMs/insurers), to incorporate more coordination, which consumers are demanding.

Similar to the insurance industry, hospitals are also merging in order to protect their market position, perhaps in response to the price pressure and technology that is shifting medical care to the outpatient ambulatory setting.[28] Recently, Memorial Hermann and Baylor Scott & White, two of the biggest hospital chains in Texas, announced their intent to merge in order to create an integrated system with cost-effective care, which, combined, will serve 30+ Texas counties through their 68 hospitals.[29] However, the concern, as with any merger, is that this will negatively affect competition on price and quality.[30] Additionally, in April 2018, Advocate Health Care finalized its merger with Aurora Health Care; the combined entities will dominate the Illinois-Wisconsin region, setting a precedent for the merger of the Texas systems.[31] Findings regarding the effects of such "*mega mergers*" have been mixed. A study on behalf of the *American Hospital Association* revealed that hospital mergers increased cost savings, resulting from the collaboration related to technology, access to capital, and standardization of clinical protocols.[32] However, mergers can increase bargaining power with insurance companies that can lead to more expensive procedures resulting in rising healthcare prices.[33] A study based in California concluded that hospital prices increased the most in multi-hospital systems (e.g., at Dignity Health) that had considerable market power, where prices per patient admission were approximately $4,000 higher than other hospitals in the state due to the system's ability to demand higher prices.[34]

Overall, the trend in healthcare is consolidation. The approval of the CVS-Aetna merger is a major milestone in governmental acceptance and allowance of vertical integration, as it is the second PBM/insurer merger approved by the DOJ this year. Similar mergers between insurers and PBM are expected to ensue, as well as new combinations of providers within the healthcare industry, in order to match the scale of these merged entities. As demonstrated by these "*mega-systems*," there may be increased cost savings with coordination; however, prices continue to rise for certain procedures, providing uncertainty on the effects of healthcare consolidation on patients.

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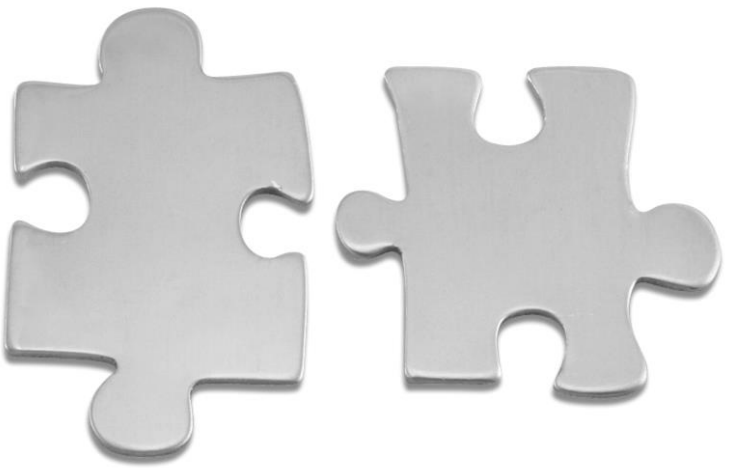

Hospitalist Pilot Model Sparks Controversy

[Excerpted from the article published in January 2019.]

A pilot program in two *Naples Community Hospital* (NCH) Healthcare System hospitals, where only NCH-employed hospitalists handle admissions and direct in-patient care (i.e., "The Hospitalist Model"), has sparked controversy within the Naples, Florida community.[1] The Hospitalist Model aims to foster a collaborative approach to in-patient healthcare through a hospitalist and support team in order to enhance patient-centered care and in-patient outcomes, congruent with the system's stated commitment to quality.[2] However, patients and independent physicians have expressed significant concern regarding the potential disruption of the doctor-patient relationship that may occur upon the expansion of this model when a hospitalist controls in-patient care, rather than the patient's established primary physician.[3]

The pilot, which initially began in June 2018 on one floor in each of the two NCH hospitals, recently expanded to a third floor, with the possibility of further expansion into a "*closed, employee only*" staff model throughout both hospitals.[4] This model utilizes "*geographic rounding*," in which an employed hospitalist handles all medical admissions for a total of 18 patients in a designated area.[5] The hospitalist rounds twice during the day, during the hours of 7:30 am to 5:30 pm, along with a support team (i.e., pharmacy, rehabilitation and ancillary services), prioritizing the patients most in need.[6] Under the pilot model, patients have the choice to either participate in the pilot program or be admitted and treated by their primary doctor (pending room availability on one of the nine non-pilot floors between the two hospitals).[7] Although the timeline is unclear, as long as the program is successful in reducing certain undesirable measures such as 30-day patient readmissions and does not harm the patient, continual expansion throughout the two hospitals will likely commence.[8]

A major concern for Naples residents regarding the pilot program is the possibility that it will jeopardize the doctor-patient relationship with their established independent primary care and concierge physicians. This leads to patient and primary physician concerns about care quality as hospitalists, who may not know the patient, their medication, or their comorbidities, would control their in-patient care.[9] The independent physicians are also concerned about the potential elimination of their admitting privileges as the program continues, effectively squeezing them out of the market.[10] Because of the pilot program, an increasing number of independent physicians will not be caring for patients at the hospital; therefore, hospital privileges may not be renewed as the hospital bylaws require physicians to have at least 24 documented patient contracts.[11]

In response to this pilot program, attorneys hired by a group of physicians and patients are demanding that the NCH board withdraw the policy, and the Collier County Commission has agreed to send a formal letter requesting an explanation for the motive behind the program's expansion.[12] Due in part to

public pressure to rescind the policy, the CEO and Chief of Staff of NCH Healthcare System resigned on January 23, 2019.[13]

While the public backlash has certainly stymied the rollout of the Hospitalist Model, the attorneys have indicated their intent to take further legal action to protect the interests of the physicians and patients involved if the current pilot stays in place.[14] Essential to the legal case, NCH-employed physicians are required to refer to NCH-employed specialists, impacting competition to third-party specialists and potentially lowering the quality of care by restricting choice.[15] According to the attorneys, this policy change could affect NCH's license with the state of Florida, due to a state statute being eliminated that ensures physicians can use admitting privileges based on expertise.[16] Additionally, the attorneys state that if the program continues, NCH could lose Joint Commission accreditation as it requires physicians to be able to use privileges based on expertise, which would be inconsistent with awarding privileges to only NCH-employed physicians.[17] The loss of such accreditations would exclude NCH from receiving Medicare reimbursement, as well as other insurer reimbursement such as Blue Cross.[18]

The NCH board has stated generally that they will do what is in the best interest of the community.[19] While primary care doctors may not have admitting privileges on the pilot floors, NCH assures that throughout the program, independent primary care physicians may consult the patient, review hospital records and test results, and give recommendations to the hospitalists.[20] Their reasoning for continued expansion of the pilot program to additional units throughout each hospital is the successful results from the initial pilot floors, resulting in reduced Medicare penalties, through a 50% reduction in hospital-acquired conditions, a 50% reduction in 30-day readmissions and a 20% reduction in length of stay.[21] An internist at NCH stated that these decreases are likely due to the current lack of primary care physicians who are completing rounds at the hospital (on non-pilot floors), and because hospitalists are proximate to the admitted patients they can see them, when needed, in minutes rather than hours, and they may be able to discharge the patient sooner.[22]

Other systems, including the UCLA Medical Center, University of Cincinnati Medical Center, and Brigham and Women's Hospital, have employed similar unit-based hospitalist models with positive results, which may indicate a trend toward increased utilization of hospitalists and this admissions model.[23] The combination of financial penalties, such as those issued by Medicare for not meeting certain quality metrics, and the transition from *volume-based* to *value-based* reimbursement models may also influence hospitals to adopt this model in an attempt to increase quality, and consequently lower penalties and receive maximum reimbursement. However, in areas where hospitals are utilizing this model, more independent physicians might leave, which could cause patients to lose their primary care physician and affect their access to and continuum of care. [24] Further, hospitals may experience physicians from other specialties leaving their organization due to the controversy; for example, four radiologists in the NCH Healthcare System have decided to leave the system due to the

allegedly toxic environment that had been created as a result of this pilot program, which, they stated, would significantly impact the operation of the facilities.[25] Additionally, a potential decrease in the number of local primary care or concierge physicians may result from this model as there might be little incentive to start independently practicing in the area.[26] These two factors, i.e., an increase in primary care physicians/specialists leaving the model and a decrease in the number of non-hospital physicians, may result in reduced competition within the area, creating a potential physician shortage. Additionally, some independent primary care physicians may feel an increased pressure to become employed by hospitals implementing this model to ensure that they can care for their patients, resulting in more anti-competitive behaviors.

As this program relies on hospitalists, it is essential that hospitals can attract these physicians, to ensure that the model will be effective. In the NCH hospitals in Naples, approximately half of admissions are made by independent physicians, and moving forward, it is estimated that a total of 35 hospitalists would need to be hired for a complete roll out.[27] For complete expansion of this program in any hospital, increased recruitment would be essential; however, there is a shortage of hospitalists nationally, making recruitment highly competitive.[28] In order to combat the demand, organizations wanting to employ this model might turn to foreign medical graduates for the hospitalist positions, as NCH is considering.[29] For organizations unable to successfully recruit and retain a substantial number of physicians, this model will likely be unattainable.

A rollout of The Hospitalist Model to the remaining floors of the NCH hospitals, as well as in other hospitals, may be precipitated by the current reimbursement landscape, in which hospitals are incentivized to meet quality metrics and thereby decrease financial penalties and increase their reimbursement yield, but may face pushback from the community similar to that of NCH, who may believe that the hospital is trying to squeeze out competition from independent and concierge physicians. However, the ultimate utilization of this model may depend on the outcome of any legal action initiated over this pilot initiative.

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Walgreens and Microsoft Form Alliance for Healthcare Innovation

[Excerpted from the article published in February 2019.]

On January 15, 2019, *Walgreens Boots Alliance Inc.* (WBA), the first global pharmacy-led health enterprise, announced a seven-year strategic partnership with Microsoft, one of largest multinational digital companies in the world, "*to develop new health care delivery models, technology and retail innovations to advance and improve the future of healthcare*."[1] Financial terms have not yet been disclosed, but the partnership has outlined that Microsoft's *artificial intelligence* (AI) cloud infrastructure and WBA's global retail and outpatient service customer reach of over 8,000 stores will combine to close current gaps in the existing U.S. healthcare delivery structure.[2] This move comes amid recent consolidation within the healthcare industry (including the CVS Health-Aetna acquisition, the Cigna-Express Scripts merger, and the joint venture between Amazon, Berkshire Hathaway and JPMorgan Chase & Co.), pressuring WBA to extend its reach beyond retail pharmacy.[3]

The overarching goals of this partnership are to utilize Microsoft's technology to "*improve medication adherence, reduce emergency room visits and decrease hospital readmissions*," while maintaining data privacy, security, and consent.[4] In order to effectively reach these goals, WBA has announced that they will transition their information technology (IT) platforms to Microsoft.[5] Soon, WBA will be integrating Microsoft Azure as their cloud structure and introducing Microsoft 365 to more than 380,000 employees globally, accelerating their technological modernization and cost effectiveness across the company.[6] With Microsoft technology, WBA will be able to connect their stores and health information systems through digital devices so that patients will be able to access healthcare resources and participate in virtual care (i.e., telemedicine).[7] The availability of virtual care will be increasingly important as rural providers face an increased risk of closure due to financial strain.[8] The increased utilization of more convenient retail pharmacies, as well as the virtual care aspect, is expected to help patients who do not often see their provider and handle health issues before the condition becomes critical.[9] Additionally, in order to offer more personalized care services, the partnership will implement patient engagement applications along with *Internet of Things* (IoT) devices, i.e., a network of devices that are able to connect to the internet and share data, for management.[10] This personalized care includes wellness and lifestyle management programs via digital applications.[11]

The companies have also established a multiyear *research and development* (R&D) investment, to fund subject experts, technology, and tools.[12] Along with R&D, the partnership anticipates establishing joint innovation centers in crucial markets with the aim of creating solutions to improve health outcomes and lower the cost of care.[13] Furthermore, WBA will pilot "*digital health corners*" in approximately 12 stores to market select healthcare hardware and devices in

2019, as part of WBA's vision to turn their stores into "*modern neighborhood health destinations.*"[14]

Such strategic partnerships are not new to WBA or Microsoft. CEO of WBA, Stefano Pessina, states that partnerships "*enable us to quickly align our products, services and people to the needs of the rapidly changing and integrated omnichannel marketplace*."[15] WBA recently partnered with Verily, Alphabet Inc.'s life sciences research organization centered on the utilization of technology to prevent, detect, and manage disease,[16] in order to help patients with chronic conditions, deploying devices and additional approaches through a medication adherence pilot.[17] WBA is also forming strategic partnerships with other healthcare providers; for instance, they are partnering with Humana to establish senior health clinics inside its drugstores.[18] In the healthcare realm, Microsoft has recently partnered with Teladoc, a virtual care delivery services company that utilizes Microsoft Azure's cloud platform.[19] Increasing amounts of strategic partnerships are becoming a trend in order to compete at a faster pace with the consolidations happening within the industry.

However, some believe that these combinations of dissimilar businesses are a "*disruptive*" move in healthcare, posing a threat to the traditional healthcare system.[20] Retail pharmacies are thought to close existing gaps in the traditional health system by providing low cost, quality providers and basic services,[21] as well as enhance the continuum of care and improve patient satisfaction, due to the convenience and cost factors.[22] This may be especially beneficial to those with chronic conditions, who see their pharmacists more frequently, while only visiting their provider once every six months, creating the opportunity for pharmacists to help monitor patients.[23] Additionally, patient polls regarding primary care physicians indicate decreased satisfaction, relating to poor service, poor communication, and delays in accessing care and follow up support,[24] potentially influencing the shift toward retail facilities to receive basic care. The emerging influence of retail pharmacies may cause disruption in the industry, as they offer an opportunity to engage with a patient more frequently, so patients may increasingly visit their retail pharmacists, rather than traditional primary care physicians, for their healthcare needs.[25]

The trend toward increased utilization of retail pharmacies for care is supported by insurance plans, which may pose an additional threat to traditional healthcare facilities. A 2018 *Employer Health Benefits Survey* conducted by *The Kaiser Family Foundation* indicated that 68% of employer respondents (with 50 or more employees) offered benefits that cover healthcare services received in retail markets, and 15% of respondents provided a financial incentive for workers to use a retail clinic.[26] The current health insurance landscape, as well as the recent partnerships and consolidations within the industry, will increase competition for hospitals and other healthcare facilities. This competition could result in closures of failing healthcare facilities (especially in already underserved areas); however, it might provide an incentive for traditional healthcare facilities to change aspects of their operations in order to compete.[27]

As consolidation becomes increasingly popular within the healthcare industry, more organizations may turn to various types of strategic partnerships in order to effectively compete, rather than turning to horizontal and vertical consolidation. The WBA-Microsoft strategic partnership was driven, at least in part, by this consolidation trend that has threatened WBA's future business. Regardless, this partnership attempts to close gaps within the healthcare industry to offer connected, consumer-centric healthcare delivery and personalized healthcare services with Microsoft's technology capabilities. The increasing capabilities of retail pharmacies through these partnerships may serve to disrupt traditional healthcare providers in hospitals. In order to compete, these hospitals will need to differentiate themselves from retail pharmacies and offer more convenient, personalized care as retail pharmacies begin to incorporate more healthcare services and technologies in their locations.

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Have U.S. Hospitals Reached their M&A Apex?

[Excerpted from the article published in April 2019.]

An April 2019 hospital merger & acquisition (M&A) report has found that the number of hospital transactions in the 1st quarter of 2019 is the fewest in almost ten years.[1] Those 14 deals is the lowest number in a single quarter since the 4th quarter of 2009.[2] In addition to the low number of deals occurring, the median of the target company's revenue was over 40% smaller than in 2018; in fact, no 1st quarter target hospital had more than $150 million in revenue.[3]

There could be a number of reasons for this slump. First, the transaction numbers throughout 2017 and 2018 were buoyed by the number of for-profit divestitures that occurred. During this time frame, Community Health Systems (CHS) announced 24 separate divestiture actions; CHS's spinoff system, Quorum Health Corporation (QHC) also announced several divestiture transactions; and, Tenet and LifePoint had 12 combined divestures.[4] The fact that these divestitures have largely trailed off may have painted a picture of a seemingly more-depressed 1st quarter; however, this reason alone does not appear to tell the full story, as this was the fourth straight quarter in which the number of hospital deals was fewer than the rolling quarterly average.[5] Other possible explanations for this dip include, but are not limited to:

(1) The healthcare delivery system's ongoing shift to outpatient care may be keeping buyers from investing in additional hospitals;

(2) Fewer "*low-performing targets*" remain to be acquired, and there are also fewer potential buyers as a result of the flurry of consolidations over the past few years;

(3) Both acquirers and targets have more alignment options available to them than simple M&A, e.g., joint ventures and management services agreements (MSAs); and,

(4) The vertical integrations that occurred in 2018, e.g., CVS-Aetna, may give pause for providers who wish to examine the significance of these transactions, and impact of these deals on their own operations, before making any strategic decisions.[6]

As to whether this low transactional volume trend is a harbinger, the M&A report's author, Ponder & Co., does not believe this trend will continue, because:

(1) There has been no correlating change in consolidation drivers (e.g., reimbursement challenges, value-based payment changes, capital requirements of healthcare technology), which drivers tend to incentivize larger-scale operations;

(2) Ponder found in its discussions with healthcare providers that a similar number of marketplace participants are still exploring M&A opportunities through strategic discussions;

(3) There are still likely to be divestiture actions in the near future by the aforementioned parties, which may serve to increase the number of transactions, at least temporarily;

(4) While the pace of transactions has been slow, the value of the transactions has been increasing – target company revenue has increased by a compound annual growth rate (CAGR) of 13.8% annually since 2008, and peaked in 2018 at $409 million;[7] and,

(5) A number of larger transactions have already been announced in the 2nd quarter of 2019, e.g.:

   (a) NY-based Health Quest and Western Connecticut Health Network have announced their intent to form Nuvance Health, a $2.4 billion not-for-profit health system;[8] and,

   (b) Elizabeth, NJ-based Trinitas Regional Medical Center is in discussions to be acquired by RWJBarnabas Health (one of NJ's largest systems).[9] Accordingly, some potential acquirers may wait to see how these deals transpire before making any moves.

Of note, another recent M&A report, by Kaufman Hall, found no slowdown in hospital M&A transactions; in fact, the report found a strong 1st quarter 2019 transactional environment. However, this contrast can be explained by the types of transactions includes in each report – Ponder & Co. utilized a "narrower definition of deals...[o]nly change-of-control transactions," in contrast to Kaufman Hall's inclusion of management agreements and other types of non-ownership structures.[10]

Ponder & Co. asserts that this 1st quarter dip indicates "*a shift to more thoughtful, slow, and highly-disciplined processes*,"[11] an approach that aligns with the current healthcare delivery environment, wherein patient care is shifting to the outpatient setting, the movement of healthcare reimbursement to a value-based system, and the uncertain future of the *Patient Protection and Affordable Care Act* (ACA). In the midst of the current sea-change in the U.S. healthcare market, providers will likely continue consolidating as needed (and required) to amass the requisite economies of scope and scale to provide efficient, high-quality patient care in order to not just survive, but thrive.

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Hospital CEO Searches Increasingly Seeking Physicians

[Excerpted from the article published in August 2019.]

A recent *Modern Healthcare* survey found a rapidly increasing shift in hospitals seeking physicians for their chief executive officer (CEO) positions.[1] The management shift to physician executives has been ongoing for the past several years (as of 2014, only about 5% of all hospitals were physician-led[2]), starting first with academic medical centers, and subsequently expanding to community health systems and large integrated delivery systems.[3] This shift may be due to a number of reasons, as discussed below.

First, empirical evidence indicates that the quality of physician-run hospitals may be higher. A 2011 study found that physician-run hospitals scored approximately 25% higher on *U.S. News & World Report's* assessment of hospital quality, in the cancer, digestive disorders, and cardiovascular care categories, than non-physician-led hospitals.[4] Additionally, a 2019 study found that large, physician-led hospital systems achieved higher quality ratings (across all specialties) and inpatient days per hospital bed in 2015 than non-physician-led hospitals, with no differences in total revenue or profit margins.[5] Notably, of the top 115 hospitals reviewed in that study, almost 30% were physician-led.[6]

Second, having been in the trenches, so to speak, may enhance a physician executive's credibility with their peers, as they were previously part of the care that they are now leading; in fact, research has found that physicians wish to be led by fellow physicians.[7] The virtues of having an "*expert leader*," i.e., an expert in the core business, at the helm has been established generally, in a number of industries. A 2016 study indicated that, in general, businesses with "*expert leaders*" had higher rates of employee job satisfactions (with low intentions of quitting).[8] This finding corroborates studies conducted in other, specific industries (e.g., universities, professional basketball, Formula One racing) that found enhanced organizational performance by those teams or enterprises run by "*expert leaders*."[9] As related to healthcare, this "*expert leader*" credibility may also extend to outside of the healthcare organization (e.g., to patients, donors, prospective employees), as it may signal (intentionally or unintentionally) a hospital's patient-first focus.[10]

Third, the current state of the U.S. healthcare delivery system, which increasingly requires better care at lower costs, seemingly demands a leader with an acute knowledge of the clinical side of healthcare, who also understands the financial limitations necessitating efficient patient care that exceeds set quality metrics.[11] Further, the particular skill sets of physicians are being increasingly sought by hospitals,[12] as they may well-position physician executives to tackle the top challenges of their hospitals, i.e., financial challenges, governmental mandates, patient safety and quality, and personnel challenges.[13]

Fourth, the stigma that physicians are not good business people, or that their training turns them into "*heroic lone healers*," who are unable to work as part of a team, has abated, due in part to the shift in the U.S. healthcare delivery system toward value-based care, a byproduct of which is an added emphasis on multi-disciplinary teamwork and the preparation of physicians for leadership roles.[14] Further, physicians have a number of options through which they can receive business, leadership, or management training, e.g., through the *American Association of Physician Leadership* (AAPL), which offers a *Certified Physician Executive* (CPE) credential.[15]

This increasing demand for physician leaders is being met by a growing number of physicians who are interested in such leadership roles.[16] Motivations for physicians to move to an executive position may include:

(1) High hospital CEO turnover rate – Turnover has held at 18% for the last five years, likely due to organizational restructuring, intra-organizational job change, and retirement.[17] This may lead to more opportunities for physicians to become involved in hospital c-suite positions.

(2) Higher pay – Between 2005 and 2015, CEO compensation at non-profit healthcare systems rose much faster than those of surgeons and physicians (as of 2015, CEOs made five times more than orthopedic surgeons).[18]

(3) Physician Burnout – This condition, "*in which physicians lose satisfaction and a sense of efficacy in their work*," has become sufficiently widespread to be designated a "*public health crisis*" by a number of industry leaders.[19] This may lead to physicians seeking to exit clinical care for a lower-pressure role with the ability to stay in the healthcare industry and effect change.[20]

Hospitals must be creative in their efforts to stay financially viable in the midst of this rapid industry sea change, resulting in large part from the shift toward value-based care. In addition, the demand for healthcare services is anticipated to increase in the coming years (due to an aging U.S. population and a greater number of insured individuals),[21] while the supply of physicians is anticipated to decrease (due to an imbalance between the number of these physicians who are moving toward retirement and the number of residents that are entering these fields).[22] In most industries, any shortage may lead to rising prices. However, in the healthcare industry, the federal government has some power to set prices through the Medicare program. Therefore, even if there is a shortage of healthcare services in the next several years, prices (i.e., reimbursement) may not rise to reflect this shortage. These obstacles have already created a challenging environment that hospitals are seeking to remedy through the appointment of "*expert leaders*," in the hope that they are in the best position to improve a hospital's quality measures and patient satisfaction, leading to increased value-based payments and credibility with industry stakeholders.

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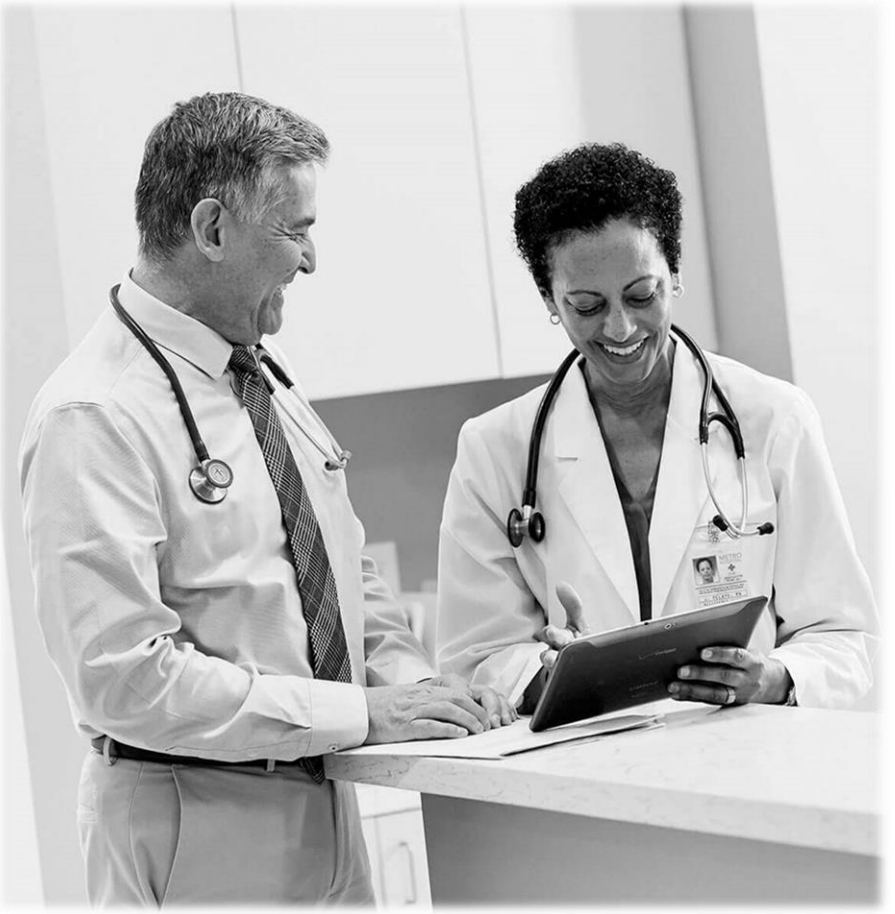

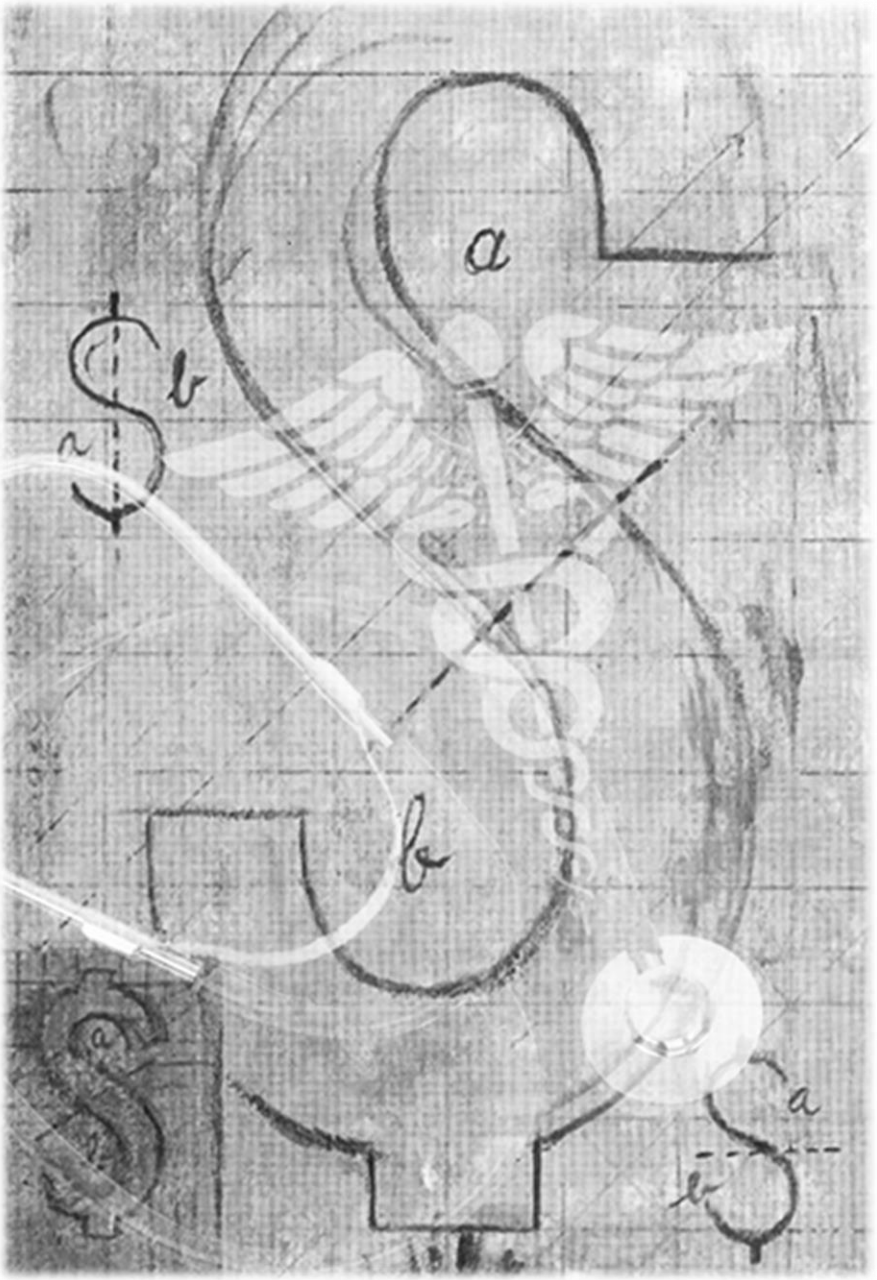
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V. TECHNOLOGY TOPICS

Healthcare Utilization Increases in Non-Traditional Settings

[Excerpted from the article published in April 2019.]

According to a new whitepaper by FAIR Health, an independent nonprofit company that manages and analyzes the nation's largest database of privately billed health insurance claims,[1] telehealth utilization increased 53% from 2016 to 2017, the largest increase of all healthcare settings examined.[2] Telehealth is often considered one of the most "*disruptive forces*" in healthcare, as it can transition care from hospitals and clinics into a patient's home or location.[3] In addition, utilization of other non-traditional sources of care, including retail clinics, urgent care centers, and *ambulatory surgery centers* (ASCs), also increased over the same timeframe.[4] To evaluate the utilization of *non-traditional* and *traditional* care, FAIR Health analyzed 28 billion commercial insurance claims within their database.[5] As the healthcare sector continues to be influenced by the rise in American consumerism, i.e., patients seeking healthcare in relation to cost and quality,[6] and the value of more convenient care, the utilization of non-traditional healthcare settings such as telehealth will likely continue to grow.[7] This growth will likely lead to traditional healthcare providers rapidly transforming their practices in order to compete and meet the demands of healthcare consumers. This *Health Capital Topics* article will examine the shift to non-traditional care and the resulting impact on healthcare entities.

Recent research published in the *Journal of the American Medical Association* (JAMA) confirms FAIR Health's observation of a large increase in telehealth use by the commercially insured population, finding that most visits were for either tele-mental health or primary care telemedicine.[8] The rapid increase in telehealth utilization is likely due to it often being a cheaper and more convenient method by which patients can access healthcare providers.[9] Influencing this trend are consumers of all ages who are demanding convenience, affordability, and quality in their healthcare.[10] Younger patients specifically are dissatisfied with the healthcare status quo, expecting more effectiveness and convenience in the care that they receive.[11] As a result, they are opting for non-traditional services, such as virtual care and retail clinics.[12] According to a 2019 survey, approximately 53% of patients are more likely to use a provider offering remote or tele-monitoring devices, up from 39% in 2016.[13] Additionally, state laws are influencing the ubiquitousness of telehealth utilization by reducing regulatory restrictions on services covered through Medicaid, as well as through commercial insurance.[14] For example, beginning in 2017, a state law in Texas allowed providers to care for patients via telemedicine without a prior in-person meeting (which was a previous stipulation).[15]

The CEO of the *American Telemedicine Association* (ATA) has noted that "*…there's a lot of technology available but the adoption engagement is really lacking…the technology is further ahead of the regulations and reimbursement*."[16] Although telehealth has increased dramatically in

comparison to recent years, telehealth medical claim lines still represented only 0.11% of all claim lines in 2017.[17] This indicates that patients accessing physicians via telehealth is still relatively uncommon, despite the increase in telehealth parity laws, i.e., laws that mandate private insurers cover and reimburse for telemedicine to the same extent as those covered in person (adopted by 35 states and D.C. as of 2019).[18] Additionally, Medicare still contains a number of telehealth payment restrictions, limiting utilization to only those in rural areas with a shortage of healthcare professionals, or in a county outside of a metropolitan area.[19] When examining Medicare *fee-for-service* (FFS) beneficiaries between 2014 and 2016, beneficiary use of telehealth services had increased, but the rate of adoption was limited, as only 0.25% of the 35 million Medicare beneficiaries took advantage of the telehealth services.[20] Similar to FAIR Health's commercial insurance data indications, Medicare has increased telehealth in utilization compared to past years; however, utilization is still scarce compared to the utilization of total Medicare beneficiaries. However, on April 5, 2019, *Centers for Medicare and Medicaid Services* (CMS) announced the Final Rule to allow Medicare Advantage Plans to include additional telehealth benefits in their basic benefits package starting in 2020.[21] Additional policies directed toward Medicare beneficiaries may further increase utilization by this group moving forward.

As noted above, in addition to increased utilization of telehealth, healthcare utilization also increased by 14% in urgent care centers, 7% in retail clinics, and 6% in ASCs.[22] This rise in utilization has led to an increase in the number of these locations in recent years.[23] In comparison to the non-traditional settings, FAIR Health also examined utilization in hospital *emergency rooms* (ERs), which are considered a "*traditional*" healthcare setting.[24] According to the analysis, ER utilization in terms of claim lines decreased by approximately 2%.[25] Another study found that, among commercial insurance beneficiaries, there has been a shift from ER to urgent care center utilization, in which visits to the ER decreased by 36%, while use of non-emergent facilities increased by 140%, given the high costs of ERs and many insurance plans creating incentives to receive care in less costly, more appropriate settings.[26] Although ER utilization dropped, the ER was still the most utilized setting compared to non-traditional care settings.[27] As a result of the increased urgent care utilization, more hospitals are investing in urgent care centers as a way to offer more appropriate, affordable services so hospitals can focus on the sicker population.[28]

The rise of healthcare consumerism, where more patients are active in healthcare decisions and seek higher quality care,[29] in addition to the increased incorporation of value-based care, has continued the trend of pushing lower-acuity conditions to less costly, more convenient settings.[30] According to a report by the *Health Care Cost Institute* (HCCI), office visits to primary care physicians dropped by 18% from 2012 to 2016.[31] The decline was due, in part, to a shortage of primary care physicians; however, the decline was partially offset by a 129% increase in office visits to *nurse practitioners* (NPs) and *physician assistants* (PAs), many of which took place in convenient care

settings.[32] The rise in American consumerism may pose a threat to existing primary care practices, as patients are demanding to be more active participants in the decision making process, and are expecting more convenient care.[33] Primary care practices will likely need to transform their practice to incorporate convenience in order to remain in business.

Consumers, especially younger generations, are expecting lower cost, higher quality care, and are seeking their routine healthcare at non-traditional sites, such as through telehealth services.[34] The increased importance of these expectations, i.e., lower cost and higher quality, has, in part, led to the rapid increase in utilization of telehealth services. Further, as coverage of telehealth services for public and private insurers continues to grow, telehealth utilization will effectively expand to reach a greater number of patients. As a result, more hospitals and health systems continue to incorporate telehealth technology in their service offerings.[35] Moving forward, healthcare organizations, such as hospitals and primary care practices, should anticipate further growth in non-traditional settings and consider ways to offset such competition, e.g., by incorporating a patient convenience aspect into their practices.

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Drones: The New Way to Transport Lab Samples?

[Excerpted from the article published in April 2019.]

A pilot program initiated at WakeMed Health's medical campus in Raleigh, North Carolina could be the future of efficiently transporting medical samples or supplies. The unmanned aircraft system integration pilot program allows laboratory samples to be flown across its medical campus, via unmanned drones, to the main hospital, rather than relying on courier cars.[1] Drone-assisted deliveries allow the option for on-demand and same-day delivery, with potentially life-saving benefits.[2] In the past, WakeMed has experienced difficulties transporting laboratory samples via courier car, which often are subject to traffic delays, leading to increased costs for couriers.[3] Through mitigating these delays and costs, the new pilot program could directly translate to cost savings by increasing supply transportation efficiency.[4] This *Health Capital Topics* article will discuss this new drone program and the utilization of drone technology in healthcare settings.

Launched by the *United Parcel Service* (UPS) and Matternet, a drone startup company, this program aims to "*shift the status quo for on-demand logistics for healthcare systems in the U.S. through drone delivery networks*."[5] The drones utilized, Matternet's M2 quadcopters, are powered by a rechargeable lithium ion battery, allowing them to carry up to five pounds of samples approximately 12.5 miles.[6] The drone will travel along a pre-determined flight path and be monitored by a *Remote Pilot-in-Command* (RPIC) to the landing pad.[7] Drone utilization reduced the journey to the laboratory from 30 minutes to three.[8] Through this innovation, WakeMed could potentially avoid having duplicate services in their facilities by consolidating all WakeMed laboratory activities at their main hospital.[9] This would free up space and resources in smaller facilities, allowing their providers to see more patients.[10] WakeMed's ultimate goal is to have a network connecting their three hospitals with other, smaller facilities such as imaging facilities and clinics.[11]

The three-year pilot program is supervised through the *Federal Aviation Administration* (FAA) and the *North Carolina Department of Transportation* (NCDOT), becoming the first revenue-generating flight in the U.S. (as sanctioned by the FAA).[12] In August 2018, NCDOT assisted Matternet in conducting the first round of drone testing on WakeMed's campus.[13] During this program, the FAA will evaluate how this technology can be effectively integrated into operational activities, as well as test practical applications of the technology.[14] The testing phase is scheduled for a minimum of two more years, and will continue to test other routes during this phase.[15] In addition, the testing phase will incorporate the development of evaluation criteria related to cost and efficiency.[16] However, this program has numerous restrictions (imposed by regulating authorities) related to payload and flight conditions.[17] As safety has not yet been established, certain restrictions, such as prohibiting pathology samples on flights, are in effect.[18]

The U.S. is not the first country to develop and test drones with the goal of improving healthcare efficiency. In 2015, Matternet initiated testing the first drone delivery system in Zurich, Switzerland, which eventually expanded to other densely populated areas of Switzerland to aid in transportation of blood and pathology samples.[19] In 2016, UPS partnered with Gavi (a public-private partnership dedicated to increasing immunization in lower-income countries[20]) and Zipline (a drone startup) to deliver blood supplies and vaccines in Rwanda.[21] This service assisted medical professionals in areas that had difficulties with land transportation, which prevented supplies (such as blood units during surgery[22]) from reaching in-need patients in time.[23] Remote clinics in Rwanda could order supplies via text and Zipline would air drop the delivery within approximately 15 minutes, leading to many hours saved in transportation and wait time.[24] In addition, drones are being created to respond to natural and other disasters. In Mississippi, researchers developed drones to deliver tele-medical kits to impacted populations, including diagnostic equipment, medical equipment, video guidance, a holographic interface, as well as medicine bins for physicians.[25] These kits were proven effective by military and civilian first responders in a large-scale federal disaster exercise. [26] In addition to transporting samples more efficiently, drones have lifesaving potential due to the faster response, potentially preventing medical trauma, such as drug delivery of EpiPens or battlefield supplies to wound care.[27]

Drone-assisted deliveries likely will continue to emerge and be evaluated in their application to healthcare. Through the successful application of drones in operational activities at WakeMed, this technology could expand to other areas of the U.S., and incorporate other applications, such as delivering medications to rural clinics.[28] Further, drones have the capability to aid providers in reaching victims who require immediate medical attention, or even increase a provider's ability to care for elderly.[29] To date, ten regional programs around the U.S. have been awarded permits by the FAA to conduct various drone application trials, which could lead to increased utilization within the healthcare field.[30] However, drones need more evaluation regarding: their ability to withstand weather challenges, concerns with losing medical samples, and other potential hindrances related to the efficacy of using drones in healthcare.[31]

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Do You See What I See? Smart Glasses in Healthcare

[Excerpted from the article published in May 2019.]

In the latest iteration of telehealth innovations, smart glasses, "*a very small, lightweight wearable computer with a transparent display that brings information into your line of sight*,"[1] are being paired with telehealth conferencing software to create a combined product that may significantly change the delivery of healthcare going forward. This product is envisioned to be utilized in a variety of settings and scenarios, including:

(1) For academic proposes, e.g., projecting on a screen for students exactly what a physician is seeing as she is performing an operation;[2]

(2) Remote training on diagnostic imaging technology;[3]

(3) Remote training on routine procedures (such as inserting IVs);[4]

(4) Remote guidance and instruction with a specialist, wherein an onsite provider wearing the glasses would be guided by the offsite provider who could see exactly what the onsite provider was seeing, from their perspective, and the onsite provider's hands would be free to carry out those instructions;[5] and,

(5) Remote scribing in the physician's office, wherein an offsite provider documents the patient visit while the onsite provider focuses on the patient in front of them.[6]

A number of companies have collaborated on various endeavors to bring such innovations to fruition. Arguably the most notable brand of smart glasses, Google Glass (now simply known as Glass) unveiled the latest iteration of its technology in 2017, Glass Enterprise Edition, after the initial version failed to take hold in the consumer space.[7] The product allows users to *"[a]ccess training videos, images annotated with instructions, or quality assurance checklists that help you get the job done, safely, quickly and to a higher standard*."[8] Glass's healthcare customers include a number of notable health systems, including CHI Health, Christiana Care Health System, Dignity Health, Eastern Maine Medicine Center, Sutter Health, TriHealth, and Trinity Health.[9]

In some cases, Glass has paired its product with Augmedix (a medical device startup affiliated with Glass) to allow for remote scribing (as detailed in the above list).[10] Those healthcare clients that have utilized this product have realized a significant gain in the amount of time that they subsequently have available, with providers now spending less than 10% of their working day on administrative work such as appointment notes (down from 33%).[11] Another Glass collaboration, with swyMed (a telemedicine software company), allows for remote visits and monitoring, for example, by dispatching a nursing/medical student (wearing Glass) to the home of a recently discharged patient or a patient with chronic conditions, with the physician assessing that patient remotely.[12] This collaboration may serve to ameliorate physician manpower shortages by allowing a physician to be in two places at once (literally and figuratively).[13]

Outside of the Glass joint ventures, Vuzix Corporation, which makes smart glasses (among other augmented reality products), and VSee, a video telehealth company, have combined to "*create a smart glasses telemedicine solution*" utilizing Vuzix's smart glasses.[14] Although Vuzix's and VSee's products were already available separately, the companies anticipate that this combined product will facilitate a number of opportunities related to training, education, and virtual care, allowing offsite specialists to provide remote guidance and instruction to onsite providers.[15] VSee already services a plethora of healthcare clients, including Ascension, Sutter Health, Healthcare Partners, Walgreens, and MDLIVE,[16] which clients will likely have a strong interest in this new telehealth product.

Smart glasses are not only being utilized by healthcare providers, but also by their patients. For example, a recent study published in *JAMA Pediatrics* found that children with *autism spectrum disorder* (ASD) who used Glass with Superpower Glass, a "*social learning aid for children with ASD to encourage facial engagement and provide feedback to the child during social interactions at home*," showed a "*significant improvement in socialization*."[17]

Over the next few years, the smart glasses market "*is projected to witness a rapid growth*."[18] This technology may serve to solve a number of current issues in the healthcare delivery system, including ameliorating the physician manpower shortage and physician distribution problems (ultimately increasing patient access through virtual care), increasing safety and reducing errors, and decreasing training time.[19] While the ultimate reach of these smart glasses innovations is still being determined, it appears from its growth to date, and the number of companies and collaborations offering such solutions, that this technology is not a passing phase, and may ultimately transform the healthcare industry.

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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 nationwide 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:

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  - 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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TODD A. ZIGRANG, MBA, MHA, FACHE, CVA, ASA, is the President of Health Capital Consultants (HCC), where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 25 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 2,000 transactions and joint ventures involving acute care hospitals and health systems; physician practices; ambulatory surgery centers; diagnostic imaging centers; accountable care organizations, managed care organizations, and other third-party payors; dialysis centers; home health agencies; long-term care facilities; and, numerous other ancillary healthcare service businesses.

Mr. Zigrang is the co-author of "*The Adviser's Guide to Healthcare – 2nd Edition*" [AICPA - 2015], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Guide to Valuing Physician Compensation and Healthcare Service Arrangements* (BVR/AHLA); *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies; Business Appraisal Practice*; and, *NACVA QuickRead*.

Mr. Zigrang holds a Master of Science in Health Administration (MHA) and a Master of Business Administration (MBA) from the University of Missouri at Columbia. He is a Fellow of the American College of Healthcare Executives (FACHE) and holds the Certified Valuation Analyst (CVA) designation from NACVA. Mr. Zigrang also holds the Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers.

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Jessica L. Bailey-Wheaton, Esq., is Senior 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.

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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Daniel J. Chen, MSF, CVA, focuses on developing 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 NACVA.

Paul M. Doelling, MHA, FACMPE, has over 25 years of healthcare valuation and operational management experience and he has previously served as an administrator for a number of mid to large-sized independent and hospital-owned physician practice groups. During that time, he has participated in numerous physician integration and affiliation initiatives. Paul has authored peer-reviewed and industry articles, as well as served as faculty before professional associations such as the Medical Group Management Association (MGMA) and the Healthcare Financial Management Association (HFMA). He is a member of MGMA, as well as HFMA where he previously served as President of the Greater St. Louis Chapter.

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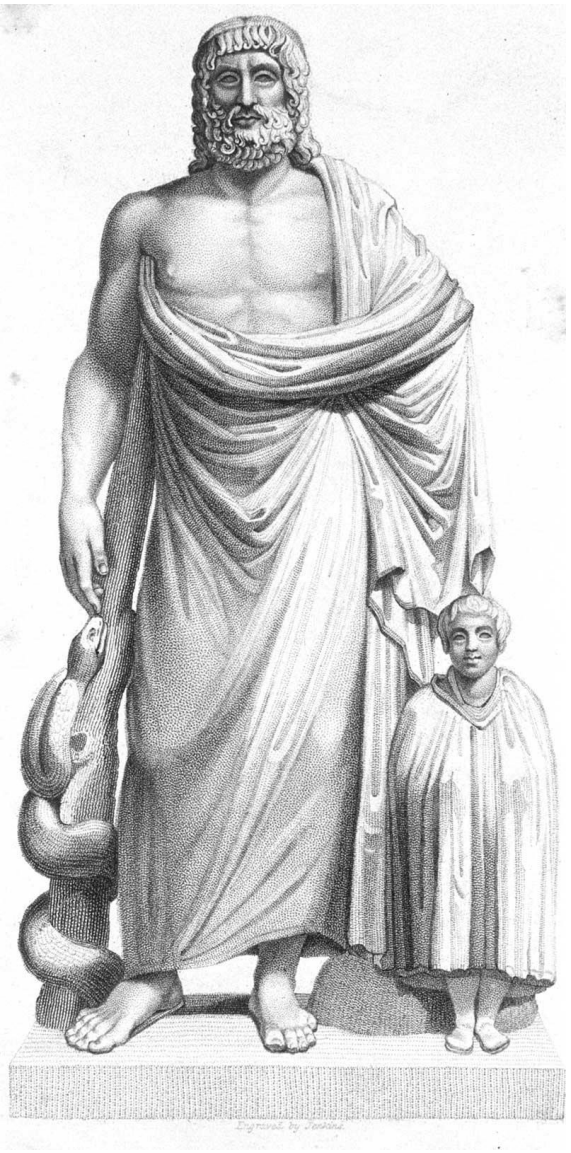
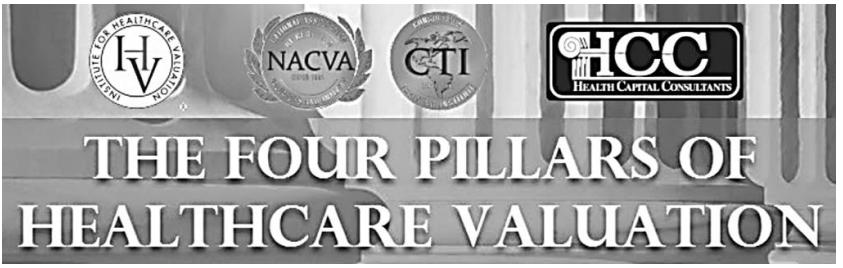


Asclepius, from the marble statue in the Louvre. Engraving by Jenkins. Greek God of Medicine & Doctors (London, ca. 1860)

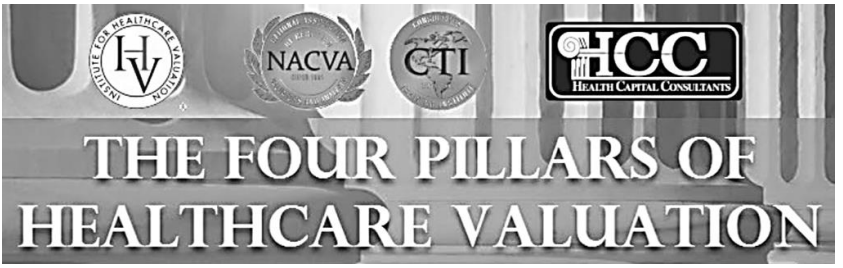


The Four Pillars of Healthcare Valuation -
Advanced Distance Education to Launch in 2020

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 2020 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.

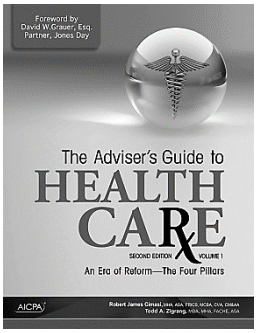
The program has been developed and is being presented by industry thought leaders **HEALTH CAPITAL CONSULTANTS** (HCC), alongside a blockbuster faculty made up of healthcare subject matter experts from the legal, federal regulatory, and valuation professions. According to Todd Zigrang:

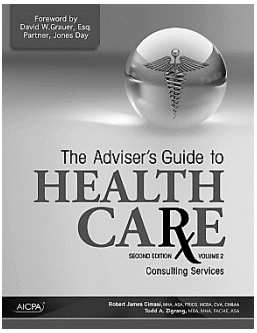


> "*With the rapid sea change resulting from the most recent iteration of healthcare reform and environmental drivers, the once well-defined, relatively stable business landscape of U.S. healthcare delivery now presents an unpredictable milieu of new provider consolidations and configurations, reimbursement 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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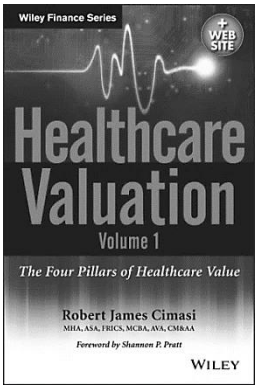

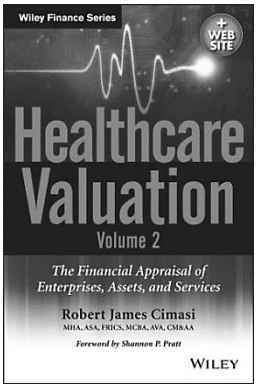

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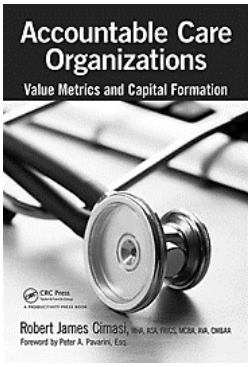

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