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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 9th 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.

Daniel J. Chen, MSF, CVA, and Janvi R. Shah, MSF, who have excelled in representing HCC throughout numerous healthcare client engagements, assisted with research, writing, review, and comments.

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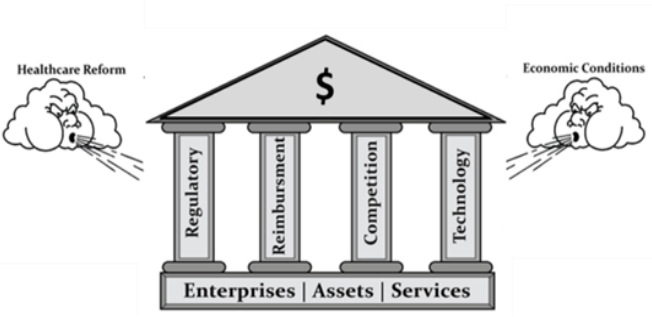
INTRODUCTION

It is impossible to discuss the U.S. healthcare industry in 2020 without addressing the global pandemic wrought by the coronavirus (COVID-19). As of September 22, 2020, this pandemic has resulted in over 200,000 deaths in the U.S. alone and caused the steepest drop in economic output in U.S. history. Such unparalleled events forced sweeping changes that most of us could not have foreseen prior to March 2020 – a mass mobilization by states to shut down public gathering spots and keep citizens in their homes; the rapid passage of unprecedented spending bills by the U.S. Congress; and, a complete transformation of American social norms.

The COVID-19 pandemic's stress test on the U.S. healthcare industry in particular has exposed critical weaknesses in the preparedness of our healthcare delivery system. The responding actions taken by the federal government, as well as by providers and other industry stakeholders, has spurred significant innovation. For example, providers have rapidly increased utilization of telemedicine technology for patient care, accelerated their shift toward value-based reimbursement models, and revamped their transactional strategies to diversify their revenue streams going forward, all with the hope of ensuring their survival. The result has been a mass transformation of the U.S. healthcare industry, which paradigm changes may have both substantial and lasting implications.

In developing an understanding of the forces and stakeholders that have the potential to drive healthcare markets, especially during a time of such uncertainty, 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 Ambulatory Surgery Centers (ASCs): Introduction

[This is the first article in a five-part series regarding Valuation of Ambulatory Surgery Centers This installment was published in September 2019.]

Until approximately forty years ago, virtually all surgeries were performed in hospitals.[1] Patients spending several days in the hospital after surgery was common. Hospitals faced numerous restrictions such as limited operating room availability, scheduling delays, slow operating room turnover, and restrictive hospital budgets and policies.[2]

An *ambulatory surgical center* (ASC) is a distinct entity that primarily provides outpatient surgical procedures to patients who do not require an overnight stay after the procedure.[3] The facilities typically provide relatively uncomplicated surgical procedures in a non-hospital setting, and most ASC cases are non-emergency, non-infected, and elective.[4] ASCs typically specialize in one or two procedures/specialties (particularly related to ophthalmology, gastroenterology, or orthopedics).[5] If there is general anesthesia administered, the procedure does not usually exceed one hour in length, and requires less than a two-hour stay in the recovery room.[6]

Since the 1970s, the ASC industry has grown at a steady pace. In 1971, the *American Medical Association* (AMA) adopted a resolution endorsing the concept of outpatient surgery under general and local anesthesia for selected procedures and selected patients.[7] In 1980, Medicare began covering facility costs of certain ASC procedures to promote the use of ASC settings as a less expensive alternative to inpatient procedures.[8] In 1982, Medicare approved payment to ASCs for approximately 200 procedures; in 1987, the ASC list was modified to use specific CPT codes and expanded to over 1,535 approved procedures.[9] As of 2017, more than 5,600 ASCs in the U.S. performed 23 million surgeries annually, and Medicare has expanded the list to over 3,500 procedures that may be performed in ASCs.[10] The rapid growth in the ASC sector is, in large part, a product of regulatory policy attempting to encourage innovation. As illustrated above, the federal government has consistently stabilized and strengthened the ASC industry over the years to ensure equal access and safety by regulating prices through its reimbursement policies and by controlling licensing and certification.[11]

ASCs are generally owned by physician investors who derive revenue from the ASC.[12] During the beginning of ASC development, physician-hospital joint ventures were uncommon; however, as of 2015, 17% were physician-hospital joint ventures.[13] Currently, 93.8% of ASCs are for profit and 92.9% are located in urban areas.[14] ASCs are subject to far less regulation and require less capital to develop than a hospital.[15]

The growth in the ASC industry has significantly declined since 2008; since supply now far exceeds demand, and ASCs are experiencing declining same center case volume. These market forces will likely lead to industry consolidation.[16] Hospitals' decisions to increase their outpatient surgery capacity may have been influenced by the higher rates that Medicare pays for

ambulatory surgical services provided in *hospital outpatient departments* (HOPDs) relative to ASCs (in 2019, Medicare's rates are 94% higher in HOPDs than in ASCs) and have further compounded problems for ASCs.[17] Oversaturation is an apparent problem for the industry, likely due in part to: the low market entry barrier for physicians as a result of relatively fewer regulations; the absence of, or less stringent, *certificate of need* (CON) requirements; and, lower capital requirements than most healthcare ventures.[18] Medicare and managed care have also created incentives for patients to use the ASC setting. Lower procedure costs, more convenient locations, and higher quality have led many managed care plans to insist that minor procedures be performed in ASCs; however, there is a paucity of empirical evidence to support this preference.[19] Physicians are increasingly choosing to be employed by hospitals rather than work in an independent practice, which may lead to fewer physicians choosing to engage with ASCs.[20] ASCs opening in the past year have been adjusting to the changes by including fewer operating rooms (ORs) than in previous years, an average of 2.7 ORs compared to 3.1 ORs in 2012.[21]

Many of the future challenges for ASCs will come from the regulatory and competitive environments, expounded upon in parts two and four, respectively. There are serious concerns regarding whether the proliferation of ASCs has outpaced the regulatory capacity to inspect them; whether the ASC industry unintentionally discriminates based on race and income; and, whether physician ownership creates an incentive to suggest unnecessary surgeries.[22] As the future of healthcare becomes increasingly more consumer- and convenience-driven, the ASCs' healthcare delivery model appears increasingly more promising. However, recent push-back from organizations such as the *American Hospital Association* (AHA) may prove formidable (see the article entitled "*Judge Strikes Down Site-Neutral Payments Rule*" in the September 2019 edition of *Health Capital Topics*).

Future installments in this ASC series will discuss: (1) the regulatory environment of the ASC industry; (2) the reimbursement environment of the ASC industry; (3) the competitive environment of the ASC industry; and, (4) the technological environment of the ASC industry.

Valuation of Ambulatory Surgery Centers (ASCs): Competition

[This is the second article in a five-part series regarding Valuation of Ambulatory Surgery Centers This installment was published in October 2019.]

As noted in the first installment of this five-part series, an *ambulatory surgery center* (ASC) is a distinct entity that primarily provides outpatient surgical procedures to patients who do not require an overnight stay after the procedure.[23] The facilities typically provide relatively uncomplicated surgical procedures in a non-hospital setting, and most ASC cases are non-emergency, non-infected, and elective.[24]

ASCs compete in an increasingly crowded industry for patients. The industry is fragmented, highly competitive, and rapidly changing with technological advancements. ASC's main industry competitors are hospitals. While the ASC industry is seeing more capital investments, indicating the profitability and attractiveness of the industry, this adds another layer of competition for existing ASCs.

This second installment in this five-part series on the valuation of ASCs will discuss the competitive environment of ASCs, by competitor type.

Hospital Outpatient Departments

ASCs compete with *hospital outpatient departments* (HOPDs) for the technical component revenues resulting from procedures and diagnostic testing provided in these facilities. HOPDs, while typically not "*freestanding*," offer many of the same services provided by ASCs and other types of freestanding outpatient enterprises. One reason that HOPDs function as significant competitors to ASCs is the financial attractiveness beholden to HOPDs. Significantly, in contrast to ASCs and other freestanding outpatient enterprises, HOPDs typically have access to the market leverage maintained by the parent hospital organization, and are reimbursed under the *Hospital Outpatient Prospective Payment System* (OPPS), which allows them to receive a "*heightened reimbursement differential*" for the same services or procedures provided in an independent freestanding facility.[25] Over the past couple of years, ASCs have received approximately 58.5% of what HOPDs receive for comparable services.[26] However, it is important to note that the demographics vary for HOPD and ASC settings.[27] ASCs primarily treat Medicare patients aged 65 to 74, and perform less complex treatments than HOPDs.[28] A study from the *American Hospital Association* (AHA) claims that HOPD clinics treat poorer and sicker (i.e., more acute) Medicare patients compared to patients treated at ASCs.[29] Further, the AHA claims that HOPD costs are higher than physician offices, due in large part to heightened regulatory requirements for HOPDs.[30] These two significant factors may diminish the role that HOPDs play in the future.

Significantly, the *Bipartisan Budget Act of 2015* (BBA)[31] prohibits off-campus HOPDs created after November 2, 2015 from collecting Medicare reimbursement for non-emergency services under the OPPS starting on January 1, 2017.[32] Effective January 1, 2017, these facilities receive reimbursement under an alternative fee schedule, such as the *Medicare Physician Fee Schedule* (MPFS) or the *Ambulatory Surgical Center Fee Schedule* (ASCFS).[33] In passing the BBA, Congress mandated site-neutral payments for all services and items furnished at new off-campus HOPDs.[34]

Overall, the ASC industry provides more low-cost services compared with HOPDs, enticing many insurers to implement more favorable reimbursement rates, and other insurers to enact policies stating that they will not pay for certain surgeries performed in HOPDs unless the site is found to be medically necessary.[35] On average, Medicare saves $2.3 billion each year due to the lower costs for procedures at ASCs than HOPDs.[36] These cost savings have incentivized insurers to increase procedure volume at ASCs.[37] Moreover, Medicare beneficiaries may also realize significant out-of-pocket savings from choosing ASCs over HOPDs.[38] A cataract extraction provided by a HOPD may cost $496 in out-of-pocket costs, whereas it may cost about $195 at an ASC.[39] Increased scrutiny by the *Centers for Medicare & Medicaid Services* (CMS) of HOPDs' high prices resulted in CMS attempting to cap payments of all HOPDs to the same as other off-campus payments.[40] However, after a legal challenge from the AHA, the rule change was struck down in court.[41] This attempt by CMS recently is likely just the beginning of their increased scrutiny of HOPDs, which will affect the financial future for HOPDs.

General Short-Term Acute Care Hospitals

Some general, short-term acute care hospitals may have competitive advantages over ASCs, including their established managed care contracts; community position; physician loyalty; and, geographical convenience for physician inpatient and outpatient practices. However, ASCs compete favorably with general, short-term acute care hospitals on the basis of cost; quality; efficiency; and, responsiveness to physician needs in a more comfortable environment for the patient.

ASCs have been able to compete better than community hospitals for more profitable patients by: (1) concentrating only on specific *diagnosis-related groups* (DRGs); (2) treating far fewer Medicaid patients, who may cost more to treat and generate significantly lower reimbursement yield; and, (3) opting out of emergency room departments and services.[42] It is expected that health systems will increasingly work to differentiate their ambulatory services provided from their inpatient services, driven by technological benefits, financial advantages, and patient service expectations. Less invasive diagnostic and therapeutic procedures will continue to transform inpatient procedures into outpatient ones, while also improving outcomes, decreasing patient discomfort, and decreasing convalescence length.

Physician Practices

ASCs may also face competition from physician practices that perform office-based surgeries and other technical component revenue producing services, e.g., cardiac catheterization services, onsite at the practice. Competition among these providers is likely to further grow as: (1) reimbursement for these services becomes increasingly based on *quality* versus *quantity*; and, (2) the market for these providers evolves due to increased integration and affiliation among hospitals; physician practices; and, other outpatient providers who become affiliated with an *accountable care organization* (ACO).

Market Rivalries, Competitors, and Consolidation

Gains by ASCs in the outpatient surgery market share has generated opposition from hospitals, who have traditionally commanded this market share generally and/or through their HOPDs.[43] Many hospitals argue that their survival is in danger because of loss of profitable revenue streams to ASCs.[44] Although ASCs do tend to exit markets in which there are high levels of ASC competition, there is no evidence that ASC exit rates are affected by hospital density.[45] On the other hand, hospitals tend to exit markets with high levels of ASC density.[46]

In some states, hospitals have been lobbying for stricter entry laws such as *Certificate of Need* (CON) laws.[47] CON laws were originally passed in many states in the 1960s and 1970s, with a significant push from hospital lobbying and federal encouragement, in part to prevent investments that could raise hospital costs.[48] However, the *Federal Trade Commission* (FTC) has found that there is no evidence that CON laws have led to resource savings and may actually raise hospital costs.[49] ASCs located in a state with a CON law must complete a regulatory review process in order to obtain a certificate. Currently, 35 states maintain some form of CON program, and 27 of those states have CON laws relating to ASCs.[50]

The consolidation in the ASC industry is driven in part by hospitals, which are increasingly developing freestanding facilities under joint ventures with physicians, adding increased competition for existing ASCs.[51] However, the arrangement does bring benefits such as managed-care contracts and purchasing power to newly-formed ASCs.[52] Hospitals are warming to the arrangement because of the lower operating costs and convenient locations.[53]

Aside from physician joint ventures, overall consolidation among outpatient centers has been modest over the past five years.[54] Currently, the rate of new entrants offsets the amount of consolidation occurring in the industry.[55] A very small percentage of companies own 10 or more ASCs, because there are few benefits to having a large operation in the ASC industry.[56] Ventures that operate in multiple states face significant challenges because every state has differing Medicaid coverage and regulation, adding complication to running consistent business models.[57] There are some advantages to larger operations, such as instituting best practices that improve patient care or cut costs, efficiency in payment processing, leveraged purchasing power, and better analysis or sample size of claims data for billing.[58]

Excess capacity could incentivize further consolidation in the ASC industry. Overall, the industry operates with a low level of market share concentration, due to many ASCs being single specialty enterprises, and catering to local and regional markets.[59] In 2019, the four largest ASCs are expected to generate less than 15% of total revenue.[60]

Future Growth in ASCs

The number of ASCs has continued to increase over the past decade, healthcare industry participants have significantly incorporated ASCs into their business strategies.[61] A series of ASC acquisitions in recent years suggest that ASCs are highly valued assets for hospitals systems, private equity firms, and insurers.[62] In general, hospital systems are turning their attention away from inpatient settings, and toward investment in ASCs and other outpatient settings.[63] Continued hospital system acquisition of ASCs is predicted as these systems attempt round out their continuum of care in order to meet value-based reimbursement requirements and provide procedures in lower cost settings.[64]

Valuation of Ambulatory Surgery Centers (ASCs): Reimbursement

[This is the third article in a five-part series regarding Valuation of Ambulatory Surgery Centers This installment was published in November 2019.]

As noted in the first installment of this five-part series, an *ambulatory surgery center* (ASC) is a distinct entity that primarily provides outpatient surgical procedures to patients who do not require an overnight stay after the procedure.[65] The facilities typically provide relatively uncomplicated surgical procedures in a non-hospital, outpatient setting, and most ASC cases are non-emergency, noninfected, and elective.[66] This third installment in this five-part series on the valuation of ASCs will discuss the reimbursement environment of ASCs.

ASCs are presumably a lower cost setting than *hospital outpatient departments* (HOPDs); however, due to the ASC industry's reluctance to offer cost data, there is no empirical data to support this belief.[67] Instead, this presumption is supported by the fact that the average time for surgical visits at ASCs are 25% to 39% lower compared to HOPDs, which may contribute to lower costs for ASCs.[68] This lower cost assumption has led to lower reimbursement for ASCs by payors such as Medicare. For example, in 2019, the Medicare payment rates to HOPDs for outpatient surgical services were 94% higher than the amount paid to ASCs for providing the same outpatient surgical services.[69] The ASCs industry's reluctance to report cost data may be hindering the equality of payment in ambulatory services and may contribute to problems with quality reporting.

The U.S. government is the largest payer 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.[70] In 2017, Medicare and Medicaid accounted for an estimated $705.9 billion and $581.9 billion in healthcare spending, respectively, combining for approximately 37% of all healthcare expenditures.[71] The spending proportionality of these public payors in the healthcare marketplace results in their reimbursement rates being used as a benchmark for private reimbursement rates.[72] However, ASCs may face less price pressure from public payors, as commercial payors typically comprise 54% of an ASC's gross charges.[73]

Medicare Reimbursement for Freestanding ASCs

Medicare has covered procedures performed in ASCs since 1982.[74] To be eligible to receive Medicare payments, a freestanding ASC must meet Medicare's conditions of coverage standards, which specify minimum guidelines for "*administration of anesthesia, quality evaluation, operating and recovery rooms, medical staff, nursing services*," and other areas.[75] Medicare pays for a bundle of surgical and facility services provided by ASCs, and also allows ASCs to bill separately for certain ancillary and physician services.[76]

The Medicare ASC payment rate for a given procedure is largely based upon the relative weight of a procedure and a conversion factor (CF).[77] First, the ASC relative weight, which indicates the resource intensity of a procedure compared to other procedures, is connected to the relative weight in the *Outpatient Prospective Payment System* (OPPS) and updated annually.[78] The OPPS relative weight for the procedure is then proportionally adjusted, in order to maintain budget neutrality, to arrive at the ASC relative weight.[79] For example, the 2019 adjustments resulted in ASC relative weights that were 12% less than OPPS relative weights.[80] Second, the ASC relative weight is "translated" into the payment amount through the CF.[81] The ASC CF, which (similar to the ASC relative weight) is purposefully lower than the OPPS CF, was historically based on the *consumer price index for all urban consumers* (CPI–U); part of the reason for that discrepancy was because the OPPS CF was updated by the hospital market basket (MB) index.[82] However, in 2019, CMS changed the ASC CF update basis, from the CPI-U to the hospital MB index; consequently, for the next five years (through 2023), the ASC payment system is being updated by the hospital MB index minus a multifactor productivity (MFP) adjustment.[83] As a result of connecting the ASC CF to the hospital MB index, the ASC CF growth rate is now expected to be higher than the OPPS CF growth rate, because the OPPS CF includes an additional reduction from the hospital MB index (hospital MB index minus a MFP adjustment minus a statutory adjustment).[84] However, beginning in 2020, both ASC and OPPS CFs will be tied to the hospital MB index minus an MFP adjustment (i.e., there will be no additional statutory adjustment).[85]

In addition, CMS updated ASC payment rates in 2018 by 2.1%, based on the hospital MB increase of 2.9% minus a 0.8% adjustment for MFP, marking the

first time CMS has tied the ACS CF to the hospital MB index.[86] The ASC CF being tied to hospital MB rate promotes "*site-neutrality*" between hospitals and ASCs because reimbursement rates between the two settings are equalized, thus encouraging migration of services from the hospital setting to the lower cost ASC setting.[87] CMS has chosen to continue this site-neutrality practice in 2020, finalizing an update to ASC rates for 2020 equal to 2.6% based on the hospital MB increase of 3.0% minus a 0.4% MFP adjustment.[88]

Regarding ancillary services, the ASC payment system largely parallels the OPPS payment system, wherein the services are paid separately.[89] However, beginning in 2015, CMS began using *comprehensive ambulatory payment classifications* (C-APCs) in the OPPS payment system, but did not implement the same for the ASC payment system.[90] CMS declined to implement C-APCs in the ASC payment model due to the ASC claim system's inability to bundle ancillary items.[91]

Certain procedures performed in ASCs are not reimbursed pursuant to the ASC CF. For example, those services performed in ASCs that are generally performed in physician offices at least 50% of the time constitute "*new, office-based procedures*."[92] In an effort to prevent physicians from migrating their practices out of their offices and into ASCs, CMS determined that it would reimburse for these services performed in an ASC at a rate that is the lower of: (1) the ASC rates; or, (2) the practice expense portion of the *Medicare Physician Fee Schedule* (MPFS) payment rate that would apply to the procedure if performed in a physician's office.[93] Further, beginning in 2008, Medicare began paying ASCs separately for certain ancillary services, including:

(1) "*Radiology services that are integral to a covered surgical procedure if separate payment is made for the radiology service in the OPPS;*
(2) *Brachytherapy sources implanted during a surgical procedure;*
(3) *All drugs that are paid for separately under the OPPS when provided as part of a covered surgical procedure (pass-through and non-pass-through drugs); and,*
(4) *Devices with pass-through status under the OPPS.*"[94]

ASC Quality Reporting

ASC quality reporting is an essential element to ASC reimbursement because compliance may result in higher Medicare reimbursement from CMS (and noncompliance may result in lower reimbursement). CMS's final 2020 OPPS rule language increased payment rates under ASC payment system by 2.6% for ASCs that meet the quality reporting requirements under the *ASC Quality Reporting (ASCQR) Program*.[95] Alternatively, ASCs that do not meet their reporting requirements may incur a two percentage point reduction in the ASC facility fee reimbursement (meaning their payment rate update would be 0.6%).[96]

The ASCQR Program was set forth by CMS in the 2012 OPPS/ASC Final Rule with Comment Period.[97] Eight quality measures were originally established by CMS;[98] that number has now increased to 12 measures.[99] In addition, CMS recently adopted a new measure, "*ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers*," which will begin in 2024.[100]

Value-Based Purchasing Program

The *Patient Protection and Affordable Care Act* (ACA) mandates that the Secretary of the *Department of Health and Human Services* (HHS) develop a plan to implement a *value-based purchasing* (VBP) program for Medicare payments to ASCs.[101] As stated in the 2017 *Medicare Payment Advisory Commission's* (MedPAC) Recommendation to Congress, in order to improve ASC quality of care, "*[t]he Commission has recommended a value-based purchasing program for ASCs that would reward high-performing providers and penalize low-performing providers*."[102] The VBP program would establish reimbursement adjustments based on quality measures linked to performance.[103] However, the ASC VBP program has yet to be implemented.[104]

Future Trends

As the pressure for price transparency in healthcare continues to increase, ASC providers will likely be forced to comply with cost data reporting in the foreseeable future. The cost reporting may prove to be burdensome, but may help ASCs to further increase quality of care. Moreover, it seems that Medicare's equalization of payment (i.e., *site-neutrality*) for ambulatory services will be a permanent fixture of the ASC payment system going forward. *Site-neutrality* should provide the ASC industry with a competitive advantage. Medicare is actively encouraging the migration of services away from the hospital setting toward the ASC setting.[105] This push from Medicare will likely lead to a significant increase in ASC volumes, which may result in increased revenue.

Valuation of Ambulatory Surgery Centers (ASCs): Regulatory

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

As noted in the first installment of this five-part series, an *ambulatory surgery center* (ASC) is a distinct entity that primarily provides outpatient surgical procedures to patients who do not require an overnight stay after the procedure.[106] ASCs typically provide relatively uncomplicated surgical procedures in a non-hospital, outpatient setting, and most ASC cases are non-emergency, noninfected, and elective.[107] This fourth installment in this five-part series on the valuation of ASCs will discuss the regulatory environment in which ASCs operate.

Federal Fraud and Abuse Laws

The *Anti-Kickback Statute* (AKS) and the *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 any healthcare industry actor 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 Medicare or Medicaid.[108] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal penalties (up to a five-year prison term per violation) and civil penalties.[109] It is also important to note that many states also have "*baby*" Stark and AKS laws, which are more restrictive than their federal counterparts.[110]

AKS

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.[111] Of note, interpretation and application of the AKS under case law has created a precedent for a regulatory hurdle known as the "*one purpose*" test, under which test healthcare providers violate the AKS if even one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[112]

The *Patient Protection and Affordable Care Act* (ACA) made two additional 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.[113] 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.[114] Therefore, in order to

prove 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.[115] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the *False Claims Act* (FCA).[116] The amended AKS points out that liability under the FCA is "*[i]n addition to the penalties provided for in [the AKS]…*"[117] 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.[118]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[119] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to the *U.S. Department of Health and Human Services* (HHS) to protect certain business arrangements by means of promulgating several safe harbors,[120] which 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.[121] Failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[122]

Under the AKS, ASCs are treated differently. ASCs must meet specific AKS safe harbor provisions: the entity must be certified in accordance with applicable regulations; the entity's operating and recovery room space must be exclusively dedicated to the ASC; all patients referred to the entity by an investor must be fully informed of the investor's ownership interest; and, all the following applicable standards must be met within one of the following categories set forth in the Table 1:

Table 1: ASC Exceptions to the AKS[123]

	A	B	C	D	E
	Category	**Surgeon-Owned ASC**	**Single-Specialty ASC**	**Multi-Specialty ASC**	**Hospital/Physician ASC**
1	Investor	General surgeons or surgeons engaged in the same surgical specialty, who are in a position to refer patients directly the ASC and perform surgery on such referred patients;	Physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients;	Physicians who are in a position to refer patients directly to the entity and perform procedures on such referred patients;	A hospital; and,
2		Surgical group practices comprised exclusively of such surgeons; or,	Group medical practices composed exclusively of such physicians; or,	Group medical practices composed exclusively of such physicians; or,	General surgeons or surgeons engaged in the same surgical specialty, who are in a position to refer patients directly to the ASC and perform surgery on such referred patients;
3		Individuals not employed by the ASC or any other investor, not in a position to provide items or services to the entity or any other investors, and not in a position to make or influence referrals directly or indirectly to the ASC or any other investors	Individuals not employed by the ASC or any other investor, not in a position to provide items or services to the entity or any other investors, and not in a position to make or influence referrals directly or indirectly to the ASC or any other investors	Individuals not employed by the ASC or any other investor, not in a position to provide items or services to the entity or any other investors, and not in a position to make or influence referrals directly or indirectly to the ASC or any other investors	Physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients;
4					Physicians who are in a position to refer patients directly to the entity and perform procedures on such referred patients;
5					Surgical group practices comprised exclusively of such surgeons;
6					Group medical practices composed exclusively of such physicians; or,

	A	B	C	D	E
	Category	**Surgeon-Owned ASC**	**Single-Specialty ASC**	**Multi-Specialty ASC**	**Hospital/Physician ASC**
7	Investor				Individuals not employed by the ASC or any other investor, not in a position to provide items or services to the entity or any other investors, and not in a position to make or influence referrals directly or indirectly to the ASC or any other investors
8	Standards	The investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;	The investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;	The investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;	The investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;
9		At least one-third of the surgeon investor's practice income for the prior fiscal year or the prior 12-month period must come from the surgeon's performance of procedures;	At least one-third of the surgeon investor's practice income for the prior fiscal year or the prior 12-month period must come from the surgeon's performance of procedures;	At least one-third of the surgeon investor's practice income for the prior fiscal year or the prior 12-month period must come from the surgeon's performance of procedures;	Neither the entity nor any investor can loan funds or guarantee a loan for an investor if the investor uses any portion of the loan to acquire the investment interest;
10		Neither the entity nor any investor can loan funds or guarantee a loan for an investor if the investor uses any portion of the loan to acquire the investment interest;	Neither the entity nor any investor can loan funds or guarantee a loan for an investor if the investor uses any portion of the loan to acquire the investment interest;	At least one-third of the procedures performed by each physician investor must be performed at the investment entity;	An investor's payment in return for their investment must be directly proportional to the amount of capital they invested;

	A	B	C	D	E
	Category	**Surgeon-Owned ASC**	**Single-Specialty ASC**	**Multi-Specialty ASC**	**Hospital/Physician ASC**
11	Standards	An investor's payment in return for their investment must be directly proportional to the amount of capital they invested;	An investor's payment in return for their investment must be directly proportional to the amount of capital they invested;	Neither the entity nor any investor can loan funds or guarantee a loan for an investor if the investor uses any portion of the loan to acquire the investment interest;	The ASC, the hospital and any physician investors must treat patients receiving medical benefits or assistance under any healthcare program in a nondiscriminatory manner;
12		Ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the ASC, and may not be billed separately to Medicare or other federal healthcare programs; and,	Ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the ASC, and may not be billed separately to Medicare or other federal healthcare programs; and,	An investor's payment in return for their investment must be directly proportional to the amount of capital they invested;	The ASC may not use (1) space, including operating and recovery room space located in or owned by any hospital investor, unless the space lease complies with the space rental safe harbor; (2) equipment provided by any hospital investor unless the equipment lease complies with the equipment rental safe harbor; nor (3) services provided by any hospital investor unless the services contract complies with the personal services and management contracts safe harbor;

	A	B	C	D	E
	Category	**Surgeon-Owned ASC**	**Single-Specialty ASC**	**Multi-Specialty ASC**	**Hospital/Physician ASC**
13	Standards	The ASC and any investors must treat patients receiving medical benefits or assistance under any healthcare program in a nondiscriminatory manner.	The ASC and any investors must treat patients receiving medical benefits or assistance under any healthcare program in a nondiscriminatory manner.	Ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the ASC, and may not be billed separately to Medicare or other federal healthcare programs; and,	Ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the entity, and may not be billed separately to Medicare or other federal healthcare programs;
14				The ASC and any investors must treat patients receiving medical benefits or assistance under any healthcare program in a nondiscriminatory manner.	The hospital's report, or any other claim for payment from a federal healthcare program, may not include any costs associated with the ASC unless the federal healthcare program requires their inclusion; and,
15					The hospital cannot directly or indirectly make or influence referrals to any investor or entity.

Stark Law

The Stark Law governs those physicians (or their immediate family members) who have a financial relationship (i.e., an ownership investment interest or a compensation arrangement) with an entity, and prohibits those individuals from making Medicare referrals to those entities for the furnishing of *designated health services* (DHS).[124] DHS encompasses the following items and services:

(1) Clinical laboratory services;
(2) Physical therapy services;
(3) Occupational therapy services;
(4) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;
(5) Radiation therapy services and supplies;
(6) Durable medical equipment and supplies;

(7) Parenteral and enteral nutrients, equipment, and supplies;
(8) Prosthetics, orthotics, and prosthetic devices and supplies;
(9) Home health services;
(10) Outpatient prescription drugs;
(11) Inpatient and outpatient hospital services; and,
(12) Outpatient speech-language pathology services.[125]

ASCs are generally not subject to Stark Law restrictions, because they typically do not furnish DHS. However, in the event that the ASC is performing DHS (e.g., radiology services), and that DHS is not reimbursed by Medicare as part of a composite rate,[126] then any financial relationship between the physicians and the hospital, and their connection to the ASC, may be subject to Stark, the application of which regulations (and any appropriate exceptions) would be determined by the structure of the financial relationship between the parties (e.g., direct/indirect, compensation/ownership investment).

Certificate of Need

Certificate of Need (CON) laws present market entry barriers for potential ASCs.[127] CON programs have the major goal of controlling costs by restricting provider capital expenditures.[128] The rationale behind CON laws mainly originates from the belief that healthcare does not operate like other markets to correct excess supply, and healthcare is plagued by market failures resulting in excess supply and needless duplication of some services, causing overall costs to rise.[129]

ASCs located in a state with a CON law must complete a regulatory review process in order to obtain a certificate.[130] Currently, 27 states have CON laws relating to the opening of an ASC.[131] Of note, states without CON laws restricting the formation of ASCs have slightly more ASCs per 100,000 individuals on average than states with CON laws restricting ASCs.[132]

Future Regulatory Trends

As mentioned in the October 2019 *Health Capital Topics* articles titled, *"Proposed Anti-Kickback Statute Changes: Healthcare Valuation Implications,"*[133] and *"Proposed Stark Law Changes: Healthcare Valuation Implications*,"[134] significant modernization and clarification of fraud and abuse laws have been outlined in the most recently proposed rule changes by federal regulators.

It is important to note that, despite the stance of the current presidential administration toward de-regulating healthcare,[135] the regulatory scrutiny of healthcare entities (especially with regard to fraud and abuse violations) has generally increased in recent years. Due to the nature of AKS, and its criminal and civil penalties, disregarding federal and state regulation of the ASC industry may result in more than an unassuming fine. With the level of regulation of the ASC industry intensifying,[136] ASC operators increasingly need to pay heed to current regulations and understand how future regulatory developments may affect the industry going forward.

Valuation of Ambulatory Surgery Centers (ASCs): Technology

[This is the final article in a five-part series regarding Valuation of Ambulatory Surgery Centers This installment was published in January 2020.]

As noted in the first installment of this five-part series, an *ambulatory surgery center* (ASC) is a distinct entity that primarily provides outpatient surgical procedures to patients who do not require an overnight stay after the procedure.[137] ASCs typically provide relatively uncomplicated surgical procedures in a non-hospital, outpatient setting, and most ASC cases are non-emergency, noninfected, and elective.[138] The last installment of this five-part series on the valuation of ASCs will review some of the technology advancements that are driving ASC industry growth and evolution.

The term technology can be all-encompassing in healthcare, ranging from tangible tools, to pharmaceuticals, to software. The modern ASC industry exists mainly due to advances in anesthesia and new surgical techniques and technology.[139] Simultaneously, the increased demand for outpatient services in general has been driven by technological advances. The technology advancements allow for more procedures to take place in an outpatient setting. Technological breakthroughs have resulted in fewer and smaller surgical wounds that require less recovery time.[140] Improvements to anesthesia have shortened recovery time and minimized post-operative side effects.[141] Advancements in *scope technology* (wherein scopes are connected to a fiber optic cable for lighting and can magnify images) have led to quicker and more minimally invasive surgeries.[142] One such form of minimally invasive surgery is *robotic surgery*, a term to denote procedures performed utilizing small robotic arms equipped with surgical instruments that the physician controls via computer,[143] and allows for far fewer incisions.[144]

One type of technology used by ASCs, due to federal regulatory requirements, is *electronic health records* (EHR),[145] which have the potential to improve efficiencies and quality of patient care.[146] Effective use of EHRs may save providers and patients money and time due to increased efficiencies.[147] Many ASCs are also starting to utilize data management systems to keep track of supplies, starting case times, personnel schedules, and financial performance.[148] EHR and management software show great potential for improving the interpretation of quality and outcomes data, as well as for meeting performance metrics. Significantly, the data produced utilizing EHR and management software can help ASCs identify profitable revenue streams.

Advances in clinical *artificial intelligence* (AI) solutions also have the potential to optimize workflow, productivity, and patient flow.[149] Current applications of AI in clinical settings help clinicians with daily tasks rather than replacing the need for clinicians.[150] The *U.S. Food and Drug Administration* (FDA) has approved 28 algorithms for use in diagnostic radiology.[151] The health research

unit of Alphabet Inc. (d/b/a Google) has developed an AI clinical solution that can match or outperform radiologists in detecting breast cancer.[152] Google's technology is able to identify cancers that were missed by humans and decrease the false-positive cancer identification rate.[153] Importantly, Google contends that the technology could reduce the workload of mammogram readers by 88%.[154] Alphabet's other venture, *DeepMind Health*, has shown the capability to predict individuals at high risk of developing *acute kidney injury*, with accuracy levels up to 90%.[155] The algorithmic model utilized medical records from the *U.S. Department of Veterans Affairs* to predict which patients are at the highest likelihood of developing a sudden deterioration in kidney function.[156] AI is poised to reduce workloads and solve some of the largest problems in healthcare.[157] However, AI's abilities in clinical settings are currently limited to the size of the datasets available to the computer programs. As the datasets available to AI programs expand, so will the capabilities of AI in clinical settings. The implementation of AI technology in healthcare will undoubtedly be felt in the ASC industry, with unnecessary procedures potentially being reduced as better diagnostic imaging technology developed with AI reduces the likelihood that patients will be referred for unnecessary surgeries.[158]

Advancements in pharmaceuticals may also mitigate the need for surgeries. For example, a recent study has shown that heart procedures, such as bypass surgery and stents, are *not* more effective than drug treatment and lifestyle changes at preventing future heart attacks.[159] The standard treatment for many individuals with heart disease is the use of stents; however, this recent study indicates surgical procedures to be unnecessary in non-emergency cases.[160] The study, which to date was the largest in size comparing the various treatment approaches, may gradually change the standard of care for the treatment of heart disease.[161] Reductions in referrals for heart surgery would likely impact a significant revenue stream for ASCs.

Inevitably, technology changes how healthcare is delivered and managed. The natural progression of healthcare technology will continue to shape the greater healthcare industry. The continuing trends in robotics, AI, and pharmaceuticals will impact the ASC industry. In turn, the ASC industry will need to adapt to technological advancements and implement innovative technology to remain competitively viable in the future. ASCs will likely be augmenting or enhancing the healthcare provided to consumers utilizing various technological advancements in the future. Consumers are becoming increasingly comfortable interacting with technology in healthcare settings. Similarly, ASCs are increasingly leveraging technology for management purposes. As healthcare technology trends persist, hopefully, optimized workflow trends and productivity will result.

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Valuation of Senior Healthcare: Introduction

[This is the first article in a five-part series regarding Valuation of Senior Healthcare. This installment was published in March 2020.]

Elderly adults have more options than ever before for where and how to receive healthcare services. Many seniors who require healthcare services still desire some form of independent living; consequently, new models of senior care have developed, which models vary as to care level and reimbursement requirements, better to meet the demands of this growing age cohort. This first installment in a five-part series on the valuation of senior healthcare services provides a brief overview of the various enterprises and services that comprise the senior care industry, in ascending order of care intensity.

Independent Retirement Community

Retirement communities are residential areas where seniors are close to fully independent, but can access many medical services within the community or nearby.[1] These communities have housing arrangements designed exclusively for seniors, which can include varied housing setups, such as apartments or freestanding homes.[2] Most communities are designed compactly to ensure easy navigation and provide yard maintenance for the residents[3] and may offer a variety of community-focused activities, services, and amenities that provide residents with opportunities to build bonds with others.[4] Residents need little or no assistance with daily living activities and do not require continuous medical monitoring.[5]

Continuing Care Retirement Community

The *continuing care retirement community* (CCRC) model allows seniors the choice of where they live based on how much assistance they need, with the option to move on to a different, more intensive care option if needed. CCRCs may combine independent living, assisted living, and nursing home care (which may include memory care), in a "*step-up*" model.[6] CCRC residents can start by living independently and, if needed, a transition to assisted living or skilled nursing to receive medical care or help with daily activities.[7] Resident living spaces are designed for elderly adults, and typically include nonslip floors, grip bars, elevators, and easily accessible entrances. Typically, a variety of meal plan options for residents is included in the amenities offered by these entities.

Adult Day Care

Adult day care (ADC) centers look after the needs of seniors during the day in a safe and monitored environment.[8] These facilities can provide an array of services, from health monitoring to speech therapy.[9] ADCs may also aid seniors with many non-medical needs, such as entertainment or grooming.[10] These facilities operate during regular business hours and are not available 24/7.[11] There are three main types of ADCs: those that focus on social interaction, those that provide medical care, and those dedicated to Alzheimer's disease care.[12] The average senior utilizing these services has some form of cognitive impairment and requires some assistance with daily activities.[13] ADCs provide

caregivers (typically family members) relief from around-the-clock care, so that caregivers have time to go to work while also providing seniors with social interaction.[14] Some centers also provide transportation, so that seniors can go to health appointments or participate in community functions.[15]

Assisted Living Facilities

Assisted living facilities (ALFs), which may also be called residential care facilities, are intended for seniors who need a relatively small amount of assistance with some daily activities, but still wish to live independently in private apartment units.[16] Most ALFs incorporate a community environment, with group dining and planned social activities.[17] Much of the assistance provided to residents centers on basic living activities, such as bathing and eating, but the services provided can be tailored to each resident's individual needs.[18] While most ALFs are not equipped for advanced skilled medical care, they often have nursing staff on-premises for residents, and some ALFs may also be equipped to care for residents with memory impairment or other degenerative aging diseases.[19] Meal service is typically considered a standard amenity at ALFs,[20] and most facilities also provide transportation, so that residents can go to healthcare providers, grocery stores, or even the movies.[21] ALFs are considered the middle ground between independent living communities and nursing facilities.[22] ALFs may be the best options for seniors who may need help soon, but can still live somewhat independently at present.[23]

Adult Foster Care

Adult foster care facilities, which are more common in rural areas, are usually more "*home-like*," which provides comfort to the resident.[24] These facilities primarily focus on non-medical care, such as assistance with daily living, but also dispense medications.[25] Most states limit the number of residents in a given foster home to five.[26] Adult foster care is contrasted with ALFs in that foster care serves fewer residents, and care providers typically live in the house with the residents.[27] The level of care provided in an adult foster care facility can vary depending on the needs of the patient, and the qualifications of the personnel – some adult foster care facilities can provide the same level of care as a nursing home facility. In contrast, other facilities provide minimal services, as if the resident was living in an independent living community.[28] Many families find adult foster care facilities to provide greater flexibility than ALFs because resident needs can change quickly, especially with degenerative aging diseases such as Alzheimer's disease.[29]

Nursing Care Facilities

Nursing care facilities dominate the senior healthcare industry, with approximately 1.3 million individuals residing in nursing homes in a given year.[30] The two senior nursing care service lines, which are typically located within the same building, are skilled nursing facilities (SNFs) and nursing home facilities.

SNFs provide a wide breadth of medical and non-medical assistance,[31] ranging from meal preparation to specialized nursing services, such as rehabilitation.[32]

SNF providers may include physicians, registered nurses (RNs), speech pathologists, audiologists, and rehabilitation specialists.[33] Skilled nursing care is provided for rehabilitation patients who do not require long-term care services,[34] with most SNF stays lasting between 20 and 100 days.[35] Care provided at a SNF is referred to as post-acute care because it serves as a transitional care point for patients between hospital discharge (typically after an emergency stay) and their return home.[36]

Nursing home care is similar to SNF care; however, it often provides more non-medical assistance and lacks on-site licensed medical practitioners.[37] Unlike SNFs, nursing homes offer permanent custodial care, which may last for the remainder of the senior's life (indefinite custodial care).[38] Residents may require more daily custodial non-medical assistance such as bathing, grooming, and help with mobility.[39] Patients in nursing homes are distinguished from patients in SNF care because they may not recover to an extent to live independently.

Hospice Care Facilities

Hospice care facilities provide seniors with symptom relief and pain management near the end of life.[40] Hospice facilities administer care in terms of comfort to seniors with life-limiting illnesses or diseases.[41] Hospice care providers may be an interdisciplinary team of care professionals to aid the patient and the family with the process of death.[42] Hospice care is utilized when a patient has six months or less to live.[43] Some hospice care can be provided in the home of the patient, while hospice clinics are used for complex patients.[44] Seniors do not always choose end-of-life care, but it is becoming a more frequently-preferred option due to increased knowledge of the option and less stigma surrounding utilizing the option.[45]

Conclusion

The demand for senior services is expected to increase. The number of Americans ages 65 and older will nearly double from 52 million in 2018 to 95 million in 2060, comprising 23% of the U.S. population.[46] Not only is the U.S. population expected to shift to comprise a larger cohort of seniors, but these individuals are also expected to live longer, with the average life expectancy in the U.S. currently at 78.7 years.[47] Consequently, senior care will undoubtedly play an increasingly important role in the U.S. healthcare industry going forward.

Future installments in this senior care series will discuss: (1) the regulatory environment of the senior healthcare industry; (2) the reimbursement environment of various senior care services; (3) the competitive environment of this industry; and, (4) the technological advancements affecting senior healthcare services and organizations.

Valuation of Senior Healthcare: Reimbursement

[This is the second article in a five-part series regarding Valuation of Senior Healthcare. This installment was published in April 2020.]

As noted in the first installment of this five-part series, senior healthcare options have dramatically expanded in the past decade, and seniors have more healthcare service choices than ever before to meet varied care needs and income levels. These myriad available options, each of which are discussed further below, also have differing reimbursement levels and coverage from Medicare, Medicaid, and/or commercial insurance, or, in some cases, no coverage at all; many long-term care options are paid for solely by the senior.

Independent Retirement Community

The cost of retirement communities can vary greatly. Some communities, such as subsidized senior housing, are funded by the *U.S. Department of Housing and Urban Development* (HUD), making this option more affordable.[48] Other communities are targeted at affluent seniors and offer numerous amenities to community residents, such as spas and housekeeping services.[49] Retirement communities branded as *all-inclusive* will often have an entrance fee,[50] and generally, the more expansive the amenities list, the more expensive the option. Entry fees to retirement communities can range from $1,800 to $600,000.[51] Additionally, retirement communities may have monthly fees based on the level of service chosen and the scope of benefits.[52] Retirement communities do not necessarily provide any medical services, but rather housing and amenities.

There is no Medicare or Medicaid coverage for housing or non-medical services provided in these communities, and minimal commercial insurance reimbursement. Consequently, retirement communities receive entry fees and monthly fees from the resident.

Continuing Care Retirement Community (CCRC)

The flexibility of CCRCs render them a more expensive option, and thus are typically marketed to the more affluent senior community. Two-thirds of CCRCs charge an entry fee,[53] with the average at $329,000, but with some charging well over $1 million.[54] Further, seniors pay additional fees upon moving in, such as monthly maintenance or service fees averaging $2,000 to $4,000 per month.[55] For CCRCs offering no up-front cost, rental units average $3,000 to $6,000 per month in addition to the maintenance or service fees.[56]

There are five categories of residency agreements offered by CCRCs:[57]

(1) *Extensive*: Residents pay an entry fee and a monthly fee that does not increase upon transfer to an assisted living or skilled nursing facility at the CCRC. The entry fee and monthly fee prepay the costs of healthcare and long-term care.

(2) *Modified life care*: Residents pay an entry fee and monthly fee that may increase upon transfer to higher levels of care, but not to the full cost of the care. There is still a prepayment of some future healthcare and long-term care costs through the entry fee, but it is limited.
(3) *Fee-for-service*: Residents pay an entry fee and monthly fee that changes as the level of care changes. Residents must pay the full costs of any care provided, and there is no prepayment.
(4) *Equity model*: Residents do not have to pay an entry fee, but instead must purchase a unit, membership, or equity stake in the community. Upon death, the resident's estate sells the unit, membership, or equity stake to a new resident, which provides additional funds to the estate. Future healthcare is provided by prepayment via monthly fees or a separate healthcare fee.
(5) *Rental/Lease*: A monthly fee is paid that increases with the level of care—no prepayment or entry fee is required.

Additionally, CCRCs may offer a variety of services on-site, including pharmacies, wellness centers, and outpatient centers.[58] A CCRC may provide some or all of the other service lines mentioned throughout this article. Depending on the service(s) provided, the CCRC may be reimbursed by Medicare, Medicaid, or the patient.

Adult Day Care (ADC)

State Medicaid programs are increasingly covering the care provided at ADCs,[59] and many programs are insisting on the use of ADCs over the use of nursing homes, because it reduces the number of nursing home admissions, which are also paid for by Medicaid, and usually at a much higher rate.[60] In 2019, the average annual cost for ADC was $19,500.[61]

As of 2019, all states offer some form of Medicaid assistance for ADC, although the circumstances under which Medicaid will pay for ADC varies.[62] The state programs most likely to cover ADC facilities are called Medicaid waivers, also referred to as *HCBS Waivers*, *1915(c) Waivers*, *1115 Demonstration Waivers*, or *Home and Community Based Waivers*.[63] Medicaid waivers allow states to provide long-term care outside of nursing homes.[64] The states with Medicaid waiver programs often have higher income limits than regular Medicaid programs,[65] resulting in a greater number of potential ADC patients; however, this often leads to enrollment caps and waiting lists.[66] Fifteen states offer ADC benefits through regular Medicaid programs,[67] which enrollments are not capped; however, there may still be waiting lists.[68]

Access to ADCs has become more prevalent as such facilities have begun providing services for patients with dementia or Alzheimer's disease.[69] Significantly, ADCs offering such specialized services may be costly to the patient, or their family, if those services are not covered by Medicaid.[70]

In addition to Medicaid coverage, many Medicare Advantage plans provide partial coverage for ADC services.[71]

Assisted Living Facilities (ALFs)

ALF services are not reimbursed by most private payors, Medicare, or Medicaid.[72] Due to the lack of reimbursement, this option can be a costly endeavor for many seniors – in 2019, the average annual cost for an ALF was $48,612.[73] However, certain ALF services may be reimbursed by Medicaid, such as nursing care, medical exams, and medication management.[74] While 44 states now provide some form of financial assistance to seniors in assisted living,[75] no Medicaid program is permitted to pay for room and board.[76] Additionally, the state may offer supplemental Social Security assistance to cover some ALF living costs.[77] Consequently, most ALF reimbursement comes from the patient.

Adult Foster Care

As with other senior care options, the cost of adult foster care can vary depending on the geographic region,[78] as well as other factors, but averages between $24,000 and $48,000 per year.[79] Further, seniors seeking more privacy and a higher level of service can expect a 30% premium or more.[80] Nevertheless, adult foster care generally costs less than an ALF or a nursing home.[81]

Adult foster care is increasingly popular in the private pay market, allowing facilities to cater to specific clientele at different price points.[82] Consequently, the majority of adult foster care reimbursement comes from individual senior payment.[83] While Medicare offers no coverage for adult foster care, Medicaid may cover a portion of the monthly fee for these facilities.[84] The model has been adapted to work for low income and Medicaid-eligible seniors, with states utilizing adult foster care as an alternative to nursing homes for Medicaid waiver beneficiaries.[85] However, Medicaid does not typically cover room and board.[86] Notably, state-specific social security benefits, in some cases, can be paid directly to an adult foster care facility to help cover the cost of care.[87]

Nursing Care Facilities

Nursing care facilities dominate the senior healthcare industry in terms of market share and house approximately 1.3 million people in a given year.[88] Nursing facilities generally care for older patients who are more prone to injury and illness and thus are more likely to require more intensive medical services.[89] The two senior nursing care service lines, which are typically located within the same building, are skilled nursing facilities (SNFs) and nursing home facilities.

SNF facilities provide care to patients for short durations after an inpatient hospital stay.[90] Medicare fully covers SNF stays for up to 20 days, and partially covers SNF stays over 20 days and up to 100 days.[91] SNF admissions and payments have declined in recent years as hospital inpatient stays (a prerequisite to a Medicare coverage of a SNF stay) have decreased.[92] Declines in SNF use may also reflect broader trends toward value-based reimbursement such as accountable care organizations (ACOs) and bundled payment models, which incentivize lower use of SNF facilities.[93] ACOs have lowered spending

by shortening stays in SNFs.[94] Value-based healthcare delivery and reimbursement trends have negatively affected SNFs, causing the reduced volume of patients, mandatorily shortened length of stays, and claims denials.[95] Currently, Medicare's SNF payment model favors treating rehabilitation patients over medically complex patients.[96] However, in October 2019, CMS adjusted the SNF payment model to better reflect the clinical needs of patients.[97] The redesign seeks to increase payments for medically complex patients who may have higher costs.[98]

In 2018, the SNF value-based purchasing (VBP) program began providing incentive payments[99] to SNFs based on the achievement of certain quality measures, such as readmissions for any cause within 30 days of hospital discharge.[100] In 2019, 73% of SNFs failed to meet the proscribed quality measures (resulting in payment reductions), and only 3.1% of SNFs have achieved the "*best performance*" category.[101] Payment reductions are likely to persist in the industry due to the mixed quality results.[102]

The Medicare margin of profit varies widely across facilities, which may reflect the shortcomings of SNFs or of the payment system generally.[103] In 2018, the average Medicare margin for SNFs was 10.3%, the 19th year it was above 10%.[104] Perhaps in a move to rectify this discrepancy, CMS increased 2020 SNF payments 2.4% from 2019 levels.[105]

Long-term nursing care (nursing homes) caters to an older demographic, with 80% of all nursing home residents over 65 years old (i.e., Medicare beneficiaries).[106] However, despite this fact, long-term nursing care (100+ days) is not covered by Medicare and is primarily reimbursed by Medicaid, the patient, or the patient's private insurance.[107] The care provided at a long-term nursing facility is less intensive than at an SNF.[108] Despite some reimbursement from Medicaid, approximately half of all nursing home residents self-pay.[109] Once a patient's savings and resources are exhausted, the patient is then eligible for Medicaid, which in some states may reimburse for long-term care.[110] While Medicaid eligibility varies significantly from state to state,[111] the average patient must typically have assets valued under $2,000 and monthly income under $2,313 to qualify.[112]

While Medicaid is unlikely to pay for a separate room for patients in long-term nursing care unless there is a medical need, some states allow for "*family supplementation*" to enable the patient to have a separate room.[113] Medicaid reimbursement rates can vary depending on the state, but on average, Medicaid reimburses at 70% of private payors.[114] In 2019, the average cost of a shared room was $90,155 annually or $247 per day.[115] There is a considerable variation based on geographic location, with shared rooms ranging from $150 per day to well over $1,000.[116]

Hospice Care Facilities

As discussed in the first installment of this series, hospice care is palliative, end-of-life care. Due to the demographics of individuals (mainly seniors) requiring end-of-life care, 90% of hospice industry revenue is derived from Medicare (which will reimburse hospice charges if the patient has been certified by a physician with less than six months to live[117]) or Medicaid.[118] Due to the heavy reliance on government reimbursement, any change in reimbursement by Medicare can have profound effects on hospice profit margins; these margins, which were 12.6% in 2017,[119] were estimated to dip to 10.1% in 2019.[120] The decline in profit is partly due to the reductions to the annual Medicare payment update; in 2014, CMS established a quality reporting program, which reduced by 2 percentage points a non-compliant hospice's reimbursement.[121] Further, the annual updates to the Medicare payment rate, which are based on the inpatient hospital market basket update, are reduced by a multi-factor productivity adjustment, as required by the *Patient Protection and Affordable Care Act* (ACA).[122]

There are four levels of hospice care, each of which garners a different base rate:[123]

Category	Description	2020 Base Rate
Routine Home Care (RHC)	Home care provided days 1-60	$194.50
RHC 61+	Home care provided days 61+	$153.72
Continuous Home Care (CHC)	Home care provided during a patient crisis	$1,395.63 (Hourly rate: $58.15)
Inpatient Respite Care (IRC)	Inpatient care for a short period to provide respite for a caregiver	$450.10
General Inpatient Care (GIC)	Inpatient care to treat symptoms that cannot be managed in other settings	$1,021.25

Additionally, Medicare imposes limits (hospice caps) on the total amount of annual payments that a hospice provider can receive for specific services and in aggregate.[124] There are two hospice caps – the *inpatient* cap and the *aggregate* cap.[125] The hospice inpatient cap is calculated as a percentage of all hospice days that were provided as inpatient days through a specific period.[126] The inpatient cap limits the number of inpatient days for which a hospice provider can provide services.[127] Once the cap is exceeded, inpatient days are paid at the lower RHC rate.[128] However, most hospice providers do not exceed the inpatient cap limit.[129] The aggregate cap limits the total payments that may

be received in a year in aggregate for an entire patient population.[130] Medicare multiplies the aggregate cap by the total number of patients, and if that number is lower than the actual amount paid to the hospice provider, then repayment is necessary.[131] In 2020, CMS set the aggregate cap to $29,964.78.[132] In 2017, 14% of hospices exceeded the aggregate cap and were forced to repay the excess amount to Medicare.[133]

Future Trends

The variation in senior healthcare delivery is likely to persist well into the future, driven by the differing needs of their patients. Further, government reimbursement for these services may be forced to expand as seniors become an increasingly more significant segment of the population. Senior care models that can scale to different income levels and reimbursement methods will likely be well positioned for future changes.

Valuation of Senior Healthcare: Regulatory

[This is the third article in a five-part series regarding Valuation of Senior Healthcare. This installment was published in May 2020.]

As noted in the first installment of this five-part series, senior healthcare options have dramatically expanded in the past decade, and seniors have more healthcare service choices than ever before to meet varied care needs and income levels. These myriad options also have varying degrees of regulation, both at the federal and state level. This third installment in this five-part series on the valuation of senior healthcare will discuss the regulatory environment in which senior care facilities operate.

Federal Fraud and Abuse Laws

Healthcare organizations face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. 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 most significant impact on the operations of healthcare providers.

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 receive funding from 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.[134] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[135]

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 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.[136] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[137] Congress amended the original statute in 1987 with the passage of the *Medicare and Medicaid Patient & Program Protection Act* to include exclusion from the Medicare and Medicaid programs as an alternative civil remedy to criminal penalties.[138] Additionally, 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.[139] Additionally, interpretation and application of the AKS under case law have created a precedent for a regulatory hurdle known as the *one purpose test*. Under the *one purpose test*, healthcare providers violate the AKS if even one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[140]

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 violate the AKS for the government to prove a kickback violation.[141] However, the ACA did not remove the requirement that a person must "*knowingly and willfully*" offer or pay remuneration for referrals to violate the AKS.[142] Therefore, to prove 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.[143] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the *False Claims Act* (FCA).[144] The amended AKS points out that liability under the FCA is *"[i]n addition to the penalties provided for in [the AKS]…*"[145] The amendment 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.[146]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[147] In response to these concerns, Congress created several statutory exceptions and delegated authority to the *U.S. Department of Health & Human Services* (HHS) to protect specific business arrangements through the promulgation of several safe harbors.[148] 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.[149] Failure to comply with all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[150] Importantly, for a payment to meet the compliance of many AKS safe harbors, the compensation must not exceed the range of fair market value and must be commercially reasonable.[151]

Of note, in October 2019, the HHS *Office of Inspector General* (OIG) proposed several revisions to the AKS, many of which are similar to those revisions to the Stark Law proposed by CMS. Additionally, the OIG proposed modifying some safe harbors currently established, such as personal services and management contracts and outcomes-based payment arrangements. These arrangements were changed to add more flexibility, e.g., by adding protections to certain outcomes-based payments.[152]

Stark Law

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).[153] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[154] Under the Stark Law, DHS include, but are not limited to, the following:

(1) Certain therapy services, such as physical therapy;
(2) Radiology and certain other imaging services;
(3) Radiation therapy services and supplies;
(4) Durable medical equipment;
(5) Outpatient prescription drugs; and,
(6) Inpatient and outpatient health services.[155]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities that also have an ownership interest in the entity that provides DHS.[156] 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*."[157]

Notably, 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.[158] Similar to the AKS safe harbors, without these exceptions, the Stark Law may prohibit legitimate business arrangements. Unlike the AKS safe harbors, however, an arrangement must *entirely* fall within one of the exceptions to shield from enforcement of the Stark Law.[159]

Certificate of Need

Certificate of Need (CON) laws present market entry barriers for senior care providers. The rationale behind CON laws mainly originates from the belief that healthcare does not operate like other markets to correct excess supply, and that healthcare is plagued by market failures resulting in excess supply and needless duplication of some services, causing overall costs to rise.[160] However, the validity of CON programs has been contested by the *Department of Justice* (DOJ) and the *Federal Trade Commission* (FTC), which have found that CON laws create barriers to competition, increase costs for consumers, and do not stop unnecessary spending.[161]

Nursing homes and skilled nursing facilities are often specifically subject to state CON laws.[162] Currently, 11 states have some form of CON regulation on

skilled nursing or nursing homes, and most states have a moratorium on the number of nursing facility beds allowed in a given region.[163] CON programs require a community need to be proven to state regulators in order to open or expand a service line in a region.[164] The healthcare facility may receive authorization to open if a set of criteria are met; many times however, CON laws set certain limitations on healthcare projects.[165] In states where CON laws exist for nursing homes, spending on nursing home care grows much faster than in states without CON laws on nursing homes.[166] Moreover, long-term care expenditures in CON states tend to be dominated by nursing homes, and there is much less diversification of (less costly) care.[167] CON laws and nursing home bed moratoria impose constraints on access to the market which, in turn, leaves seniors unable to access care.[168]

Licensure & Compliance

Generally, healthcare facility licensure, which is intended to ensure that patients receive high-quality healthcare,[169] is typically the domain of state governments because Medicare plays less of a role in senior care from a reimbursement perspective. However, there exists a *Catch-22* between state and federal government regulations pertaining to senior care licensure.[170] Most states require entities to meet certain practice standards set forth by Medicare as a condition of licensure, while Medicare requires state licensure as a condition of reimbursement.[171] Moreover, while the federal government may define licensure standards, it relies on state governments to physically assess and survey the facilities.[172]

All 50 states (as well as the District of Columbia) require nursing homes to be licensed.[173] To maintain licensure, facilities may need to meet certain building requirements, as well as comply with limits on the number of beds allowed in the facility.[174] While states and the federal government share regulatory responsibilities of long-term care (e.g., licensure), states usually control licensure and other standards for many residential care arrangements because there is no federal funding.[175]

Central components of long-term care regulation at a state and federal level include: (1) establishing quality standards; (2) designing a survey process to measure conditions of residents and assess compliance; and, (3) specifying remedies or sanctions for noncompliance.[176] Overall, federal government regulation of long-term care is aimed at protecting the residents' safety and holding facilities accountable for the use of public funds.[177] For example, the nursing home licensure reforms in the *Omnibus Reconciliation Act of 1987* (OBRA 87) require nursing homes to comply with standards such as patient rights relating to admission and discharge, the right to be free from abuse, and restraints, and the overall promotion of resident quality of life.[178] OBRA 87 places a focus on processes of care and resident outcomes.[179]

The scope and enforcement of state regulations of many specific senior care services vary widely across the U.S. Although a 50-state survey is beyond the scope of this article, this does not render compliance with state regulations and

guidance any less important, as compliance with these regulations may be a condition precedent to receiving Medicaid reimbursement.

Future Regulatory Trends

The COVID-19 pandemic has greatly affected senior healthcare services. For example, reporting requirements have increased, with the federal government requiring nursing homes to inform residents and their representatives of any COVID-19-related infections or deaths among nursing home staff or residents.[180] Such requirements have shined a spotlight on the failures of nursing homes to control infections, with providers under intense pressure from regulators to limit the spread of COVID-19 among residents. Nursing homes and other long-term care facilities are likely to face increased government enforcement post-COVID-19,[181] with providers that fail to take appropriate infection control measures likely to face government investigation.[182] However, many states have taken actions to shield nursing home operators from liability.[183] Nonetheless, federal regulatory scrutiny, such as from the *Office of Inspector General* (OIG) of *Health and Human Services* (HHS), has continually focused on oversight of nursing homes and other long-term care facilities,[184] and it is likely that federal regulatory oversight of senior care services will persist going forward.

Valuation of Senior Healthcare: Competition

[This is the fourth article in a five-part series regarding Valuation of Senior Healthcare. This installment was published in June 2020.]

As noted in the first installment of this five-part series, senior healthcare options have dramatically expanded in the past decade, and seniors have more long-term care choices than ever before to meet varied care needs and income levels. These myriad options also have varying degrees of competitive pressures. This fourth installment in this five-part series on the valuation of senior healthcare will discuss the competitive environment in which these facilities operate. Due to the outsized role the nursing home industry plays in senior care, this article will focus primarily on the nursing home industry.

Consolidation plays a significant role in the senior care industry, particularly in the nursing home sector, where corporatization has become a growing trend.[185] While an accurate number is difficult to ascertain, it is estimated that 50% of nursing homes in the U.S. are part of a corporate chain.[186] The prevalence of corporate chains in the nursing home industry ultimately may result in negative competitive effects. For instance, in some states, all of the nursing home facilities may be under common ownership, resulting in reduced competition from the presence of monopoly power.[187] Despite this extensive consolidation, regulatory scrutiny of, and challenges to, nursing home consolidation have been relatively rare.[188] As of 2017, at least 64% of nursing homes are characterized

as being in highly concentrated markets, rendering them an area of concern per the *Federal Trade Commission* (FTC) and *Department of Justice* (DOJ) merger guidelines.[189] Further, 2% of markets are classified as "*monopoly markets*," i.e., markets with only one consumer option.[190] Due in part to the lack of antitrust enforcement, the market consolidation of nursing homes has led to higher prices without identifiable improvements in the quality of care delivered.[191]

Nursing homes have been the subject of a number of scandals and complaints,[192] resulting in a reputation as the place "*where people go to die*," which has allowed other long-term care competitors to emerge.[193] Moreover, changes in demographics and technology have further allowed the growth of new senior care industry segments that fill the gap "*between independent housing and full institutionalization.*"[194] As a result, nursing homes have experienced consecutive yearly declines in occupancy rates.[195] Notably, this downward trend does not take into account any of the negative publicity associated with rampant COVID-19 outbreaks and deaths that have occurred at nursing homes throughout 2020.[196]

The precipitous decline in the utilization of nursing homes (and the expected continuation of this trend) can be largely attributed to three factors. First, the elderly population is experiencing a declining prevalence in disability rates.[197] These rates have declined substantially in the past decade, but the trend is expected to level out, with moderate increases in disability in the future due to increases in obesity rates among older Americans, as well as in the number of Americans age 75 and over.[198] Second, the care preference of seniors with disabilities has shifted away from nursing homes, toward noninstitutional options.[199] Home healthcare and community-based services are increasingly being utilized by seniors with early-to-moderate disability onset.[200] For example, dementia (which accounts for the largest single group of long-stay nursing home residents) is increasingly being treated using noninstitutional options such as adult foster care and assisted living.[201] Nursing homes have adapted to the change in demand with special care units (SCUs) intended to attract dementia patients with specialized dementia-related services.[202] However, evidence shows that the SCU response has not been able to halt the loss of business, as assisted living facilities and other noninstitutional alternatives have begun to dominate the industry.[203] Third, capacity limitations on the number of beds available to nursing home residents, at first intended to protect entrenched market nursing homes from the competition, has contributed to the decline in the use of these facilities.[204] The absence of a sufficient number beds for seniors with disabilities has led many potential patients to not consider nursing homes as an option for care.[205] The limitation successfully acted as a restrictive competitive control during the latter half of the 20th century, but also caused nursing homes to not meet the pace of growth of the elderly population.[206] Ultimately, alternatives to nursing homes were able to gain a market presence because they were the sole option for many seniors due to the lack of nursing home beds available; those alternatives eventually became the preferred option by seniors, causing a precipitous fall in occupancy rates at nursing homes.[207]

A significant concern across all senior care facilities has been a chronic problem of healthcare worker shortages.[208] Nursing homes and other senior care facilities rely on certified nursing assistants for most of the nonclinical care for patients in these facilities.[209] The worker shortage can force some senior care facilities to turn away patients due to a lack of staffing.[210] The shortage of nursing assistants is expected to worsen as the population continues to age, which will require more nursing assistants to care for America's seniors.[211] *The Bureau of Labor Statistics* predicts the job growth for medical assistants to increase by 23% from 2018 to 2028, which is much faster than the average job growth rate of 5%.[212] Undoubtedly, the worker shortage will continue to negatively affect senior care facilities in the future.

The growth of alternatives to nursing home care, such as adult foster care and assisted living, is difficult to assess due to the lack of data; however, the data that is available indicates a rise in the use of alternatives.[213] Further, alternatives to institutional long-term care facilities will likely grow as the population grows older.[214] Significantly, assisted living, independent housing that allows seniors access to disability services, has been welcomed as the "*new paradigm*" for eldercare.[215] Assisted living facilities require seniors to pay privately for care, similarly to nursing homes, and the growth of assisted living facilities has corresponded with the decline in seniors choosing to pay privately for nursing home care.[216] There is some evidence to clearly show the growth in popularity of assisted living facilities and continuing care retirement communities; however, due to the lack of clear definitions to track the development, a definitive growth rate is difficult to ascertain.[217]

Valuation of Senior Healthcare: Technology

[This is the final article in a five-part series regarding Valuation of Senior Healthcare. This installment was published in July 2020.]

As noted in the first installment of this five-part series, senior healthcare options have dramatically expanded in the past decade, and seniors have more long-term care choices than ever before to meet varied care needs and income levels. These myriad options also have varying operational needs that can be addressed through diverse technological solutions. The final installment in this five-part series on the valuation of senior healthcare will discuss emerging technological trends in senior care services.

Telemedicine utilization has grown exponentially over the past few years, significantly outpacing the growth of other points of care.[218] As payors, providers, and consumers become more familiar (and comfortable) with this expanding technology, providers have begun to utilize telemedicine to improve patient outcomes, patient satisfaction, employee morale, and reimbursement.[219] Telemedicine is a broad category encompassing a number of methods that use

technology to enhance the delivery of healthcare services.[220] Some of the most common modalities include live video, remote patient monitoring (RPM), and mobile health (a/k/a mHealth).[221]

Live video is the most commonly-used telemedicine modality and involves a real-time, two-way interaction between a provider and a patient, caregiver, or other provider.[222] Recently, there has been an increase in the number of senior care facilities utilizing live video to reduce unnecessary hospitalizations. Typically, when a doctor is not on-site at a senior care facility and a patient's condition changes, protocol suggests that the patient be transferred to the hospital.[223] Because less than 10% of senior care facilities have physicians on-site at all times, patients are transferred to the hospital more often than is medically necessary.[224] Studies suggest that up to two-thirds of these hospitalizations are unnecessary and could be avoided if senior care facilities had better access to physician consults and the ability to more accurately assess acute changes in a patient's condition.[225] To address this need, senior care facilities are contracting with telemedicine companies.[226] Instead of transporting patients to the hospital when their condition changes, staff arrange for the patients to meet with an emergency medical technician (EMT) or physician through live video, to determine if transportation to the hospital is necessary.[227] Live-video consultations can improve the quality of care provided to patients by avoiding hospitalizations that are stressful and costly to the patient and his/her family.[228] Additionally, reducing unnecessary hospitalizations through live video consults can help senior care facilities avoid increased administrative expenses, lost bed days, and Medicare penalties caused by unnecessary hospitalizations.[229]

In addition to avoiding hospitalizations, senior care facilities are leveraging access to live-video physician consults to reduce the need to transport patients off-site for specialist appointments. Transporting patients to specialist appointments can be costly and disruptive to patients' lives. By utilizing live-video physician consults in senior care facilities, annual cost savings to the provider (both physician offices and senior care facilities) of up to $305 million can be achieved.[230]

In addition to live video consultation, senior care facilities are using RPM and mHealth to improve patient outcomes, address staffing shortages, and promote patient independence.[231] RPM is a form of telemedicine that securely sends patient health information, collected from a variety of sources, to a healthcare provider at another location.[232] RPM is often used in conjunction with mHealth to provide real-time vitals to the remote healthcare provider. mHealth encompasses the provision of healthcare services and collection of health data through electronic devices worn by an individual that collect, and send to a remote provider, real-time data.[233] These wearables include well-known devices such as Fitbit or smartwatches, as well as specific medical devices equipped to collect information such as blood pressure, temperature, blood oxygen saturation level, and electrocardiogram (ECG) reports.[234] RPM allows

for remote providers to monitor senior care facility patients' condition in real-time, using data transmitted from wearables.[235]

Experts cite inadequate ability to assess changes in patients' conditions as a contributing factor for unnecessary hospitalizations of skilled nursing facility (SNF) patients. RPM allows for a remote provider to continuously monitor a patient's condition and alert SNF personnel to any concerning changes.[236] Shifting from a reactive to a proactive approach in senior care can significantly reduce hospitalizations and improve patient outcomes.[237] Research suggests that use of RPM could reduce hospitalizations by up to 60%, significantly improving patient outcomes.[238]

In addition to reducing hospitalizations, RPM in senior care facilities has the potential to address the significant staffing shortages being faced by the senior care industry.[239] The stress of the patient workload is cited as a contributing cause of the staffing shortage;[240] RPM addresses some of this stress by providing reassurance to staff through the remote oversight of their patients' conditions.[241] Knowing that there is a resource to help identify crucial changes in a patient gives staff additional confidence, significantly improving employee morale.[242]

RPM and mHealth are also being used by senior care facilities to promote patient independence. A continuing care retirement community (CCRC) opening later this year has announced plans to use RPM and wearables to promote independence among memory patients.[243] Using wearables equipped with real-time location management capabilities, memory patients, who may have otherwise been under close supervision and unable to freely utilize the entirety of the facility, will have the ability to independently walk about the facility.[244] If a patient wanders beyond their defined boundaries, CCRC staff will be notified.[245] Other facilities have been using mHealth to extend the time that patients spend in an independent living community before moving to a higher level of care.[246] Using in-home sensors placed in the living room of a patient's home and under the patient's mattress, information on the patient's heart rate, respiration rate, overall cardiac activity, walking speed, and movement patterns can be collected.[247] This information can be used to indicate pending health complications and assess a patient's fall risk.[248] A study found that patients monitored using these in-home sensors had an average length of stay in an independent living community of 4.3 years, compared to the national average of 1.8 years.[249]

Expansion of the field of telemedicine has also allowed for innovation in the delivery of senior care. For example, the last few years has seen the emergence of *telehospice*, remotely-delivered hospice services.[250] Under this new branch of hospice services, several existing hospice providers have launched a telemedicine program to provide a less-invasive alternative with the benefit of specialized physicians and personalized end-of-life assistance, without the need for as much in-person involvement.[251] Originally, telehospice services were designed to primarily target rural populations and populations that have historically under-utilized hospice care for social, cultural, or spiritual

reasons.[252] However, in recent months, to protect vulnerable palliative-care patients from exposure to COVID-19, hospice providers have begun to offer telehospice services to patients outside of the original target market of rural populations and populations that under-utilize hospice services.[253]

The impact of COVID-19 on the adoption of telemedicine is not limited to hospice agencies. In response to the *Center for Disease Control and Prevention's* (CDC's) recommendation to utilize telemedicine to limit senior patients' exposure to COVID-19 and the removal of restrictions surrounding Medicare reimbursement for the use of telemedicine in SNFs, the demand for telemedicine technology by senior care facilities has grown rapidly.[254] While the expansion of telemedicine utilization in senior care facilities is a response to COVID-19, it is expected that adoption of this technology will continue to grow long after the end of the pandemic.[255]

In addition to increased telemedicine utilization, adoption of artificial intelligence (AI) technology and predictive analytics by senior care facilities is expected in the future. Deep learning neural nets are being used to learn patterns in senior patient behavior that may predict future health complications such as depression, urinary tract infections, and increased fall risk.[256] Additionally, in recent years, a team at the Stanford AI Laboratory developed a predictive algorithm to identify patients in need of palliative care earlier, which could improve quality-of-life for terminal patients as well as become a more proactive alternative to referrals for hospice providers.[257] The development of these technologies shows promise for the application of AI and predictive analytics in senior care delivery.

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otherwise noted in this subpart, the term 'designated health services' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)."

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Healthcare Valuation Implications of COVID-19

[Excerpted from the article published in March 2020.]

As of March 31, 2020, more than 160,000 Americans have been diagnosed with the coronavirus (COVID-19) – the greatest number of confirmed cases of any country in the world – resulting in approximately 3,100 deaths.[1] The COVID-19 global pandemic has brought a time of grave uncertainty for U.S. healthcare and the greater economy. Both the legislative branch and the executive branch of the federal government have taken a number of unprecedented actions in an effort to stem the effects of the pandemic. Consequently, the uncertainty surrounding the resulting paradigm changes on the U.S. healthcare industry may have lasting and significant valuation implications – both now and in the future.

Recent Legislative Actions

During March 2020, the U.S. Congress has passed various pieces of legislation to combat both the surge in demand for healthcare services (and resulting shortages in healthcare workforce manpower and supplies) and the detrimental effects that the pandemic has had on the U.S. economy to date.

On March 6, 2020, President Trump signed the $8.3 billion *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*,[2] which authorizes several significant activities and expenditures by the U.S. government, including the following:

(1) The *Telehealth Services During Certain Emergency Periods Act* (TSDCEPA) of 2020, which gives authority to the Secretary of the *Department of Health and Human Services* (HHS) to lift some telehealth delivery restrictions;[3] and,

(2) $6.2 billion delegated to HHS for activities such as:

  (a) The *Public Health and Social Services Emergency Fund* (PHSSEF) – $3.4 billion in funding is delegated to: the *Biomedical Advanced Research and Development Authority* (BARDA) to research potential vaccines and therapeutics relating to coronavirus; contingency funding for vaccines and other therapeutics; and, the *Health Resources and Services Administration* (HRSA) to provide grants under the Health Center Program;

  (b) $1.9 billion delegated to the *Centers for Disease Control and Prevention* (CDC), to be directed to state and municipal response efforts relating to the pandemic and replenishment of the *Infectious Diseases Rapid Response Reserve Fund*;

  (c) $836 million delegated to the *National Institute of Allergy and Infectious Diseases* (NIAID), for the research of therapies and vaccines; and,

(d) $61 million delegated to the *Food and Drug Administration* (FDA), to develop and review vaccines and other treatments to COVID-19.[4]

On March 15, 2020, Congress also passed the *Families First Coronavirus Response Act* (drafted by House Democrats and endorsed by President Trump), which provides for free COVID-19 testing, paid leave, enhanced unemployment insurance, expanded food security initiatives, and increased Medicaid funding.[5]

On March 27, 2020, Congress passed (and President Trump signed) a $2 trillion economic stabilization package, the *Coronavirus Aid, Relief and Economic Security (CARES) Act*, that provides funds to individuals, businesses, and states. The CARES Act will also provide direct funding to the healthcare industry through a number of additional measures, including:

(1) $100 billion to hospitals, for the purpose of reimbursing expenses and lost revenue related to COVID-19, plus an additional $250 million to increase their surge capacity;
(2) A 20% increase in Medicare payments to hospitals related to treatment of COVID-19 inpatients;
(3) A delay in disproportionate-share hospital (DSH) payments through November 2020, which will effectively increase reimbursement to those safety-net hospitals; and,
(4) A suspension of Medicare sequestration (which will effectively increase most Medicare provider reimbursement by 2%) through the end of 2020; and,
(5) Advance Medicare payments to critical access and other hospitals that request them to help balance out their cash flows (based on payments received in 2019), which may be paid back over a one-year period;
(6) An extension of several Medicare and Medicaid programs until November 30, 2020, which may allow Congress to revisit certain healthcare programs and policies (e.g., surprise billing, prescription drug prices) after the 2020 U.S. Presidential Election.

Recent Executive Branch Actions

In addition to the various laws passed by the U.S. Congress, the president and various government agencies have taken a number of steps to ameliorate the crisis. On March 11, 2020, President Trump announced aggressive measures to combat the spread of coronavirus, including:

(1) Instructing the *Internal Revenue Service* to allow high deductible health plans (HDHP) to provide health benefits associated with testing and treatment of COVID-19 without application of the deductible or below the deductible amount without losing tax status as an HDHP thus allowing tax-favored contributions to health savings accounts (HSA) by patients;[6]
(2) Collaborating with national health insurers to cover all American patients' COVID-19 testing and treatment, without copayments;[7] and,

(3) Instructing the *Department of Treasury* to defer tax payments for individuals and businesses impacted by COVID-19.[8]

On March 13, 2020, President Trump officially declared the COVID-19 pandemic a national emergency.[9] This proclamation allows for greater flexibility for healthcare providers and access to additional resources for states. Following the proclamation, the *Centers for Medicare & Medicaid Services* (CMS) issued a number of waivers for healthcare providers and announced other, additional measures, which are active for the duration of the pandemic:[10]

(1) The *skilled nursing facility* (SNF) three-day rule (which requires Medicare beneficiaries to have a three-day hospital stay before Medicare pays for SNF services) has been waived;
(2) *Critical access hospitals* (CAHs) are no longer required to (a) limit the number of beds to 25; or, (b) limit patient length of stay to 96 hours;
(3) The requirement that acute care hospitals house acute care patients and psychiatric patients in distinct units separate from the rest of the hospital has been waived;
(4) Lost or damaged durable medical equipment (DME) may be replaced without a face-to-face patient encounter;
(5) Providers already licensed in one state may now practice in another state without a license;
(6) Providers (both physicians and non-physician practitioners) may receive expedited temporary Medicare billing privileges, waived application fees, and waived background checks;
(7) States may apply for section 1135 waivers, which would allow their Medicaid programs to relax various restrictions, including:
    (a) Reimburse out-of-state licensed providers under the state's Medicaid program;
    (b) Authorize providers to provide care in alternative settings; and,
    (c) Suspend prior authorization requirements.[11]

Recent Federal Reserve Actions

In response to the economic instability, the Fed (a governmental agency) has also made a number of drastic moves to offset the greater market panic resulting from COVID-19:

(1) On March 15, 2020, the federal funds rate was reduced 1% to between 0.00% and 0.25%;[12]
(2) On March 15, 2020, the Fed directed the Open Market Trading Desk (the Desk) to increase holdings to $500 billion in Treasury securities, and $200 billion in mortgage-backed securities in the coming months;[13] and,
(3) On March 17, 2020, a lending facility was established to support short-term commercial debt markets (similar to what was used during the *Great Recession*).[14]

These unprecedented measures are the most aggressive since the *Great Recession*, the most significant economic downturn since the Great Depression, which lasted from December 2007 to June 2009.[15] Subsequently, on March 23, 2020, the Fed announced additional, broader measures, including:

(1) Removal of the March 15 limit on the purchase of treasury securities and mortgage-backed securities. The Open Market Trading Desk will make purchases in "*the amounts needed*" to support smooth market functioning and effective transmission of monetary policy to the broader economy;
(2) Establishment of new credit programs to support up to $300 billion in financing to employers, consumers, and businesses;
(3) Establishment of two facilities to support credit to large employers – the *Primary Market Corporate Credit Facility* to provide new bond and loan issuance, and the *Secondary Market Corporate Credit Facility* to provide liquidity for outstanding corporate bonds;
(4) Establishment of the *Term Asset-Backed Securities Loan Facility* to support credit to consumers and businesses;
(5) Expansion of the *Money Market Mutual Fund Liquidity Facility* to include additional securities, including municipal variable rate demand notes and bank certificates of deposit, in order to facilitate the flow of credit to municipalities; and,
(6) Expansion of the *Commercial Paper Funding Facility* to include high-quality, tax-exempt commercial paper and reduction of facility pricing.[16]

Despite these measures, financial market conditions have remained volatile:[17]

(1) As of March 16, 2020, the Dow Jones Industrial Average, the Standard and Poors 500, and the Nasdaq indices have all entered bear market territory (a fall of more than 30% from recent highs);[18]
(2) Selloffs in the S&P 500 have triggered multiple trading halts;
(3) All 11 sectors of the S&P 500 have seen considerable stock price declines;
(4) Stocks of airline and cruise industries have tumbled more than 20%;
(5) International financial markets have seen precipitous declines;
(6) Most multinational corporations project a decline in earnings due to the pandemic;
(7) The U.S. dollar has surged against all major currencies, an indication of stressful market periods;[19] and,
(8) A record number of Americans, 3.28 million, filed for unemployment benefits the week ending March 26, 2020.[20]

Valuation Implications

The financial market conditions above will impact valuations performed on or after December 31, 2019.[21] Previous *Black Swan Events*, i.e., an unpredictable event that is beyond normal expectations for a situation and has potentially severe consequences (such as the *Great Recession*),[22] as well as evaluation of current events and market conditions, can help provide guidance for the impact upon the valuation of healthcare enterprises, assets, and services.

Valuation Approaches for Healthcare Enterprises, Assets, and Services

The impact of the financial market conditions above on the valuation of healthcare enterprises, assets, and services will partially depend on the valuation approach utilized. The three general classifications of valuation approaches are:

(1) Income approach-based methods:

Income approach-based methods seek the present value of anticipated future economic benefits that will accrue to the willing buyer of the business, asset, or service. In addition to estimating the future economic benefits of post-transaction ownership, an appropriate discount rate, risk-adjusted for the property interest, by which the benefits are discounted to present value, must also be developed.

(2) Market approach-based methods:

Market approach-based methods are premised on the foundation that actual transactions of similar property interests guide value. The efficient market hypothesis posits that prices derived from well-functioning, publicly traded markets are reflective of all pertinent information available to the participants in the market, i.e., a price derived from market transactions represents the market consensus present value of the expected future economic benefit to be received from the ownership of the enterprise, asset, or service by a willing buyer.

(3) Asset/Cost approach-based methods:

Asset/cost approach-based methods seek an indication of value by determining the cost of reproducing or replacing an asset or providing a service.

No matter which valuation methodology is selected, economic value is quantified as the expectation of future economic benefit to be derived from the ownership or receipt of the property or service, respectively.

Impact on the Valuation of Healthcare Enterprises and Assets

Hospitals and other healthcare enterprises will see significant financial impacts from the cancellations of financially vital procedures. In a recent survey of orthopedic surgeons, interventional cardiologists, and anesthesiologists, 23% of responding physicians noted an increase in deferrals or cancellations of procedures, and 55% of responding physicians expected that deferrals and cancellations will continue to increase.[23] While the cancellations of elective procedures have been primarily initiated by patients, the need for additional

inpatient capacity at healthcare facilities could drive a further reduction in elective procedures,[24] especially given the direction from the *Centers for Disease Control and Prevention* (CDC) that hospitals in affected regions cancel non-urgent procedures for an indefinite amount time[25] and the recommendation from professional societies such as the *American College of Surgeons* that hospitals be prepared to call off all elective surgeries during the pandemic.[26] Cancellations of profitable cardiac and orthopedic elective surgeries will undoubtedly hurt hospital margins. In addition to the loss of revenue from elective procedures, there will also be increased costs related to space, supplies, and staffing needed to respond to COVID-19 cases. According to *S&P Global Ratings*, hospitals could see up to a 20% decline in admissions for up to six months.[27] *S&P Global Ratings* has lowered its financial outlook for hospital companies *LifePoint* and *Tenet Healthcare* due to the pandemic and the effects on revenue.[28]

These factors could lead to a negative impact on the short-term economic benefits that would be derived from ownership in healthcare enterprises and assets, even with current legislative actions.

The long-term impact of the COVID-19 outbreak on U.S. economic growth and the U.S. healthcare industry is currently uncertain. This uncertainty may also present significant opportunities for healthcare providers, especially for providers that are providing telehealth services.[29] In fact, the temporary roll-back of regulations has increased demand for telemedicine services 10- to 20-fold.[30]

In addition to adoption and provision of telehealth services, there is an increase in the use of additional tools and technologies to help manage patient outcomes, such as remote clinical observation and disease management; improved communication tools; self-service diagnostics and self-care tools; predictive analytics and knowledge management; artificial intelligence; informational chatbots; cross-industry collaborations; and, innovative care models.[31] Those companies and providers that can make this transition, or already have, may differentiate themselves from their competition and guideline comparables (which may lead to a higher indication of value based upon market approach based methods), and/or provide enhanced economic benefit of ownership with reduced uncertainty (which may increase value under income approach based methods), both of which may warrant a positive impact on value. In addition, those companies and providers that have already spent the resources, time, and funds may increase value under a cost approach based method.

Further, it is important to note that when considering income-based valuation methods, up to 75% of the value could exist in the terminal period (i.e., period beyond the short-term discrete projection of economic benefits).[32] The long-term impact of the COVID-19 outbreak on the valuation of healthcare enterprises and assets remains to be seen. However, the long-term prospects of those companies who are positioned to deliver care in a high quality, cost-effective manner in the post-COVID-19 world may outweigh any short-term negative impact on valuations from COVID-19.

Impact on the Valuation of Healthcare Services

The majority of compensation arrangements have not factored in compensation during extreme public health crises such as the current COVID-19 outbreak. Regulatory guidance will continue to change around compensation arrangements that are revised or entered into during and after the COVID-19 outbreak.

Currently, there is strong demand for essential services in the emergency departments and intensive care units at the epicenter of the COVID-19 outbreak, and hospitals are attempting to redeploy specialists who do not typically treat infectious diseases to meet the excess demand.[33] There may be a need to change compensation arrangements to provide payment to these providers for working extra hours and facing additional risk. The amount of hazard pay that providers would qualify for would depend upon the selection of an appropriate proxy for the determination of the hazard pay premium and would likely vary on a case-by-case basis as some providers may already work in inherently dangerous environments and some amount of compensation may already be factored into existing arrangements. Certain qualitative factors may also impact the necessity for hazard pay, such as situations where there is insufficient personal protective equipment for providers, which would require providers to reuse equipment and increase risk of infection.[34]

Physicians and non-physician providers providing non-essential services under provider services agreements (PSA) will likely experience a near-term decline in productivity due to the limitation or cancellation of elective procedures. Hospitals may consider converting affected specialists to a fixed salary or stipends to temporarily stabilize their income and minimize the impact to these specialists.

On March 30, 2020, CMS published "*Blanket Waivers of Section 1877(g) of the Social Security Act*," wherein the HHS Secretary waived certain requirements under the Stark Law (subject to certain conditions), including:

(1) Remuneration between an entity and a physician (or the physician's immediate family member) that is above or below fair market value for:
   (a) "*services personally performed by the physician (or the immediate family member of the physician) to the entity*;"
   (b) "*items or services purchased by the entity from the physician (or the immediate family member of the physician)*;"
   (c) The use of premises or for items or services purchased, medical staff incidental benefits;
   (d) Nonmonetary compensation that surpasses the current Stark Law limit of $300 per year; and,
   (e) Remuneration resulting from a loan with an interest rate below fair market value; and,

(2) Rental charges between an entity and a physician (or the physician's immediate family member) that is above or below fair market value for the lease of office space or equipment.[35]

CMS provided specific examples wherein these blanket waivers may apply, including a hospital compensating a physician above the contracted rate in recognition of "*particularly hazardous or challenging environments*."[36]

While these waivers provide needed relief to healthcare providers, this does not eliminate the need for a fair market value analysis in order to comply with fraud and abuse laws. Fair market value of these arrangements will vary on an individual basis and adequate documentation for the necessity of these arrangements will reduce regulatory risks should the arrangement be subject to scrutiny in the future.

Fair market value of compensation arrangements will vary on an individual basis and adequate documentation for the necessity of these arrangements will reduce regulatory risks should the arrangement be subject to scrutiny in the future.[37] Further, documenting the commercial reasonableness of these arrangements may prove vital to substantiating the extraordinary circumstances of the change in compensation, as a commercial reasonableness opinion may serve to set forth the qualitative aspects of such an arrangement and provide the reasoning behind compensation changes.

In addition to the above, existing pay-for-performance compensation models may require normalizing adjustments for the period impacted by COVID-19.

Future physician compensation arrangements will need to take into consideration normalizing adjustments to industry normative benchmark compensation data for 2020. Some healthcare systems are temporarily reducing non-essential physician compensation, which may impact the compensation reported in the industry normative benchmark compensation data for 2020.[38]

Conclusion

While the focus of healthcare providers and regulators is, appropriately, on the access to and delivery of care to those impacted by the COVID-19 outbreak, the regulatory scrutiny related to fraud and abuse issues will persist. This current uncertainty creates a plausible scenario wherein a valuation professional may be required to deviate from industry normative benchmark data to account for those specific facts and circumstances related to a given transaction. As a result, valuation professionals opining on these transactions should utilize an evidence-driven methodology that includes both qualitative and quantitative assessments of the specific facts and circumstances related to the transaction; document their consideration of these facts and circumstances; and, articulate their ultimate applicability to the transaction in support of their opinion.

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Is Healthcare Recession-Proof?

[Excerpted from the article published in May 2020.]

Is healthcare recession-proof? Or perhaps the more accurate question to ask is: "*is healthcare pandemic-proof?*" Paradoxically, the COVID-19 public health crisis has wreaked havoc on the U.S. healthcare industry. The *U.S. Bureau of Labor Statistics* (BLS) forecasted that healthcare occupations would grow at a much faster rate between 2018 and 2028 than the average for all other occupations (14%), with the healthcare sector expected to add approximately 1.9 million new jobs.[1] However, as of the end of the first quarter of 2020, healthcare has lost 1.4 million jobs, and real personal consumption for healthcare services has plummeted by 4.97% from the fourth quarter of 2019.[2] Correspondingly, the *American Hospital Association* (AHA) estimates that between March 1 and June 30, 2020, hospitals and health systems stand to lose a combined $202.6 billion in revenue as a consequence of the COVID-19 pandemic.[3] COVID-19 has been the direct cause of the impending economic recession that has upended not only the U.S. economy generally, but also, the once-thought recession-proof healthcare industry.[4] Such an atypical situation warrants a review of how this economic fallout in the healthcare industry has deviated from prior recessions, and the degree to which COVID-19 is disrupting the finances of the healthcare sector.

With more than 1.5 million COVID-19 cases as of May 2020;[5] no clear end to the pandemic in sight; and, a possible resurgence of the virus in the fall and winter, it may be assumed that such a public health emergency would be a boon for the healthcare industry. However, that assumption could not be further from the truth. COVID-19 has impacted the U.S. healthcare industry in ways that were near impossible to forecast. This virus is not only novel in a sense that it is (still) an enigma, but also in the way that it has caused mass economic destruction in healthcare, which strongly deviates from decades past. Historically, healthcare has been generally resistant to economic recessions.[6] In fact, some economists and healthcare analysts view the healthcare industry as recession-proof, because it has acted as a buffer against the normal cyclical business cycle.[7] For example, during the 2007-2009 Great Recession, the healthcare sector actually added jobs (more than 850,000 between 2007 and 2010),[8] while the broader U.S. economy lost almost 8 million jobs.[9]

However, healthcare has never been completely recession-proof, i.e., unconditionally shielded from economic contractions.[10] The belief that healthcare is recession-proof is derived from the notion that even in economic recessions, people will still get sick and need to utilize healthcare services.[11] Generally, healthcare reacts differently to economic downturns than other industries. Precedent shows when the labor force begins to post significant job losses, individuals begin to change their healthcare consumption habits as they lose their employer-sponsored health insurance.[12] In other words, healthcare consumers (i.e., patients) choose to delay elective procedures until the future of the broader economy looks more promising.[13] This consumer behavior leads

the healthcare sector to experience economic downturns on a delay, and experience a recovery after the broader economy does.[14] During such times, physicians and hospitals bear the most risk, because they are the most vulnerable to immediate consumer spending changes.[15] Moreover, McKinsey & Company estimates for both for-profit and nonprofit providers during a typical economic recession, they are likely to incur a 30% drop in *earnings before interest, taxation, depreciation, and amortization* (EBITDA).[16] Payors and *pharmacy benefit managers* (PBM) are slightly less at risk, with a 5% to 20%, and 5% to 15%, EBITDA drop, respectively.[17] Although providers, payors, and PBMs do feel a financial drag during recessions, the healthcare industry does not usually experience financial stress as acutely as the broader U.S. economy.[18]

In past recessions, healthcare has been less volatile than other cyclical sectors.[19] Healthcare's insulation is primarily the result of most Americans having health insurance.[20] Payors will continue to inject capital into the healthcare economy, whereas in other cyclical sectors of the economy, spending dries up significantly.[21] In fact, the biggest users of the insurance system are older Americans, who tend to be sicker (i.e., utilize a disproportionate amount of healthcare services) and receive comprehensive insurance coverage through Medicare.[22] This spending by government payors, as well as by commercial insurers, has been the main driver of new jobs in healthcare during economic downturns, and why healthcare is viewed by some economists as leading economic recoveries, because the durable jobs created subsequently helped strengthen local economies.[23]

While a comprehensive study as to the ultimate quantified financial impact of the COVID-19 pandemic on providers has, understandably, not yet been completed, early evidence reveals a grim situation. Job loss in the healthcare sector has been staggering thus far, and behind all of the pay-cuts, furloughs, and layoffs is the extraordinary revenue loss.[24] Hospitals and health systems are facing catastrophic financial challenges in light of the COVID-19 pandemic,[25] with multiple health systems reporting revenue losses of more than 50%.[26] After accounting for the net financial impact of COVID-19 on hospital costs, total revenue losses stemming from the cancellation of non-emergency (i.e., elective) procedures; the reduced volume of emergency room visits and hospital admissions; additional costs associated with the purchase of needed *personal protective equipment* (PPE); and, the costs of additional compensation that some hospitals are providing to their front line workers, the AHA estimates that, on average, hospitals are losing a combined $50.7 billion per month in revenue.[27] Additionally, with the cancelation of elective procedures, emergency room visits, admissions, and surgeries are all down substantially. Consequently, the healthcare professionals that are not caring for COVID-19 patients are effectively out of demand, which is unique to previous economic recessionary periods.[28]

The COVID-19 pandemic has also exposed the precarious method by which hospitals seek to maintain profitability. Healthcare tends to be a low-margin industry that includes high fixed costs to providers. If revenues abruptly stop, that may be (quickly) disastrous for functional operations. For hospitals, treating patients for a deadly illness is far less profitable than conducting elective surgeries.[29] Elective cases are the primary source of revenue for many hospitals, which allows them to take a loss on certain other services while remaining profitable.[30]

A similar revenue shock has taken place in many physician practices.[31] Some primary care practices are reporting reductions in the use of healthcare services of up to 70%,[32] which, similar to hospitals, has led to clinical staff pay-cuts, furloughs, and layoffs.[33] Many physicians have chosen to close their offices to reduce the risk spreading the disease.[34] The others that have remained open are seeing a drastic reduction in demand as older patients are afraid to visit for fear of being exposed to COVID-19, and other treatments are deferred due to economic uncertainty. But this time, unlike during the Great Recession, another barrier to healthcare access exists, which is specifically affecting commercially insured beneficiaries – rising healthcare out-of-pocket costs, particularly with respect to insurance policy deductibles.[35] Currently, 25% of private insurance beneficiaries have an insurance deductible of $2,000 or more, which is four times more individuals than a decade ago.[36] Consequently, even more so than during the Great Recession, patients that may still be willing to go to a physician's office for a visit or procedure may choose not to for financial reasons.

As with the sudden drop in demand for services, high costs (factoring in the healthcare business model discussed above and the greatly-increased need for additional PPE and ventilators)[37] and very little revenue coming in for providers, COVID-19 has greatly distorted the economics of healthcare.[38] The unprecedented nature of this virus has inflicted devastating financial injury on the healthcare industry, which may lead to economic recession. The indeterminate length of the pandemic further confirms that the COVID-19 pandemic, and the resulting economic crisis, is unlike anything the U.S. economy has experienced in modern times, and the ultimate financial impact on the healthcare industry remains to be seen.

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II. REIMBURSEMENT TOPICS

Private Sector's Innovative Approaches to Rising Healthcare Costs

[Excerpted from the article published in November 2019.]

As the federal government stalls on making meaningful improvements to the healthcare industry, the private sector is stepping up to the task. Employers are increasingly seeking ways to cut healthcare costs for practical profit purposes. The *Centers for Disease Control and Prevention* (CDC) reports that productivity losses linked to absenteeism cost U.S. employers $225.8 billion annually.[1] Employees fatigued at work due to illness causes errors and puts an additional financial burden on employers. Additionally, employers do not want to pay for unnecessary medical care, and approximately 30% of healthcare spending is wasted on unnecessary services.[2] There is also an increased risk of medical error from unnecessary services, including subsequent complications from those unnecessary services.[3] Employees with health conditions, and/or at a high risk for health problems, can cause significant productivity losses for employers.[4] Going forward, these losses may grow, driven by the increased population of Americans choosing to work past the age of 65.[5] In response to these factors, employers have resorted to implementing their own innovative ideas to lower healthcare costs.

Walmart, for example, has begun a new program to decrease the cost of employee healthcare by motivating their employees to use higher quality, lower cost physicians. Employees that obtain healthcare services from "*featured providers*" will ultimately pay less out of pocket for the use of those services compared to utilizing a non-featured provider.[6] Walmart is working with Embold Health, a healthcare analytics company, to use data to analyze whether physicians are providing appropriate, effective, and cost-efficient care.[7] The provider analysis will be given to employees seeking care to help steer them in the direction of those "*featured providers*."[8] The quality metrics used by Embold Health will also be shared with providers, so the providers know which areas they need to improve to achieve the quality distinction, with the ultimate goals of improving quality and reducing unnecessary services and procedures.[9] The ultimate savings achieved by Walmart and by their employees is unknown, but Walmart estimates that the amount could be "*material*."[10] The new approach mirrors a similar approach Walmart currently uses with regard to hospital care.[11] Walmart has directed all of their U.S. employees and dependents on their health plan to utilize better-performing hospitals for high-cost services.[12] The strategy may sometimes cost more for the procedure than using a local alternative, but may save money by averting complications and unnecessary care.[13] Walmart also directs its employees to diagnostic imaging facilities found to provide more accurate care.[14]

Amazon has taken an alternative approach to tackling high healthcare costs by directly providing medical care to their employees through *Amazon Care*, a pilot employee benefit program.[15] The service is a combination of virtual and in-person care, offering home health services, telehealth appointments, and

prescription delivery.[16] Employees are encouraged to use the Amazon-created telehealth smartphone application for non-urgent issues like colds and minor injuries; preventative health consults and vaccines; sexual health services; and, general health questions.[17] *Amazon Care* is currently exclusive to Amazon health insurance plan members who live and work within the Seattle service area.[18] Of note, Amazon is ensuring that it will not have knowledge of employees' health conditions by utilizing the separate legal subsidiary *Oasis Medical*.[19] *Amazon Care* follows last year's announced plan to open, and hire physicians to staff, primary care clinics at Amazon's Seattle headquarters, which clinics have not yet opened.[20] For Amazon, the *Amazon Care* program provides a way to hopefully lower healthcare costs for the company while also testing new healthcare products in an internal research and development laboratory. Presumably, *Amazon Care* also provides a new market opportunity for Amazon in areas such as population health management and health technology.

Amazon Care follows Amazon's previous announcement that it was teaming up with Berkshire Hathaway and JPMorgan Chase to form *Haven*, a joint venture whose goal is "*to transform health care to create better outcomes and overall experience*."[21] *Haven* hired prominent surgeon and Harvard professor Atul Gawande to lead up the organization as its CEO.[22] While specific details regarding the joint venture are currently limited, *Haven* is being touted generally as a push for the organizations to figure out ways to create better outcomes, greater satisfaction, and lower costs for U.S. employees.[23] *Haven* is expected to utilize the power of data and technology to drive better incentives and create a better patient experience.[24]

As the employers' share of healthcare costs are set to rise six percent in 2020,[25] employers are under increased pressure to directly address healthcare cost concerns. These recent employer moves to contain healthcare costs highlight corporate America's willingness to tackle rising healthcare costs in new and innovative ways while focusing on quality. Further, many of these corporate moves allow the companies to position themselves to launch healthcare services and products to a larger audience of other employers or even directly to patients, should the employee pilot program succeed. With no progress on healthcare reform appearing imminent on Capitol Hill, large corporations are leading the way in an attempt to find the "silver bullet" in lowering costs while increasing quality.

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Healthcare Spending Accelerates in 2018

[Excerpted from the article published in December 2019.]

Economists, actuaries, and statisticians from the *Centers for Medicare and Medicaid Services* (CMS) recently conducted a full analysis of 2018 U.S. healthcare spending.[1] The research found that the healthcare spending growth rate rose to 4.6% in 2018, from 4.2% in 2017, equating to approximately $11,172 per person.[2] However, continued U.S. economic growth, which contributed to a growing overall gross domestic product (GDP) in 2018,[3] resulted in the share of the economy devoted to healthcare actually *declining* from 17.9% in 2017 to 17.7% in 2018.[4] This is the first time since 2013 that this share declined, although the ratio remained stagnant between 2016 and 2017.[5]

Medical price growth, which had the quickest one-year increase since 2011, accounted for the majority of the increase in per capita spending, "*more than offset[ing] slower growth in the use and intensity of health care goods and services*."[6] The authors attributed much of the medical price growth to the inflation across the U.S. economy, as well as medical-specific price inflation.[7]

Total personal healthcare spending accounted for 84% of total national health expenditures (NHE) in 2018.[8] However, the growth rate for total personal healthcare spending remained constant from 2017 to 2018, at 4.1%.[9] Despite the overall stability of this segment, the trends within separate spending categories were mixed. The three largest goods and services categories together accounted for 73% of total personal healthcare expenditures: (1) hospital care (2) physician and clinical care; and, (3) retail prescriptions.[10] Hospital care spending grew at approximately the same rate as in 2017 (4.5% in 2018, compared to 4.7% in 2017), while physician and clinical services spending decreased, from 4.7% in 2017 to 4.1% in 2018.[11] Perhaps unsurprisingly, prescription drug spending increased 2.5% in 2018, much faster than the 2017 increase of 1.4%.[12]

Importantly, the majority of the faster spending growth resulted from the growth in the net cost of health insurance.[13] The net cost of health insurance[14] grew much more rapidly in 2018, at a pace of 13.2%, compared to a rate of 4.3% in 2017.[15] The reinstatement of the health insurance tax[16] in 2018, following the one-year moratorium in 2017,[17] primarily drove the faster growth rate of the net cost of health insurance in 2018.[18] The tax was originally mandated by the 2010 *Patient Protection and Affordable Care Act* (ACA), beginning in 2013, and sunsetting in 2017.[19] Section 201 of the *Consolidated Appropriations Act of 2016* then suspended the collection of the health insurance provider fee for the 2017 calendar year.[20]

The implications of this health insurance tax reinstatement are multifaceted. If payors pass the health insurance tax on to consumers in the form of higher premiums, it could spark lower enrollment in the exchanges and consequently contribute to a larger uninsured population.[21] Further, this health insurance tax reinstatement disproportionately impacts Medicare Advantage beneficiaries.[22]

The Medicare Advantage market is highly competitive compared with other health insurer markets;[23] consequently, Medicare Advantage payors cannot pass along the cost of the tax to enrollees, leaving Medicare Advantage payors with the choice of either paying the tax or leaving the market.[24] Fewer Medicare Advantage payors in the market lead to less patient choice and higher premiums for Medicare Advantage beneficiaries, due to decreased competition in the marketplace.[25] The Medicare Advantage market relies heavily on high levels of market competition to ensure better quality and lower prices for beneficiaries; market concentration suggests that taxpayers and beneficiaries will overpay.[26] Of note, the health insurance tax was subsequently suspended for 2019, but not for 2020.[27] The tax is estimated to increase all health insurance premiums by an average of 2.2% in 2020.[28]

Importantly, the number of uninsured Americans grew by one million in 2018, marking the second year in a row of at least 30 million Americans being uninsured.[29] The greater number of uninsured Americans may have contributed to the average slower rate in the use and intensity[30] of healthcare services (1.3% in 2018 compared to 1.6% in 2017[31]), as individuals without health insurance may utilize fewer services.[32]

The Trump Administration has taken a number of steps to combat rising healthcare spending levels. Two recent *Health Capital Topics* articles, "*Trump Administration Brings Transparency to Healthcare*" (November 2019)[33] and "*Hospitals Sue to Keep Prices Secret*" (December 2019), address the administration's policies seeking to combat the rising costs of health prices (in particular, hospital prices) and the current litigation brought by hospitals against the administration related to those policies. Hospital prices in particular continue to be a leading factor in growth despite the use and intensity of service growth remaining stagnant.[34] With hospital prices increasing by 2.4% in 2018,[35] the Trump Administration may have ample support to pursue more aggressive agency action related to healthcare pricing. Healthcare spending growth trends will continue to be affected by regulatory decisions, including the future of Medicaid Expansion and the repeal of the *Individual Mandate*,[36] as well as by economic and demographic trends.[37]

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1 "National Health Care Spending In 2018: Growth Driven By Accelerations In Medicare And Private Insurance Spending" By Micah Hartman, Anne B. Martin, Joseph Benson, Aaron Catlin, and The National Health Expenditure Accounts Team, Health Affairs, Vol. 39, No. 1 (January 2020), p. 8.

2 *Ibid.*

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5 *Ibid.*

6 *Ibid*, p. 10-11.

7 *Ibid*, p. 11.
8 *Ibid*, p. 8.
9 *Ibid.*
10 *Ibid.*
11 *Ibid*, p. 15.
12 *Ibid.*
13 The net cost of health insurance is defined as the amount of insurance spending attributed to nonmedical expenses, including administration, taxes, and underwriting gains or losses. *Ibid*, p. 8; CMS includes in the net cost of health insurance other administrative costs such as: net additions to reserves, rate credits and dividends, advertising, sales commissions, et. "Quick Definitions for National Health Expenditure Accounts (NHEA) Categories" Centers for Medicare and Medicaid Services, https://www.cms.gov/files/document/quick-reference-national-health-expenditure-category-definitions-0 (Accessed 12/17/19), p. 2.
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26 Frank and McGuire, p. 1-4.

27 Internal Revenue Service, December 6, 2019.

28 The tax will cost $241 per Medicare Advantage beneficiary on average in 2020. Carlson, Giese, and Sauder, p. 3.

29 Hartman, Martin, Benson, Catlin, and The National Health Expenditure Accounts Team, p. 11.

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COVID-19 Financial Relief Available to Hospitals and Physicians

[Excerpted from the article published in April 2020.]

The COVID-19 global pandemic has brought a time of grave uncertainty for U.S. healthcare and the greater economy. While the focus of healthcare providers is, appropriately, on the access and delivery of care to those impacted by the COVID-19 outbreak, there are many providers who will require financial resources to persevere during a time when all sectors of the U.S economy are being significantly impacted. The federal government has announced a myriad of programs in the form of grants and loans to reimburse hospitals and physicians for some expenses and loss of revenue. It is more than likely that unless the public health emergency quickly subsides, many providers will suffer dire consequences without additional financial assistance. This *Health Capital Topics* article sets forth those programs and resources currently available, to assist providers in accessing these opportunities.

During the months of March and April 2020, the U.S. Congress passed four economic relief packages, including the $2.2 trillion *Coronavirus Aid, Relief and Economic Security* (CARES) *Act* on March 27, 2020,[1] and the $480 billion *Paycheck Protection & Health Care Enhancement Act* (PPHCEA) on April 23, 2020.[2] These two bills, among other things, provide direct funding to the healthcare industry (including hospitals, medical practices, and physicians) through a number of measures. Most significantly, the acts provide a collective $175 billion to the *Department of Health & Human Services* (HHS) *Public Health and Social Services Emergency Fund* (Provider Relief Fund).[3] Of this total:

(1) $50 billion is being "*generally disbursed*" to providers directly,[4] based on the provider's share of 2018 net patient revenue,[5] for the purpose of reimbursing expenses and lost revenue related to COVID-19;[6]

(2) $10 billion is being targeted to COVID-19 hot spots, which funds are expected to be released on or about April 29, 2020.[7] While HHS has not yet released the exact formula for determining funding amounts, it will be generally based on a provider's COVID-19 admissions and number of intensive care unit (ICU) beds;[8]

(3) $10 billion is being paid to rural hospitals and rural health clinics, based on their operating expenses.[9] Those funds are expected to be paid out the week of April 27, 2020;[10]

(4) $400 million will be disbursed to Indian Health Service (IHS) providers, which (similar to rural providers) will be based on operating expenses;[11]

(5) An undetermined amount to providers caring for uninsured patients. The amounts will be paid on a claims-basis (at the Medicare rate), and will cover services and products.[12] As a condition of payment, providers will be required to attest that they will not balance bill any patient for treatment related to COVID-19;[13] and,

(6) An undetermined amount to "*other*" providers, such as *skilled nursing facilities* (SNFs) operating in COVID-19 hot spots, dentists, and Medicaid providers.[14]

The additional $75 billion that was part of the PPHCEA did not include any guidance to HHS regarding how these funds must be utilized.[15] As of the publication of this article, HHS has not announced how these funds will be allocated, but it did state that its priorities include funding to rural providers, providers that serve a large Medicaid patient population, and others whose payor mix is heavily reliant on payors other than traditional fee-for-service Medicare.[16]

These funds do not have to be repaid, but providers must accept certain terms and conditions, certifying, among other things, that all received funds will "*only be used to prevent, prepare for, and respond to coronavirus*."[17] Additionally, note that these advances (much like the other programs discussed below) will be remitted to the organization whose tax identification number (TIN) bills Medicare; consequently, individual physicians would not directly receive these payments.[18]

In addition to direct healthcare provider payments, the CARES Act implemented a number of, and PPHCEA added additional funding to, temporary *Small Business Administration* (SBA) loan programs for small businesses (such as physician practices):

(1) The *Paycheck Protection Program* (PPP), to which a total of $659 billion has been allocated;[19]

(2) The *Emergency Economic Injury Disaster Loans* (EIDL) to which a total of $20 billion has been allocated;[20]

(3) The *Coronavirus Economic Stabilization Act* (CESA); and,

(4) The Small Business Debt Relief Program.[21]

HHS has also taken agency action, separate from Congress, to distribute over $100 billion to providers operating under Medicare Part A and Part B through the much-expanded Accelerated and Advance Payment Program.[22] Prior to the COVID-19 pandemic, this program had approved only 100 requests for accelerated/advance payment over the past five years.[23] During April 2020, CMS approved approximately 45,000 payment requests; on April 26, 2020, CMS announced that it was suspending the program.[24]

A couple of noteworthy points regarding these programs:

(1) Businesses may obtain loans under both the PPP and the EIDL, so long as they cover different expenses;[25] and,

(2) Providers who receive more than $150,000 in total federal government funding related to COVID-19 will be required to submit a report to HHS disclosing the total amount received and an itemized list of how the received funds were spent.[26]

Although not immediate, businesses may also be eligible for various tax credits. For example, the Employee Retention Tax Credit provides an employee retention tax credit of 50% on wages, up to $10,000 per employee.[27] This credit is applicable to wages paid or incurred between March 13 and December 31, 2020, as well as a portion of the cost of employer-provided healthcare benefits.[28] Eligible businesses include those who are not in receipt of a PPP loan and whose: (1) operations have been fully/partly suspended due to a Stay at Home Order; or (2) gross receipts declined by more than 50% compared to same quarter of 2019.[29]

The federal government is also alleviating burdens for healthcare providers (through waivers or other rule changes) to make it easier to be reimbursed for various services during the pandemic. Such changes include, but are not limited to, the following:

(1) A 20% increase in Medicare payments to hospitals related to treatment of COVID-19 inpatients;[30]

(2) A suspension of Medicare sequestration (which will effectively increase most Medicare provider reimbursement by 2%) through the end of 2020;[31]

(3) An expansion of the scope of practice for non-physician providers and medical residents;

(4) An expansion of reimbursable telehealth services, allowing Medicare providers to provide more than 80 additional services to beneficiaries, regardless of whether the beneficiary is in a rural community, or whether the provider is located out of state. These services are currently allowed to be provided via non-secure apps, such as Skype and Facetime;[32]

(5) Ambulatory surgery centers (ASCs) can enroll and bill as a hospital, or alternatively, contract with hospitals to provide hospital services;[33] and,

(6) Physician-owned hospitals may increase their number of beds.[34]

In the coming weeks, healthcare providers can expect the federal government to distribute the additional $75 billion received through the PPHCEA; as noted above, how that amount will be allocated has not yet been determined. Further, it is possible that Congress will pass a fifth stimulus plan, although when that bill may be brought to the floor for a vote remains to be seen, due to political partisanship.[35] How these next steps to deal with the financial challenge for

healthcare providers unfold may largely depend on the length of the COVID-19 pandemic. While it is impossible to predict the long-term consequences on the U.S. healthcare system, in the short term, providers are reeling from the effects of the pandemic. During March 2020, hospital median operating margins decreased over 150%, down 14 percentage points compared to March 2019.[36] Similarly, a Medical Group Management Association survey found that independent physician practices have experienced an average decline in patient volume of 60% and revenues of 55% since the beginning of this public health crisis.[37] Further, 48% have been forced to enact temporary furloughs and 22% have permanently laid off staff.[38] A HealthLandscape and American Academy of Family Physicians study estimates that approximately 60,000 family practices will close or significantly scale back, laying off 800,000 employees, if things remain the same.[39] Should healthcare providers, and particularly physicians, not receive additional funding, the COVID-19 pandemic could decimate the U.S. healthcare workforce.

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1 "Coronavirus Aid, Relief, and Economic Security Act'' H.R. 748.

2 "Paycheck Protection & Health Care Enhancement Act" H.R. 266.

3 Of that total, $100 billion was disbursed from the CARES Act, and an additional $75 billion was allocated from the PPHCEA. "Coronavirus Aid, Relief, and Economic Security Act'' H.R. 748-283, §16004; "Paycheck Protection & Health Care Enhancement Act" H.R. 266

4 The quoted language is utilized repeatedly throughout CMS's press releases to explain its original disbursement method, discussed in Footnote 3, below, and to underscore the fact that HHS sought "[t]o expedite providers getting money as quickly as possible." "HHS Announces Additional Allocations of CARES Act Provider Relief Fund" Department of Health & Human Services, April 22, 2020, https://www.hhs.gov/about/news/2020/04/22/hhs-announces-additional-allocations-of-cares-act-provider-relief-fund.html (Accessed 4/22/20).

5 Note that, prior to April 22, 2020, first $30 billion was disbursed based on providers' 2019 Medicare fee-for-service (FFS) reimbursement. After this disbursement methodology was strongly criticized by the provider community as not helping those most in need, i.e., hospitals treating the greatest numbers of COVID-19 patients, the formula was revised, and the remaining $20 billion was disbursed so as to reconcile payments to the new model, which includes revenue from all payors. "HHS Distributes $30B to FFS Medicare Providers" By Paul Gerrard, MD, et al., McDermott+Consulting, April 11, 2020, https://www.mcdermottplus.com/insights/hhs-distributes-30b-to-ffs-medicare-providers/ (Accessed 4/15/20), "HHS Announces Additional Allocations of CARES Act Provider Relief Fund" Department of Health & Human Services, April 22, 2020, https://www.hhs.gov/about/news/2020/04/22/hhs-announces-additional-allocations-of-cares-act-provider-relief-fund.html (Accessed 4/22/20).

6 "CARES Act Provider Relief Fund" Department of Health & Human Services, April 22, 2020, https://www.hhs.gov/provider-relief/index.html (Accessed 4/23/20).

7 "COVID-19 hotspots, rural hospitals to score half of $40B CARES grants" By Rachel Cohrs, Modern Healthcare, April 22, 2020, https://www.modernhealthcare.com/finance/covid-19-hotspots-rural-hospitals-score-half-40b-cares-grants (Accessed 4/23/20).

8 *Ibid*; Department of Health & Human Services, April 22, 2020.

9 This is in addition to the approximately $165 million that was allocated by the CARES Act to the Health Resources and Services Administration (HRSA), which money was disbursed on April 22, 2020, to rural hospitals and Telehealth Resource Centers (to "provide technical assistance on telehealth to help rural and underserved areas combat COVID-19"). Department of Health & Human Services, April 22, 2020; "HHS Awards Nearly $165

Million to Combat the COVID-19 Pandemic in Rural Communities" Department of Health & Human Services, April 22, 2020, https://www.hhs.gov/about/news/2020/04/22/hhs-awards-nearly-165-million-to-combat-covid19-pandemic-in-rural-communities.html (Accessed 4/23/20).

10 Cohrs, Modern Healthcare, April 22, 2020; Department of Health & Human Services, April 22, 2020.

11 Department of Health & Human Services, April 22, 2020.

12 "COVID-19 Claims Reimbursement for Testing and Treatment to Health Care Providers and Facilities Serving the Uninsured" Health Resources & Services Administration, April 2020, https://www.hrsa.gov/coviduninsuredclaim (Accessed 4/23/20); Cohrs, Modern Healthcare, April 22, 2020.

13 Department of Health & Human Services, April 22, 2020.

14 *Ibid*; Cohrs, Modern Healthcare, April 22, 2020.

15 *See* "Paycheck Protection & Health Care Enhancement Act" H.R. 266-3 et seq.

16 "Congress to replenish COVID-19 provider grant fund with $75 billion" " By Rachel Cohrs, Modern Healthcare, April 21, 2020, https://www.modernhealthcare.com/politics-policy/congress-replenish-covid-19-provider-grant-fund-75-billion (Accessed 4/23/20).

17 "Acceptance of Terms and Conditions" Department of Health & Human Services, https://www.hhs.gov/sites/default/files/relief-fund-payment-terms-and-conditions.pdf (Accessed 4/15/20).

18 Department of Health & Human Services, April 13, 2020.

19 Note that $349 billion of that total was allocated from the CARES Act, which funding ran out less than three weeks later. Subsequently, the PPHCEA allocated an additional $310 billion to the program, $60 billion of which was set aside for businesses without established banking relationships. "Coronavirus Aid, Relief, and Economic Security Act'' H.R. 748-283, Div. A, Title I; "Paycheck Protection & Health Care Enhancement Act" H.R. 266-1 § 101; "SBA's $349B Paycheck Protection Program officially runs out of money" By Andy Medici, St. Louis Business Journal, April 16, 2020, available at: https://www.bizjournals.com/stlouis/news/2020/04/16/sbas-349b-paycheck-protection-program-officially.html?ana=e_stl_bn_breakingnews_breakingnews&j=90504349&t=Breaking%20News&mkt_tok=eyJpIjoiWldZeE1HUTVOamRoWVRJMSIsInQiOiJDeEhlYjRPeWNvRUNWNGxFMDIwdjlqQ1E0NVYyU3FIczRORXkxK1p1MU00Q1EzMmRiYW9Fa3liSytteEl0Y3VncmJvblVidGhYcDBmOURtaElycjJsY2ptTXE2VkhSXC9hb29YYWs2VHVpWEtEMHFOR2xOMVZSSTNHQTBcL0U0bkpudlF3Ynk1aVBCOEtLbjFTVkdTSmxVZz09In0%3D (Accessed 4/16/20).

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Outpatient Revenue Outpaces Inpatient Revenue

[Excerpted from the article published in April 2020.]

On February 21, 2020, professional services firm Deloitte published a report analyzing the financial data of Medicare-certified hospitals between 2011 and 2018.[1] During this timeframe, hospital outpatient revenue grew at a compounded annual rate of 9%, to 48% of total hospital revenue, while inpatient care saw its revenue grow at a compounded rate of 6%.[2] These numbers seem to correlate with the rise in utilization of non-traditional sites of service such as ambulatory surgery centers (ASCs), urgent care clinics, primary care clinics, retail clinics, and telehealth.[3] These outpatient revenue trends significantly impact the operations of hospital and other healthcare organizations, and with payors seeking to move healthcare reimbursement toward value-based models, these trends are expected continue, or even accelerate.

With outpatient revenue at approximately 95% of inpatient revenue,[4] healthcare entity reliance on revenue from inpatient care (which used to be the most profitable) has been necessarily declining.[5] In fact, the significant shift toward outpatient care has been building for the last three decades.[6] The *American Hospital Association*'s (AHA) 2018 *Trend Watch Review* of inpatient and outpatient data between 1995 through 2016 indicated the following trends:[7]

	Inpatient	**Outpatient**
Admissions per 1,000	-12%	N/A
Inpatient Length of Stay	-15%	N/A
Outpatient Visits per 1,000	N/A	+47%
Surgeries	-7%	+35%

In addition to these volume changes, a 2018 study conducted by Deloitte's Center for Health Solutions found that gross hospital outpatient revenue grew by 45% between 2005 and 2015, from $1,352 per visit to $1,962.[8]

As noted in the Deloitte report, the main catalysts for this growth in outpatient care have been reimbursement drivers, technological advancements, and patient preference.[9] The shift from *volume*-based to *value*-based reimbursement has strongly incentivized the provision of care in outpatient settings. In 2013, the *Centers for Medicare & Medicaid Services* (CMS) established the *Two-Midnight Rule*, wherein hospital admissions are only billed as an inpatient stay if it spans two (or more) midnights; otherwise, the "*observation stay*" will be billed as an outpatient visit.[10] Additionally, propelled in large part by the *Patient Protection and Affordable Care Act* (ACA), both private and public payors have begun linking provider reimbursement to cost containment and quality metrics.[11] Payment arrangements such as shared savings, bundled payments, and capitation,[12] seek to improve care coordination and healthcare delivery efficiency.[13] This push to reduce costs has spurred hospitals, health

systems, and providers to provide a greater number of services in the lower-cost outpatient setting. For hospitals and health systems, this shift to the outpatient setting may be achieved through physician practice acquisition;[14] such vertical integration can support the hospital's market position by allowing for a more fully integrated network, and the physicians can then be reimbursed at higher rates if they bill as a hospital-based outpatient department[15] (in contrast to a freestanding physician practice or an ASC). This shift to value-based reimbursement is significantly changing the focus of healthcare delivery and access.

Additionally, a number of significant technological advancements over the past decade have allowed for this shift to the outpatient setting. Clinical advancements, such as minimally invasive surgery, have allowed procedures that could previously only be done in the hospital to be rendered in outpatient settings, such as ASCs, with shorter recovery times. Further, investment in virtual services, such as telehealth, is expected to further move patients from the inpatient to outpatient setting.[16] The benefits associated with telehealth include increasing patient access to care (as patients would not necessarily have to leave their home to obtain medical advice), satisfying the demand of patients who prefer the convenience of web-based engagement, enhanced population health management, and the prevention of (more costly) emergency room and inpatient visits.[17] Telehealth's potential has been well exhibited during the COVID-19 pandemic, as the technology has helped to prevent further spread of the virus by keeping people at home and hospitals from becoming overwhelmed.[18]

Many hospitals and healthcare systems have also significantly invested in outpatient, non-hospital care settings in response to demand from patients, who prefer outpatient settings because of their convenience and lower cost.[19] Outpatient facilities, such as ASCs, imaging centers, and urgent care clinics, are typically located closer to patients' homes, and are easier to quickly enter and exit, in contrast to obtaining care at a large hospital campus. Additionally, outpatient providers can perform the procedures at a much lower cost to the payor and patient, due to the reduced overhead and services offered. In an inpatient setting, more staff (with a wider specialty range), services, and equipment drive up costs that are then pushed on to the patient, unlike in an outpatient setting, where minimally invasive surgical procedures and other simpler tasks are cheaper and far more convenient for the patient, thus fueling demand for outpatient growth.[20]

With hospital admissions increasing less than 1%, and outpatient visits increasing 1.2%, year-over-year,[21] it is likely that outpatient care will continue to become a greater part of hospital revenue going forward.[22] In the short term, current healthcare trends may be accelerated by the COVID-19 pandemic, which pushed a significant amount of patient care to the outpatient setting and paved the way for an expanded provision of virtual health services.[23] The extent to which this shift is accelerated may largely depend on whether CMS extends its various regulatory waivers and relaxations post-pandemic.

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CMS Proposes IPPS Updates for 2021

[Excerpted from the article published in May 2020.]

On May 11, 2020, the *Centers for Medicare and Medicaid Services* (CMS) released its proposed rules for payment and policy updates for the Medicare *Inpatient Prospective Payment System* (IPPS) and *Long-Term Care Hospital* (LTCH) *Prospective Payment System* (PPS) for fiscal year (FY) 2021.[1] Other than the changes in IPPS and LTCH payments, the most notable portion of the proposed rule is the innovation incentives proposed by CMS.[2] This *Health Capital Topics* article discusses the various provisions outlined in the CMS proposed rule.

Payment Rate Update

The proposed rule includes an estimated 3.1% total increase in operating payments for general acute care hospitals paid under IPPS if the hospital participates in the *Hospital Inpatient Quality Reporting* (IQR) Program and are meaningful *electronic health record* (EHR) users.[3] The payment increase is lower than the 2020 increase of 3.7%.[4] This percentage increase translates to a growth in Medicare spending on inpatient hospital services of about $2.07 billion in 2021.[5] However, proposed changes to payment policies will decrease IPPS payments by approximately 0.4%, leading to a true overall increase in IPPS payments of only 1.6%.[6] Proposed changes in new technology add-ons, capital payments, and uncompensated care payments will lead to decreases in overall IPPS payments.[7] Further, the proposed rule subjects hospitals to other payment adjustments under the IPPS, including:

(1) "*Penalties for excess readmissions, which reflect an adjustment to a hospital's performance relative to other hospitals with a similar proportion of patients who are dually eligible for Medicare and full-benefit Medicaid*;"
(2) "*Penalty (1 percent) for worst-performing quartile under the Hospital-Acquired Condition Reduction Program*;" and,
(3) "*Upward and downward adjustments under the Hospital Value-Based Purchasing Program*."[8]

For 2021, LTCH PPS payments will decrease by 0.9%, reflecting the statutorily required reductions to LTCH payments.[9] The decrease is a reversal from last year's increase of 1.75%.[10] The LTCH PPS operates under a dual-rate system consisting of site neutral payments and traditional LTCH payments.[11] Currently, the number of cases paid using this blended payment rate represents approximately 25% of all LTCH cases and 10% of all LTCH PPS payments.[12] The number of LTCH cases paid under this dual model is expected to decrease by 20% by the end of 2021.[13]

Technology Add-On

In this proposed rule, CMS suggests approving 24 applications for the new technology add-on payment (NTAP) program.[14] Under this program, CMS provides enhanced reimbursement (i.e., an add-on payment) to inpatient

hospitals for new medical services or technologies.[15] Three of the 24 technologies were submitted to the *Food and Drug Administration* (FDA) as *Breakthrough Devices*,[16] and six have received FDA *Qualified Infectious Disease Product* (QIDP)[17] designation.[18] CMS has proposed expanding the technology add-on payment to other technology that addresses the "*unmet needs of patients with serious bacterial and fungal infections*."[19] CMS is proposing conditional approval for antimicrobial products that meet the FDA standard but have not yet been approved as a QIDP in order for the antimicrobial product to receive payment sooner.[20] The proposed rule highlights CMS's significant concern relating to antimicrobial resistance.

Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program is a quality reporting program that may reduce payments to hospitals that fail to meet quality reporting requirements.[21] Major proposed changes to the Hospital IQR Program include publicly displaying *electronic clinical quality measures* (eCQM) on the *Hospital Compare* website. The data will be required to be reported by hospitals for the 2021 reporting period and subsequent years so that it may be included and periodically updated on the *Hospital Compare* website for healthcare consumers to view.[22] CMS proposes streamlining the validation process for the Hospital IQR Program by requiring quality reporting information to be submitted electronically only and prohibiting the submission of CDs, flash drives, or other physical copies.[23]

Additional Proposals

The changes proposed by CMS would affect approximately 3,200 acute care hospitals and 360 LTCHs.[24] According to CMS, the proposed changes to the payment systems are intended to "*support the agency's key priorities, which include Strengthening Medicare and Fostering Innovation*."[25] Further, CMS proposes the implementation of some aspects of the 2019 price transparency rules by proposing the collection of hospitals' median payor-specific negotiated inpatient services charges for Medicare Advantage organizations and third-party payors.[26] CMS is also requesting comments pertaining to potentially using the data to set Medicare payment rates for hospital procedures.[27] The price transparency rule is further discussed in the November 2019 *Health Capital Topics* article entitled, "*Trump Administration Brings Transparency to Healthcare*."[28] CMS notes in the proposed rule its recognition of the impact of COVID-19 on limiting the ability of impacted parties from commenting on the proposals, so it has limited its annual rulemaking to focus on essential policies, as well as policies that may help providers responding to the COVID-19 pandemic.[29] Comments from industry stakeholders regarding the proposed rule are due by July 10, 2020.[30]

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COVID-19 Forces Value-Based Reimbursement Model Revision

[Excerpted from the article published in June 2020.]

On June 3, 2020, Seema Verma, the Administrator of the *Centers for Medicare & Medicaid Services* (CMS), announced in a *Health Affairs* article that CMS is providing significantly more flexibility for healthcare entities participating in CMS-sponsored value-based reimbursement (VBR) models for the duration of the COVID-19 pandemic.[1] CMS has made a number of changes related to these models to provide added flexibilities to participating entities and to respond to participant concerns that VBR models will incur losses this year due to both the general disruption in operations and the greater expense associated with treating COVID-19 patients.[2]

In determining the changes to enact, CMS relied on the following principles:

- "*Utiliz[ing] flexibilities that already exist in current model design*
- *Continu[ing] sufficient financial incentives that encourage higher quality outcomes to participate in value based arrangements*
- *Ensur[ing] equity and consistency across models*
- *Align[ing] as much as possible with national value based and quality payment programs.*
- *Minimiz[ing] risk to both model participants, the Medicaid program, and the Medicare Trust Funds*
- *Minimiz[ing]delays in new model implementation while providing additional opportunities for participation in new models*
- *Minimiz[ing] reporting burden*
- *Complement[ing] and build[ing] off of new CMS COVID-19 [public health emergency] flexibilities as outlined in regulation and waivers*."[3]

Some of the general modifications that affect all of the 16 CMS-sponsored models include:

(1) Moving back the model implementation date for new models, and modifying deadlines for existing models;

(2) Delaying some reporting requirements; and,

(3) Adjusting some payment methodologies.[4]

Additionally, specific changes made to some of the more well-known CMS-sponsored VBR-sponsored models are listed below:

(1) *Bundled Payments for Care Improvement* (BPCI) *Advanced*: CMS will allow participants to eliminate upside and downside risks by excluding model year 2020.[5] If a participant chooses to remain in two-sided risk, the participant may exclude certain Clinical Episodes from model year 2020 related to COVID-19.[6] Notably, no changes were made to quality reporting requirements or the model timeline.[7]

(2) *Comprehensive Care for Joint Replacement* (CJR) Model: CMS will remove downside risk for participants by capping episode payments at a target price for episodes with a date of admission during, or adjacent to, the Public Health Emergency (PHE) period. [8] Additionally, Year 5 of the performance period (i.e., the final year of the model) has been extended by three months, to March 31, 2021.[9]

(3) *Direct Contracting* Models (both Global and Professional): The start period for first cohort of participants in this new model will be delayed until April 1, 2021, with the second cohort launching on January 1, 2022.[10] CMS recognizes that this change may result in financial methodology and quality reporting changes, but the agency has held off on making those decisions at this time.[11]

(4) Medicare ACO *Track 1+* Model: Although this limited-duration model is closed to new applicants, current participants may elect to extend their participation for an additional year, through December 2021.[12] CMS will remove the episodes of care relating to treatment of COVID-19 from consideration in the financial methodology.[13] Additionally, the *Medicare Shared Savings Program's* (MSSP's) *Extreme and Uncontrollable Circumstances* policy clause will apply to the 2020 financial reconciliation.[14]

(5) *Next Generation ACO* (NGACO) Model: This limited-duration model (which was supposed to end in 2020) will be extended through December 2021.[15] Additionally, as regards the financial methodology for 2020, downside risk will be adjusted by reducing shared losses by the length of the PHE (i.e., number of months), while upside potential will be capped at 5% of participants' gross savings.[16] As with the Track 1+ model, CMS will remove the episodes of care relating to treatment of COVID-19 from consideration in the financial methodology.[17] CMS will also remove the financial guarantee requirement for 2020.[18]

CMS hopes that these changes will help minimize the reporting and compliance burdens, as well as the risk to model participants, and that the changes in various deadlines may give providers additional time to transition to value-based care.[19] In her announcement, Verma advocated for the (perhaps counterintuitive) idea that VBR models may be in the best position to weather this and future pandemics, stating:

> "*Going forward, value-based care can help ensure health care resiliency. By accepting value-based or capitated payments, providers are better able to weather fluctuations in utilization, and they can focus on keeping patients healthy rather than trying to increase the volume of services to ensure reimbursement. Value-based payments also provide stable, predictable revenue—protecting providers from the financial impact of a pandemic.*"[20]

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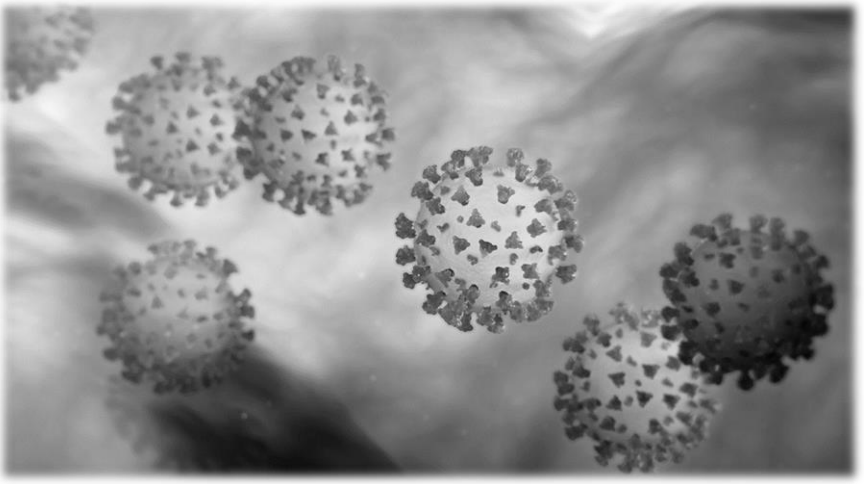

CMS Proposed Rule Supports Value-Based Purchasing for Drugs

[Excerpted from the article published in June 2020.]

On June 19, 2020 the *Centers for Medicare & Medicaid Services* (CMS) issued a proposed rule regarding *Medicaid Drug Rebate Program* (MDRP) regulations, with the aim of lowering drug prices, increasing patient access, and encouraging innovation in the insurance and pharmaceutical industries.[1] This proposal is consistent with the Trump Administration's *Blueprint to Lower Drug Prices* (Blueprint) released in May 2018, in which the administration highlighted its goal to "*avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid*" and to "*speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers*."[2] The proposed rule seeks to accomplish the Blueprint's goals by reducing regulatory barriers that have previously prevented commercial plans and states from entering into *value-based purchasing* (VBP) arrangements with drug manufacturers.[3]

Over the past decade, there have been significant strides in the development of curative therapies.[4] In 2017, the *U.S. Food & Drug Administration* (FDA) approved its first gene therapy[5] – since then, three additional gene therapies have been approved.[6] This exponential growth in the approval of curative therapies has highlighted the need for innovation in drug payment models, putting increasing pressure on CMS to remove the regulatory barriers that allow for such innovation.[7] The Administrator of CMS, Seema Verma, cited this urgency for new drug payment models to keep pace with the pharmaceutical industry's innovation in curative therapies in announcing the proposed rule.[8] With its publication of the proposed rule, CMS highlighted the potential of the adoption of VBP arrangements by state Medicaid programs and commercial payors in increasing patient access to innovative treatments, lowering healthcare spending, and encouraging innovation in the pharmaceutical industry.[9]

The proposed rule seeks to increase patient access to innovative drugs by allowing for payors to facilitate VBP arrangements.[10] Despite the rapid emergence of curative therapies, patient accessibility to these treatments remains largely restricted.[11] Due to the high price tag and the novelty of curative therapies, many patients are finding it difficult to obtain coverage from their insurance provider for curative therapies.[12] Under traditional payment models, there is significant financial risk for insurers to provide coverage for curative treatments such as gene therapy.[13] For example, Luxturna, a one-time gene therapy treatment, approved by the FDA in 2017 to treat a rare form of inherited vision loss, has a list price of $850,000.[14] Given the high cost of treatment, under traditional payment models, many insurance companies would wait to cover the treatment until the drug had demonstrated efficacy.[15] However, for a drug designed to treat rare diseases, treating enough patients to reach the insurance provider's threshold of demonstrated efficacy could take several

years, preventing patients from receiving that treatment in the interim.[16] However, under a VBP arrangement, payors and drug manufacturers could agree to drug rebates based on patient outcomes.[17] The Luxturna manufacturer has pursued a VBP arrangement with select payors to offer a rebate based on the efficacy of the drug at 30 days, 90 days, and 30 months.[18] Outcome-based VBP arrangements such as this can mitigate some of the risk that is preventing payors from covering these curative treatments. Subsequently, with the risk of coverage minimized under a VBP arrangement, payors could expand coverage for curative treatments, increasing patient access to the novel therapies.[19]

Moreover, the expansion of patient access to curative treatments has the potential to decrease healthcare spending as a whole.[20] Treating the symptoms and complications of the conditions most frequently addressed with curative therapies over the course of a patient's lifetime is costly.[21] However, if treated by emerging curative therapies, lifetime costs for these conditions may be significantly reduced.[22] For example, the lifetime costs of hemophilia A, a condition with a curative treatment that is currently under FDA priority review, can exceed $25 million per person.[23] However, a new, one-time gene therapy designed to treat hemophilia A is projected to cost $2 to $3 million for a single treatment.[24] If approved, this treatment could reduce lifetime healthcare expenditures by more than $20 million per patient.[25] However, the reduction in healthcare expenditures can only be realized if there is substantial improvement in patient access to these curative treatments, highlighting the need for flexibility to implement VBP arrangements for such drugs.[26]

Finally, the proposed rule aims to encourage further innovation in the pharmaceutical industry. Drug manufacturers invest significant resources in the development of new drugs with the intention that they will receive a profit generated from drug reimbursement. Under a VBP arrangement, drug manufacturers must be confident in the efficacy of their drug to ensure that they will not lose money in rebates to payors for ineffective drugs.[27] This demand for quality may serve to encourage increased competition and further innovation in the pharmaceutical industry.[28]

Despite the promising implications of VBP arrangements, regulatory roadblocks have prevented these benefits from being realized.[29] For the past 30 years, MDRP regulations have largely impeded the implementation of VBP arrangements.[30] Under the MDRP, to be covered under Medicaid, drug manufacturers must enter into a rebate agreement with CMS, affirming that they will rebate a portion of what state Medicaid programs pay for the drug back to the states.[31] The size of the rebate is determined by what is commonly known as the "*best price*" rule.[32] Under this requirement, the rebate required to be paid to the states is either: (1) a certain percentage (23.1%, 17.1%, or 13%, depending on the type of drug) of the drug's *average manufacturer price* (AMP); or, (2) the manufacturer's "*best price*,"[33] i.e., the lowest price after rebates and discounts that a drug manufacturer offers to any other party (e.g., retailer, provider, wholesaler) in the U.S.[34] The "*best price*" rule is largely attributed to the lack of VBP arrangements currently in effect.[35]

Under the current MDRP requirements, manufacturers are required to rebate states so that the net price of the drug paid by state Medicaid programs is no greater than that manufacturer's "*best price*."[36] For example, a drug manufacturer could enter into a VBP arrangement with a commercial payor wherein the manufacturer receives reimbursement only if the drug is effective in treating a patient.[37] If, in a single beneficiary of the commercial payor, the drug is not effective, the lowest net price for a single unit of that drug paid by the commercial payor would be $0.[38] Subsequently, under the MDRP's current definition of "*best price*," the best price of that drug is $0.[39] This means that the manufacturer would be required to rebate the entire price of the drug to states regardless of overall patient outcomes.[40] This possibility has prevented manufacturers from entering into VBP arrangements.[41] Additionally, many payors are interested in entering into VBP arrangements with manufacturers that consist of rebates contingent on patient outcomes over an extended period to evaluate the performance of a drug over a patient's lifetime.[42] This is to mitigate the financial burden taken on by the payor if, for example, after 10 years, disabling side effects present or the effectiveness of the drug diminishes over time.[43] However, because of the "*best price*" rule, manufacturers cannot offer rebates contingent on a drug's performance more than 3 years after the drug is administered to a patient since that would reduce the price of the drug beyond the 12-quarter MDRP reporting period.[44] The lack of flexibility to evaluate patient outcomes from a drug over a longer period of time has diminished the appeal of VBP arrangements.[45]

To address the limitations of current MDRP requirements, the proposed rule redefines the "*best price*" reporting requirements for manufacturers.[46] Instead of reporting using the current method of reporting the lowest price of a single unit offered in the U.S., manufacturers can report the best price of "*bundled sales*."[47] This would allow manufacturers to report the lowest average net price of a drug.[48] For each VBP arrangement entered into by the manufacturer, the manufacturer would calculate the average net price of all the units sold under that arrangement and report the lowest average net price as the "*best price*."[49] For example, a manufacturer could enter into an agreement requiring the sale of 500 units at $1,000 per unit, with a rebate of 75% if the patient has a negative outcome.[50] Since all of the units sold in the agreement were subject to the same performance terms, a manufacturer could treat this agreement as a bundled sale.[51] If 10 patients have a negative outcome, the manufacturer would then calculate the average net price as follows:

500 units x $1,000 = $500,000 – [10 patients with a negative outcome x ($1,000 x 75%)] = $492,500 ÷ 500 = $985[52]

If $985 was the lowest average net price of all of the agreements entered into by the manufacturer for that drug, then the manufacturer would report $985 as the best price.[53] Alternatively, the proposed rule allows for manufacturers to report "*best price points*" to enable VBP arrangements that have multiple price points for a drug depending on the patient outcome realized.[54] Under this structure, manufacturers would report a set of best prices based on the various

outcome- or evidence-based measures offered by the manufacturer through its various VBP arrangements.[55] The manufacturer would supplement these "*best price points*" with a single "*best price*."[56] This would allow for state Medicaid programs to participate in VBP arrangements with drug manufacturers while still ensuring the best price is being awarded to Medicaid and keeping the integrity of the MDRP intact.[57] Additionally, to address the restriction of the three-year evaluation period caused by the MDRP 12-quarter reporting period, the proposed rule allows for manufacturers to make changes to the reported AMP or best price outside of the 12-quarter reporting period, to allow for VBP arrangements that consider outcomes beyond a three-year period.[58]

Thus far, there has been support for VBP arrangements from industry stakeholders.[59] Over the past few years, commercial payors and drug manufacturers alike have been calling for changes in regulation that would allow for the facilitation of VBP arrangements.[60] Some stakeholders, such as Harvard Pilgrim Health Plan and pharmaceutical companies Spark Therapeutics and Repatha, have already begun small-scale VBP arrangements.[61] However, many industry players remain skeptical over the value of VBP arrangements.[62] Critics emphasize the complexity of developing VBP arrangements and cite concerns that VBPs may encourage pharmaceutical companies to set higher drug prices.[63] In announcing the proposed rule, Verma stated that the proposed rule "*doesn't necessarily guarantee low prices, but what it does do is it provides a tool in the toolbox for plans to negotiate with manufacturers*."[64] The proposed rule is open for public comment until July 20, 2020.[65]

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Are Primary Care Physicians Finally Ready for Value-Based Reimbursement?

[Excerpted from the article published in July 2020.]

The call from primary care physicians for changes to the current healthcare reimbursement structure is growing louder in the face of the hardships endured as a result of the coronavirus (COVID-19) pandemic. In response, professional organizations, payor organizations, and payors themselves are answering that call, in the form of two July 2020 announcements related to innovative payment systems directly targeted at independent medical practices and primary care physicians.

Currently, the most commonly-used reimbursement structure in the U.S. healthcare delivery system is *fee-for-service* (FFS) payment models.[1] Under an FFS model, healthcare providers receive separate compensation for each service provided, such as an office visit or procedure.[2] Over the past several decades, however, the U.S. healthcare system has been moving away from FFS and toward value-based reimbursement (VBR).[3] The *Centers for Medicare & Medicaid Services* (CMS) has introduced numerous VBR models over the past decade, largely as a result of legislation such as the *Medicare Improvements for Patients & Providers Act* (MIPPA), the *Patient Protection and Affordable Care Act* (ACA), and the *Medicare Access & CHIP Reauthorization Act* (MACRA), all of which place more emphasis on VBR.[4] The adoption of VBR models has similarly skyrocketed on the state level over the past decade, with the number of states utilizing VBR models increasing from three in 2011 to 48 states as of 2018.[5] In addition to government payors, commercial payors have established various VBR models over the years, albeit at a slower rate than the federal government.[6]

The key difference between these two reimbursement systems is the emphasis placed on *quantity* of services provided (emphasized by FFS) versus *quality* of services provided (emphasized by VBR). Many VBR models use benchmarks to compare facility performance in categories such as immunization rates, Medicare spending per beneficiary, and patient feedback, and rewards those above those benchmarks.[7] Other VBR models utilize *bundled payments* (also known as *global* or *capitated* payments) in reimbursing providers for all of the treatment related to a specific disease/condition or a specific timeframe, which in turn rewards hospitals who provide high-quality care for a lower cost than the bundled payment.[8]

Physicians, especially primary care physicians, have previously been unwilling to take on the financial risk inherent in VBR models.[9] However, perhaps as a result of the pandemic, physicians are beginning to petition for this shift to value-based care as well. The COVID-19 pandemic has particularly devastated the healthcare services sector, as it caused a dramatic drop in FFS reimbursement even as expenses increased due to the higher costs of obtaining *personal protective equipment* (PPE) and the costs related to implementing

technology for those physicians seeking to provide telehealth services.[10] Further, both before and during the pandemic, physicians have been providing a greater number of non-billable services, such as monitoring chronic disease and coordinating the delivery of pharmaceuticals to patients.[11] Many primary care physicians are being forced to reconsider their financial viability in light of this public health emergency (especially those who did not already have telehealth capabilities);[12] the recognition that the subsequent closing of many of these practices could result in reduced healthcare access has led to significant pushback against this development, as well as against the lack of reimbursement sufficient to drive intended outcomes, as many industry stakeholders point to higher quality, more proactive, and more inclusive primary care as a means to slowing the rise of overall healthcare costs.[13]

An additional weakness in the healthcare delivery system exposed by this pandemic has been providers' dependency on elective procedures. This reliance is incentivized by FFS – providers earn more for performing more procedures and for over-treating patients.[14] However, since the start of the pandemic, elective procedures, which comprise the majority of hospital revenue, have plummeted, leading to serious financial issues for many providers.[15] While many elective procedures are essential,[16] others (despite bringing in significant revenue) have been found to be ineffective or even harmful for patients.[17] This overuse has created a considerable amount of waste resulting in substantial healthcare costs.[18] In fact, payors have stated that the money being saved from cancelled procedures exceeds the amount of funds being expended for the treatment of COVID-19 patients.[19]

In response to these issues, and the growing call for change, the *American Academy of Family Physicians* (AAFP) and *National Alliance of Healthcare Purchaser Coalitions* (National Alliance) announced on July 15, 2020, their creation of a partnership for the purpose of leveraging regional employer coalitions and physician networks to create a national prospective payment system for primary care.[20] This effort builds on the work of many business groups and alliances across the U.S., all of whom are committed to reorganizing primary care and transforming the U.S. healthcare system in order to maintain a healthy workforce and help their communities thrive.[21] The AAFP and National Alliance asserted that "*[t]he primary care system in the United States is collapsing*," pointing to causes such as long-standing underinvestment, poor financing structures, and overwhelming administrative work.[22] These organizations believe that prioritizing and properly funding "*comprehensive and continuous*" primary care will lead to better health outcomes and lower per-capita costs.[23] Under such a system, primary care physicians would have the resources needed to perform patient-centered care and provide patients with the requisite support through a core team of care coordinators, case managers, social workers; a centralized network pharmacy; and, programs to address social determinants of health.[24] Physician practices would also be able to invest in telehealth offerings and expand service lines to provide vital services to patients, both during the pandemic and thereafter.[25]

Private payors are also seeking solutions to ameliorate the shortcomings of FFS models in relation to primary care and independent medical practices. Blue Cross Blue Shield (BCBS) of Massachusetts announced in July 2020 the establishment of a new value-based payment model that extends financial support through "*global payment, upside risk incentives, and an immediate support payment*" to small practices.[26] Notably, BCBS of Massachusetts was the architect of the 2008 *Alternative Quality Contract* (under which providers were rewarded for quality), one of the first modern shifts to a VBR system.[27] While many physicians recognize the importance and potential of value-based care for their patients, it may be difficult to implement these changes without a payment structure that incentivizes these priorities.[28] The barriers of entry may be especially high for small practices, for whom caring for seriously ill patients is a significant cost burden.[29] BCBS's new program aims to change this.[30] The new upside-only risk model consists of three primary payment strategies:

(1) Providers are given a "*global*" fund based on their number of patients, which funds are detached from billing codes, for the provider to use at their discretion;

(2) Incentive payments for providers who achieve high scores on certain quality measures; and,

(3) Immediate support payments for providers who sign the VBR contract with BCBS.[31]

These two announcements are indicative of changing perspectives relating to reimbursement models, particularly as relates to independent primary care physicians. While the AAFP and National Alliance announcement, and creation of other such alliances across the U.S., indicates rapidly-growing support for systematic change, the BCBS announcement provides an example of a financially-feasible entry point for primary care providers (and other independent medical practices) into value-based care. The advantages to these innovative models are numerous: reduced spending for patients, payors, and the entire healthcare system; greater provider efficiency; higher patient satisfaction; reduced payor risk; supply prices aligned with real value to patients; and healthier communities overall.[32] However, it is not without risks or weaknesses – increased regulations may restrict providers' activities, and bundled payment or other shared savings programs may be difficult to implement and sustain, often requiring considerable initial investment from the provider in order to collect the data needed to report quality metrics.[33] Critics are also concerned about the establishment of appropriate historical benchmarks and changing expectations once healthcare costs start to decline.[34] While there may be some immediate drawbacks in the form of costs and implementation difficulties, the current healthcare environment has exposed the fact that the current healthcare reimbursement system has been one public health emergency away from a virtual collapse. Payors are adopting different strategies to combat this frailty and protect primary care providers, including innovative reimbursement strategies and programs to help providers secure funding.[35] Whatever the method, the consensus among industry stakeholders

appears clear: changes need to be made to prevent a critical physician manpower shortage resulting in significantly decreased access to care. More and more primary care physicians are committing to the VBR shift, and the formal alliances and reimbursement model initiatives have now begun to follow.

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2021 Physician Fee Schedule & Quality Payment Program Proposed Rules Released

[Excerpted from the article published in August 2020.]

On August 3, 2020, the *Centers for Medicare & Medicaid Services* (CMS) released two proposed payment rules for *calendar year* (CY) 2021: the *Medicare Physician Fee Schedule* (MPFS) and the *Quality Payment Program* (QPP). CMS included in the MPFS proposed rule adjustments to physician payment rates and an expansion of telemedicine services. The proposed QPP rule, meanwhile, takes into account adjustments made for the COVID-19 *public health emergency* (PHE) and seeks to reduce unnecessary regulatory burden on providers by eliminating some requirements. These rules, which have garnered mixed reactions from stakeholders, are both open for comment until October 5, 2020.[1]

MPFS Proposed Rule

Payment Rate Updates

The MPFS payment rate is being reduced for 2021, due to the proposed conversion factor. CMS proposes a 2021 conversion factor of $32.26, a 10.6% decrease from CY 2020's conversion factor of $36.09.[2] This reduction is due in part to several "*standard technical proposals involving practice expense, including the implementation of the third year of the market-based supply and equipment pricing update, and standard rate-setting refinements to update premium data involving malpractice expense and geographic practice cost indices*."[3]

The conversion factor was also reduced due to the statutorily-mandated budget neutrality adjustment. This adjustment, which accounts for changes in work relative value units (wRVUs) that are converted into payment rates, must remain budget neutral, which means that if some procedure codes are increased in value so that RVU expenditures differ by more than $20 million from 2020, other codes must consequently be reduced.[4] The wRVU changes emanate from the CY 2020 MPFS final rule that made several changes to the outpatient office-based *evaluation and management* (E/M) wRVUs. The effect of these upward adjustments to E/M RVU changes is that payment rates for other services were reduced, as exemplified in the table below:

Proposed MPFS Payment Rate Changes For CY 2021[5]

Physician Specialty	Percent Change from CY 2020
Anesthesiology	-8%
Cardiac Surgery	-9%
Family Practice	14%
Hematology/Oncology	14%
Interventional Radiology	-9%

Physician Specialty	Percent Change from CY 2020
Neurosurgery	-7%
Ophthalmology	-6%
Radiology	-11%
Thoracic Surgery	-8%
Vascular Surgery	-7%

Telemedicine Changes

In CMS's 2021 MPFS proposed rule, coverage for several telemedicine services was permanently implemented or temporarily expanded. Services such as E/M and some visits for patients with cognitive impairment are proposed to be permanently covered for telemedicine under Medicare.[6] CMS also seeks to extend payments for some telemedicine services, such as emergency department visits, only temporarily until the end of the CY when the COVID-19 PHE officially ends.[7] Nine telemedicine service codes will remain covered permanently under this proposed rule, 13 will remain covered temporarily, and 74 will be removed immediately after the PHE is ended.[8]

Other MPFS Proposed Changes

Other changes in the proposed rule include:

(1) Updates that better reflect services provided to patients with complex or chronic diseases, an area of growing need for Medicare beneficiaries and one whose importance has been emphasized by the COVID-19 pandemic;

(2) Permanent flexibility measures that would allow physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse-midwives to perform and supervise certain diagnostic tests; and,

(3) Easing selected billing and coding requirements for E/M visits, improvements which would save clinicians an estimated 2.3 million hours per year.[9]

Stakeholder Responses

In response to the MPFS proposed rule, a number of professional associations and industry trade groups criticized a number of CMS's proposals, but focused in particular on the budget neutrality adjustment. The *American Medical Association* (AMA) released a critical statement wherein it pointed out that the MPFS payment increases (particularly those related to E/M services) result in "*unsustainabl[e]*" offsets by effecting large payment reductions to other services.[10] The AMA urged Congress to waive the budget neutrality requirement, asserting that physicians have experienced extraordinary economic hardship during COVID-19 and cannot afford to subsequently undertake reduced payments.[11]

Similarly, the *American Association of Neurological Surgeons* (AANS) and *Congress of Neurological Surgeons* (CNS) issued a joint statement condemning the budget neutrality adjustment, which would result in neurosurgeons facing overall payment cuts of at least 7%.[12] The *American College of Surgeons* (ACS), *Surgical Care Coalition*, and *American College of Physicians* (ACP) also asserted suspending budget neutrality adjustments and asked Congress to waive these mandates.[13] Despite these and other concerns, many groups, including the AMA, the *American College of Obstetricians and Gynecologists* (ACOG), and the ACP also praised other aspects of the proposed rule, such as increased payments for office visits and reduced documentation requirements.[14]

QPP Proposed Rule

At the same time that it released the MPFS proposed rule, CMS also released the 2021 QPP proposed rule. Some of the notable changes, which are discussed further below, include updates to QPP performance categories, updates for *accountable care organizations* (ACOs), and delays to a quality reporting system set to be launched in 2021.

Proposed Updates to the Merit Based Incentive Payment System (MIPS)

MIPS is one of the two QPP programs in which providers may participate. For the 2021 performance year (PY), CMS proposes altering some of the performance categories, and the weights for those categories, as follows:

(1) Quality performance category – To be weighted at 40% (was previously 45%);

(2) Cost performance category – To be weighted at 20% (was previously 15%);

(3) Promoting Interoperability (PI) performance category – To be weighted at 25% (same as previous); and,

(4) Improvement Activities performance category – To be weighted at 15% (same as previous).[15]

These above changes are in accordance with statutory requirements that the Cost and Quality performance categories each be weighted at 30% by PY 2022.[16]

Additionally, MIPS Value Pathways (MVPs),[17] a new MIPS framework which was originally set to be implemented in 2021, is now set for release in 2022 at the earliest.[18]

Proposed Updates to the Medicare Shared Savings Program (MSSP)

For ACOs, CMS proposes streamlining reporting, and reducing unnecessary reporting, in a number of ways. First, CMS proposes retiring the current CMS Web Interface that ACOs use to report quality measures, and instead require ACOs to report through the *Alternative Payment Model* (APM) *Performance Pathway* (APP), a framework similar to MVPs.[19] This will allow MSSP ACOs to only report one set of data to satisfy requirements under both the MSSP and MIPS.[20] Second, CMS proposes eliminating the current APM scoring standard

and replacing it with the APP, which would introduce fixed measures for each performance category.[21] Third, CMS proposed significantly reducing the number of measures that MSSP ACOs must report. The number of reportable quality measures would be reduced from 23 to six, and the number of those measures that MSSP ACOs must actively report would be reduced from ten to three.[22]

Another proposed change was the threshold for the Quality performance standard – this percentile has been raised from the 30th percentile to the 40th, meaning that MSSP ACOs must score at or above the 40th percentile in all Quality performance category scores to qualify for shared savings.[23]

Stakeholder Responses

Stakeholders have voiced both praise and concern about the QPP rule as well. The ACP, for example, praised the broad relief from MIPS penalties in the 2021 proposed rule and COVID-19 allowances for providers.[24] Because of the proposed rule's strong focus on ACOs, the *National Association of ACOs* (NAACOS) released a comprehensive statement on both the MPFS and QPP proposed rules, stressing that the significant reporting system changes suggested in both of the proposed rules would lead to a "*considerable undertaking*" for ACOs (as those organizations would consequently have to change reporting mechanisms), especially during the PHE.[25] NAACOS appreciated the expansion of telemedicine coverage but urged stronger action on helping providers meet the considerably higher *qualifying participant* (QP) thresholds necessary to earn value-based care bonuses in 2021.[26] NAACOS asked Congress to assist in helping to further the transition to value-based care, especially in these difficult times.[27]

Conclusion

While not all changes proposed in the 2021 MPFS and QPP rules were taken well by stakeholders, many commended the rules' responses to the COVID-19 crisis in expanding telemedicine coverage and increasing payments for some healthcare services. Concerns related to decreased payments mostly stemmed from the Medicare budget neutrality mandate. Many professional associations and industry trade groups called for Congress to waive this mandate, citing the extraordinary financial burden from the COVID-19 pandemic that would only be exacerbated by some of these proposed changes, should the mandate remain in place. Comments are open for both until October 5, 2020.[28]

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CMS Includes Several Changes in OPPS Proposed Rule

[Excerpted from the article published in August 2020.]

On August 4, 2020, the *Centers for Medicare & Medicaid Services* (CMS) released the latest in a series of recently-published proposed rules, the *Outpatient Prospective Payment System* (OPPS) and *Ambulatory Surgical Center* (ASC) proposed rule for fiscal year (FY) 2021. This proposed rule builds upon executive orders such as "*Protecting and Improving Medicare for Our Nation's Seniors*," signed by President Trump in October 2019[1] and Trump Administration initiatives such as "*Patients Over Paperwork*."[2] In a press release, CMS highlighted the proposed rule's focus on increasing competition among providers to give patients more choice, lowering out-of-pocket surgery costs, increasing provider flexibility, and allowing patients to make more informed decisions about their care.[3] This year, achieving these ends may mean major changes to the current system, as evidenced by CMS proposals such as the elimination of the *inpatient only* (IPO) list, cutting payments for 340B pharmaceuticals, reducing taxpayer spending, and changing physician-owned hospital rules.[4]

Payment Rate Updates

For 2021, CMS proposes increasing OPPS payment rates by 2.6% for hospital outpatient departments (HOPDs) that meet the requisite quality criteria – this rate increase is calculated as the estimated inpatient market basket increase of 3.0% minus the *multifactor productivity* (MFP) adjustment of 0.4%.[5] For HOPDs that fail to meet quality requirements, CMS proposes implementing a 2% reduction in payments through the application of a 0.9805 factor (termed a "*reporting ratio*") to all payments and copayments.[6] CMS estimates that it will provide approximately $83.9 billion in total payment to OPPS providers in 2021, a $7.5 billion increase from 2020.[7]

ASC rates will also increase 2.6%, by way of the same calculation described above for OPPS rates, for a total of approximately $5.45 billion, a $160 million increase from 2020.[8]

Elimination of the Inpatient Only (IPO) List

CMS proposes two measures to increase patient choice and to potentially pass on savings to patients through lower out-of-pocket expenses. First, CMS would phase out the IPO list and the 1,740 services currently included in it.[9] The IPO list was first established in 2000 and is a list of treatments and procedures that are only allowed to be performed in an inpatient setting, to maintain quality and control over more complex procedures.[10] The proposed elimination of the IPO list is an acknowledgement by CMS of: (1) the many stakeholders that have long requested that a physician to be able to use their clinical judgement to determine where procedures should be performed; and, (2) medical and technological advances that now allow for many more procedures to be performed safely in an outpatient setting.[11] According to the proposed rule, the IPO list would be gradually phased out through 2024, beginning with the

removal of musculoskeletal services in 2021 (e.g., arthroplasties, osteotomies, replacements, revisions/reconstructions, fusions).[12] Removed procedures would be subject to the "*two-midnight rule*" for inpatient admission eligibility,[13] but would be exempt from medical review activities for two years.[14]

Addition to ASC Covered Procedures List

In addition to eliminating the IPO list, CMS proposes designating 12 codes as *permanently* office-based under the ASC *Covered Procedures List* (CPL), five of which were *temporarily* office-based in 2020 and seven of which would be newly designated as office-based.[15] Further, CMS proposes to continue 11 codes that were *temporarily* office-based in 2020 through 2021.[16] Two codes that were designated as *temporarily* office-based in 2020 are proposed to not be renewed as office-based in 2021.[17] Additionally, CMS proposes two options for expanding the ASC-CPL in future years: (1) modifying criteria for addition and allowing stakeholders to nominate procedures to be added to the CPL; or, (2) keeping general standard criteria while eliminating five general exclusion criteria.[18] CMS hopes that either of these options will allow the ASC-CPL to increase services offered and lower costs for patients.[19]

340B Program Cuts

CMS proposes further cutting reimbursement for drugs acquired under the 340B drug discount program. 340B allows hospitals that meet certain qualifications (e.g., specialized clinics, sole community hospitals, federally qualified health centers, and critical access hospitals[20]) to buy select outpatient drugs at or below cost.[21] The program was created to extend scarce resources, but has been criticized by officials from the *Department of Health and Human Services* (HHS) for the large profit margin it has created between what hospitals pay for those drugs and their reimbursement from Medicare.[22]

Just weeks before CMS published the OPPS proposed rule, the U.S. Court of Appeals for the District of Columbia settled a case against CMS and HHS, holding that the agencies were within their bounds to make 28.5% cuts in the 340B program in previous years' OPPS rules.[23] Seemingly heartened by the ruling, CMS now proposes cutting the program once again from an *average selling price* (ASP) of -22.5% to an ASP of -28.7%, resulting in lower reimbursements for 340B hospitals.[24] This percentage was calculated from a subtotal ASP of -34.7% plus a 6% add-on for overhead costs to reach an ASP of -28.7%, a number that is based partially on the results of Hospital Acquisition Cost Surveys.[25] As in previous years, CMS suggests that rural *Sole Community Hospitals* (SCHs), *prospective payment system*-exempt (PPS-exempt) cancer hospitals, and children's hospitals would all be exempt from this payment policy in 2021 and beyond.[26]

Quality Reporting Changes

In order to emphasize quality care and improve measurements, the CMS suggests several changes to quality reporting for HOPDs and ASCs in 2021.[27]

In its light revisions to both quality programs, CMS updates and refines language regarding reporting requirements and limiting compliance burden.[28] No measures were removed or added in the proposed rule.[29]

Hospital quality star ratings, by contrast, received numerous methodology updates, including simplifying calculations and reducing the number of measure groups.[30] Under the proposed rule, hospitals will have to report on at least three measures in three different groups, with one group being either *Mortality* or *Safety of Care*, in order to receive an overall star rating.[31] CMS hopes that these changes will reduce provider burden, allow ratings to be more predictable, and increase comparability between ratings.[32]

Prior Authorization

CMS will also expand its prior authorization requirement for HOPDs (whereby providers must submit an application to CMS explaining the medically necessary nature of the treatment before providing treatments to patients and submitting a claim for payment) to two new treatments (cervical fusion with disc removal and implanted spinal neurostimulators) in order to encourage the provision of only medically necessary care.[33] An October 2019 review from the *Journal of the American Medical Association* (JAMA) found that between $12.8 and $28.6 billion could be saved annually from eliminating overtreatment and low-value care.[34] CMS believes that prior authorization is an effective method for discouraging these two practices.[35]

Flexibilities for Physician-Owned Hospitals

Physician-owned hospitals may see more flexibility in 2021. The *Patient Protection and Affordable Care Act* (ACA) placed a moratorium on physician-owned hospitals, wherein those already in existence could not expand the number of operating rooms, procedure rooms, or beds in their facilities.[36] CMS proposes that physician-owned hospitals that are classified as "*high Medicaid facilities*," i.e., hospitals that serve more Medicaid beneficiaries than other hospitals in the area,[37] be allowed to apply for an expansion exception once every two years; no longer have a cap on the number of beds that can be approved in that exception; and, no longer be allowed to only expand those facilities located on the hospital's main campus.[38]

Stakeholder Reactions

Stakeholders expressed both praise of and concern for the changes in the 2021 OPPS proposed rule. *Ambulatory Surgery Center Association* (ASCA) CEO, Bill Prentice, acknowledged greater ASC use with future Medicare savings of billions of dollars, but said he "*remain[s] concerned that… [this proposal] does not take the needed step of addressing [the negative impact of weight scaling on ASC rates]*."[39] *American Hospital Association* (AHA) Executive Vice President, Tom Nickels, strongly criticized the proposed rule in general as a threat to hospital viability.[40] As regards the 340B program changes, he stated that the cuts "*decimate the intent of the 340B program*" and "*exacerbate the strain… on hospitals serving vulnerable communities*."[41] Nickels cited the

COVID-19 crisis in asserting that the proposed rule "*will result in the continued loss of resources for 340B hospitals*."[42] 340B Health, which represents over 1,400 hospitals, similarly stated that it was "*disappointed*" in this "*damaging payment policy… that hurts safety-net hospitals and their patients*."[43] Bruce Siegel, President and CEO of America's Essential Hospitals, similarly noted that the hospitals targeted by these cuts are the same ones "*straining under the heavy costs of responding to COVID-19*."[44] The cuts, he says, undermine "*program savings for hospitals that operate with little or no margin*" and will jeopardize "*access to care in underserved communities*."[45]

Nickels stated that the AHA also strongly opposes loosening restrictions on physician-owned hospitals, citing research that shows higher costs through physician self-referral.[46] He also expresses worry about the "*cherry-picking*" of profitable patients in these facilities, which could jeopardize the community's "*access to full-service care*."[47] The elimination of the IPO list was also a source of concern for the AHA, which asserted that many complex surgical procedures need the "*care and coordinated services provided in the inpatient setting*."[48]

Conclusion

The potential impact of the 2021 OPPS proposed rule has yet to be determined. CMS Administrator Seema Verma characterized the potential changes as an opening of options for patients so that they can make the best decisions possible along with physician guidance to help surgeries cost less for patients without lowering the quality of treatment.[49] However, as noted above, other stakeholders expressed strong concerns about the cuts to 340B and the elimination of the IPO list. Many believe that these changes would undermine protections put in place for at-risk hospitals that have been further hurt by the COVID-19 pandemic, and may lessen quality of care while increasing the burden of administration for hospitals.

The final rule is set to be released before the end of 2020, with comments due by October 5, 2020.[50]

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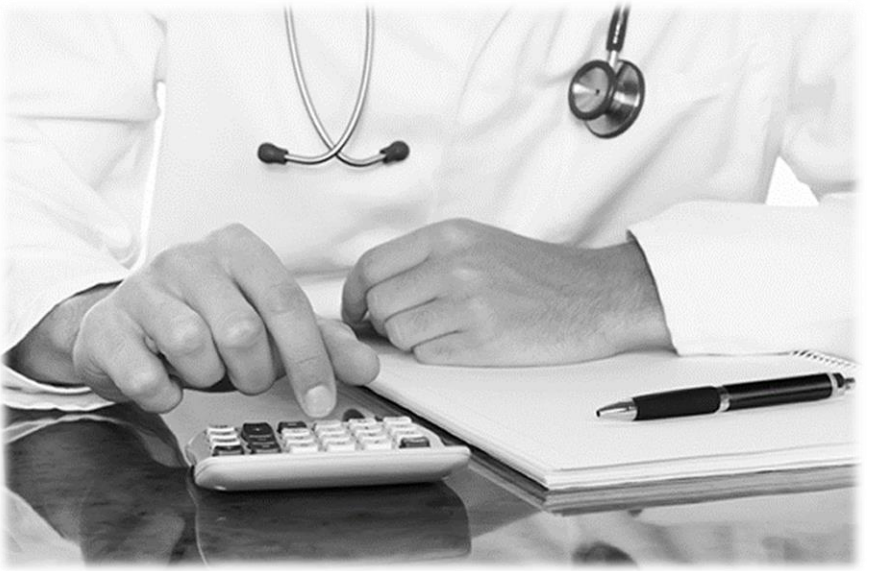

Final Rule Payment Changes Released for SNFs, Hospices, and IPFs

[Excerpted from the article published in August 2020.]

On July 31, 2020, the *Centers for Medicare & Medicaid Services* (CMS) released finalized Medicare payment rules for three types of providers: *skilled nursing facilities* (SNFs), hospices, and *inpatient psychiatric facilities* (IPFs).[1] While these *prospective payment system* (PPS) updates for *Fiscal Year* (FY) 2021, which go into effect on October 1, 2020, aim to better align payments among these three providers, CMS largely limited their rulemaking, in recognition of the "*significant impact of the COVID-19 public health emergency, and limited capacity of health care providers to review and provide comment on extensive proposals*."[2]

While this *Health Capital Topics* article will discuss each finalized payment rule separately, one change that is pervasive across all three updates is CMS's adoption of the revised statistical area delineations by the *Office of Management and Budget* (OMB). These statistical area delineations are used by these payment systems in calculating their respective wage indexes, based on whether a provider is in an urban or rural area.[3] CMS will adopt the most recent OMB delineations in FY 2021 to better define these areas and facilitate more accurate measurements.[4] To guard against any large decreases in reimbursement as a result of a reclassification, CMS has implemented a cap of 5% on any provider wage index decreases (as a result of the updated delineations) under these payment systems for FY 2021.[5]

SNF PPS Final Rule for 2021

The changes to the SNF PPS include a 2.2% increase in payment rates (based on a 2.2% market basket increase and no productivity adjustment), with total projected payments for FY 2021 totaling $750 million.[6] This adjustment works out to per diem federal rates as follows:

Final FY 2021 SNF PPS Unadjusted Federal Rates Per Diem[7]

Rate Component	Urban	Rural
Physical Therapy	$62.04	$70.72
Occupational Therapy	$57.75	$64.95
Speech-Language Pathology	$23.16	$29.18
Nursing	$108.16	$103.34
Non-Therapy Ancillaries	$81.60	$77.96
Non-Case Mix Adjusted	$96.85	$98.64

The 2.2% overall payment rate increase is less than both the FY 2020 increase of 2.4% and the FY 2021 proposed rule's anticipated increase of 2.7%.[8]

CMS also finalized several changes and additions to the *International Classification of Diseases, 10th Revision* (ICD-10), which will affect the SNF *Patient Driven Payment Model* (PDPM).[9] The PDPM is a new case-mix

classification system established in FY 2019, which utilizes ICD-10 codes in several ways, including assigning patients to clinical categories and adding in clinical categories for major procedures during prior inpatient stays that could impact the patient's plan of care.[10] Code changes made for FY 2021 include:

(1) Codes created within surgical default clinical categories where no surgery was performed; and,

(2) Codes added to existing ICD-10 categories to account for subsequent care.[11]

Lastly, minor changes to the *SNF Value-Based Purchasing* (VBP) program were finalized, but most policies and procedures remained consistent with FY 2020.[12]

Separately, CMS added provisions to help those SNF providers that are offering telehealth visit options for their patients. While CMS has not waived billing requirements during the COVID-19 pandemic, it has added new codes so that more telehealth services to Medicare beneficiaries can be reimbursed.[13] The newest code additions, which include telephone evaluation and physician management services, represent an ongoing expansion of telehealth codes by CMS to aid providers during (and possibly beyond) the pandemic.[14]

Hospice Payment System Final Rule for 2021

Similar to SNFs, hospice payment rates will increase 2.4% in FY 2021 (based on a 2.4% market basket increase and no productivity adjustment) – for a total of $540 million.[15] The hospice cap amount, which limits the total amount of payments made to a hospice in an annual period, will also increase 2.4% in FY 2021, to $30,683.93.[16] These payment increases are lower than the FY 2020 increase of 2.6%;[17] further, hospices who do not meet quality guidelines will only receive a 0.4% increase.[18] The final rates for hospices with satisfactory quality data are set forth below:

Final FY 2021 Hospice Medicare Reimbursement Rates[19]

Service	Daily Reimbursement Rate
Routine Home Care (≤ 60 Days)	$199.25
Routine Home Care (> 60 Days)	$157.49
Continuous Home Care	$1,432.41 ($59.68/hour)
Respite Care	$461.09
General Inpatient Care	$1,045.66

IPF PPS Final Rule for 2021

CMS adjusted IPF PPS payments for FY 2021 by 2.2% (based on a 2.2% market basket increase and no productivity adjustment),[20] for a total increase of $95 million.[21] This increase is less than FY 2019's 2.9% adjustment.[22] The federal per diem base rate for IPF was increased to $815.22 for those who report

quality data and to $799.27 for those who do not.[23] In addition, the IPF PPS final rule made the following changes:

(1) Payments changed for certain types of therapies;[24]

(2) Labor-related share increased 0.4% for FY 2021[25] compared to 2.1% in FY 2020;[26]

(3) Wage index budget neutrality factor set to 0.9989 in 2021,[27] lower than the 1.0026 factor in FY 2020;[28] and

(4) Fixed dollar loss threshold decreased by $330,[29] compared to an increase of over $2,000 in FY 2020.[30]

CMS also finalized measures that would allow IPF non-physician practitioners (e.g., physician assistants, nurse practitioners, psychologists, clinical nurse specialists) to operate within state scope of practice laws by documenting progress in the medical record of psychiatric hospital patients.[31] This corrects some previously inconsistent regulations related to this matter.[32]

The CMS changes to its SNF, hospice, and IPF payment systems for FY 2021 reflect many of the stakeholder criticisms, comments, concerns, and suggestions made during the comment period, but do not take into account the numerous issues highlighted by the current pandemic. CMS reflected on the uncertainty and unknowns associated with COVID-19 and discussed the particularly apparent economic repercussions throughout the healthcare industry from the pandemic and associated lockdown measures.[33] CMS cited several varying projections and a lack of certain types of data as their reasons for not permanently implementing many of the COVID-19 changes, adjustments, and allowances suggested by stakeholders in these final rules.[34] Instead, CMS opted to make several (relatively minimal) across-the-board changes, including increasing payment rates and implementing the newest OMB delineation data, with protections for those negatively impacted, leaving providers to wonder whether those issues highlighted by the current pandemic will be addressed independently, or at all.

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1 "CMS Updates Medicare Payment Policies for Several Types of Healthcare Providers" Centers for Medicare & Medicaid Services, July 31, 2020, https://www.cms.gov/newsroom/press-releases/cms-updates-medicare-payment-policies-several-types-healthcare-providers (Accessed 8/3/20).

2 *Ibid*; "Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Value-Based Purchasing Program for Federal Fiscal Year 2021" Federal Register Vol. 85, No. 151 (August 5, 2020) p. 47594; "Medicare Program; FY 2021 Hospice Wage Index and Payment Rate Update" Federal Register Vol. 85, No. 150 (August 4, 2020) p. 47070; "Medicare Program; FY 2021 Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) and Special Requirements for Psychiatric Hospitals for Fiscal Year Beginning October 1, 2020 (FY 2021)" Federal Register Vol. 85, No. 150 (August 4, 2020) p. 47042.

3 Federal Register Vol. 85, No. 151 (August 5, 2020) p. 47604.

4 *Ibid.*

5 *Ibid.*

6 *Ibid,* p. 47631.

7 *Ibid,* p. 47600.

8 "Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2020" Federal Register Vol. 84, No. 152 (August 7, 2019) p. 38732; "Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Value-Based Purchasing Program for Federal Fiscal Year 2021: Proposed rule" Federal Register Vol. 85, No. 73 (April 15, 2020), p. 20917.
9 Federal Register Vol. 85, No. 151 (August 5, 2020) p. 47619-47623.
10 *Ibid*, p. 47619-47620.
11 *Ibid*, p. 47619-47623.
12 *Ibid*, p. 47605.
13 "COVID-19: Coverage of Physician Telehealth Services Provided to SNF Residents" Centers for Medicare & Medicaid Services, July 31, 2020, https://www.cms.gov/files/document/2020-07-31-mlnc-se.pdf (Accessed 8/3/20)
14 *Ibid.*
15 Federal Register Vol. 85, No. 150 (August 4, 2020) p. 47094.
16 *Ibid*, p. 47086.
17 "Medicare Program; FY 2020 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements" Federal Register Vol. 84, No. 151 (August 6, 2019) p. 38484.
18 Federal Register Vol. 85, No. 150 (August 4, 2020) p. 47083.
19 *Ibid*, p. 47084.
20 Federal Register Vol. 85, No. 150 (August 4, 2020) p. 47045.
21 *Ibid*, p. 47065.
22 "Medicare Program; FY 2020 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2019 (FY 2020)" Federal Register Vol. 84, No. 151. (August 6, 2019) p. 38424.
23 Federal Register Vol. 85, No. 150 (August 4, 2020) p. 47043.
24 *Ibid*, p. 47043.
25 *Ibid*, p. 47043.
26 *Ibid*, p. 38424.
27 *Ibid*, p. 47043.
28 Federal Register Vol. 84, No. 151. (August 6, 2019) p. 38424.
29 Federal Register Vol. 85, No. 150 (August 4, 2020) p. 47043.
30 Federal Register Vol. 84, No. 151. (August 6, 2019) p. 38424.
31 Federal Register Vol. 85, No. 150 (August 4, 2020) p. 47063.
32 "Fiscal Year 2021 Final Medicare Payment and Policy Changes for Inpatient Psychiatric Facilities (CMS-1731-F)" Centers for Medicare & Medicaid Services, July 31, 2020, https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2021-final-medicare-payment-and-policy-changes-inpatient-psychiatric-facilities-cms-1731 (Accessed 8/12/20).
33 Federal Register Vol. 85, No. 151 (August 5, 2020); Federal Register Vol. 85, No. 150 (August 4, 2020).
34 *Ibid.*

III. REGULATORY TOPICS

11th Circuit Holds: No Remuneration for Fair Market Value

[Excerpted from the article published in September 2019.]

On July 31, 2019, the U.S. Court of Appeals for the Eleventh Circuit affirmed a lower court's decision, in favor of HCA (a publicly-traded healthcare services provider), to grant summary judgment on certain claims, and dismiss other claims, brought by Thomas Bingham, a real estate appraiser and "*serial relator*."[1] Bingham alleged that HCA provided "*sweetheart deals*" to physician tenants in connection with medical office building (MOB) projects in Missouri and Florida, through the provision of subsidies to developers, which developers in turn passed on to the physician tenants in the form of office improvements, low initial lease rates, cash-flow participation agreements, marketing, and restricted use waivers.[2] Bingham alleged that the benefits provided by the developers induced physician tenants to refer patients to HCA hospitals, which, Bingham alleged, violates the *Anti-Kickback Statute* (AKS), physician self-referral laws (the "*Stark Law*") , and the *False Claims Act*.[3]

Healthcare organizations face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. Fraud and abuse laws, specifically those related to the AKS and 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.[4] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[5]

Enforcement of the AKS and the Stark Law may occur under the *False Claims Act* (FCA), which creates liability for any person who "*knowingly presents, or causes to be presented, to an officer or employee of the United States government...a false or fraudulent claim for payment or approval.*"[6] The FCA has become an increasingly important statute in enforcing federal healthcare fraud and abuse laws, as it allows any private citizen to enforce the FCA by filing a complaint against a party alleging fraud against the federal government.[7]

In analyzing the *Bingham v. HCA* case on appeal, the Eleventh Circuit separately reviewed the Florida MOB allegations, which claimed FCA violations, and the Missouri MOB allegations, which claimed AKS and the Stark Law violations.[8] The appellate court affirmed the lower court's ruling on the Florida MOB FCA allegations on procedural grounds, but did note that Bingham did "*...not state with any particularity*," which is a requirement of FCA allegations, "*how HCA conveyed remuneration directly or indirectly to specific tenants of the [Florida] MOB*" and, instead, simply stated "*...in a*

conclusory fashion that...the total amount of the ground lease payment...was less than fair market value."[9]

Perhaps the greatest takeaway from the court's order was its language regarding the Missouri MOB allegations. In affirming the lower court's ruling on summary judgment, the Eleventh Circuit focused on the AKS claims, and, specifically, the definition of "*remuneration*." Because the AKS does not specifically define "*remuneration*", the court reviewed the term as defined in *Black's Law Dictionary* and in the *Civil Monetary Penalties* (CMP) law; the court pointed out that "*remuneration*" under the CMP law was defined, in part, as those "*items or services...for other than fair market value*."[10] Because, the court noted, "*[i]n a business transaction like those at issue in this case, the value of a benefit can only be quantified by reference to its fair market value*", it asserted that "*fair market value...is rather something Relator must address in order to show that HCA offered or paid remuneration to physician tenants*."[11] Therefore, the "*critical question*" to ask in examining Bingham's AKS allegations is "*whether physician tenants received anything of value from [the developer] under or in connection with their leases in excess of the fair market value of their lease payments*."[12] In answering this question, the court found that Bingham was unable to substantiate his claims that the rents and cash-flow participation agreements were not fair market value; in fact, HCA had two market rent studies conducted that found these arrangements to be within the range of fair market value.[13] Therefore, the court held that the "*Relator has not shown that HCA conveyed any remuneration to physician tenants...*"[14]

The discussion of remuneration by the Eleventh Circuit in this case may be used by future defendants to defend lease agreements (and other financial arrangements) that are alleged to be in violation of the AKS. Pursuant to the court's reasoning, the relators/government bear the burden of alleging and proving that the payments at issue are not fair market value. As one law firm noted "*The Bingham decision will thus likely be cited for the proposition that fair market value compensation is an absolute defense to an AKS allegation*."[15] This assertion underscores the importance of obtaining a certified opinion, prepared by an independent certified valuation professional and supported by adequate documentation, as to whether a proposed transaction is at fair market value, as it will significantly enhance the efforts of healthcare providers to establish a defensible position that a prospective financial arrangement is in compliance.

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1 "United States of America ex rel. Thomas Bingham v. HCA, Inc." Case No. 1:13-cv-23671-MGC (S.D. Fla. July 31, 2019), Judgment, p. 2-3; "A Hospital's Deserving Stark and AKS Victory—But At What Cost?" By Tony Maida, T. Reed Stephens, and Nicholas Alarif, McDermott Will & Emery, May 31, 2017, https://www.fcaupdate.com/2017/05/a-hospitals-deserving-stark-and-aks-victory-but-at-what-cost/ (Accessed 9/24/19).
Of note, this lawsuit is also not Bingham's first allegations relating to financial relationships between health systems and physician tenants. A June 2017 *Health Capital Topics* article entitled, "*Free Parking for Physicians? Federal Court Dismisses Whistleblower Suit*," discussed Bingham's case against BayCare Health System related to free parking access to

physician subtenants. The court in the suit held that amenities such as free parking for physicians may not be illegal remuneration if there is no evidence that those amenities are tied to the volume or value of referrals. "Free Parking for Physicians? Federal Court Dismisses Whistleblower Suit" Health Capital Topics, Vol. 10, Issue 6 (June 2017), https://www.healthcapital.com/hcc/newsletter/06_17/HTML/BVB/10.6_formatted_hc_topics_baycare_draft_6.30.php (Accessed 9/24/19).

2 "United States of America ex rel. Thomas Bingham v. HCA, Inc." Case No. 1:13-cv-23671-MGC (S.D. Fla. July 31, 2019), Judgment, p. 4.

3 *Ibid*, p. 8-14.

4 "Fundamentals of the Stark Law and Anti-Kickback Statute" By Asha B. Scielzo, American Health Lawyers Association, Fundamentals of Health Law: Washington, DC, November 2014, https://www.healthlawyers.org/Events/Programs/Materials/Documents/FHL14/scielzo_slides.pdf (Accessed 9/23/19), p. 4-6, 17, 19, 42.

5 *Ibid*, p. 42.

6 "False Claims" 31 U.S.C. § 3729(a).

7 "Civil Actions for False Claims" 31 U.S.C. § 3730(b).

8 "Bingham v. HCA" (S.D. Fla. July 31, 2019), Judgment, p. 8-20.

9 *Ibid*, p. 19.

10 *Ibid*, p. 9-10 (citing 42 U.S.C. § 1320a-7a(i)(6)).

11 *Ibid*, p. 10.

12 *Ibid*.

13 *Ibid*, p. 10-11.

14 *Ibid*.

15 "Remuneration? Not if It's Fair Market Value, Says Eleventh Circuit" By Amy Hooper Kearbey and Tony Maida, McDermott Will & Emery, September 17, 2019, https://www.mwe.com/insights/remuneration-not-if-its-fair-market-value-says-eleventh-circuit/ (Accessed 9/24/19).

Judge Strikes Down Site-Neutral Payments Rule

[Excerpted from the article published in September 2019.]

On September 17, 2019, U.S. District Court Judge Rosemary Collyer ruled in favor of the *American Hospital Association* (AHA) and other related healthcare organizations, and found that the *Centers for Medicare & Medicaid Services* (CMS) exceeded its statutory authority when it reduced payments for hospital outpatient services provided in off-campus provider-based departments grandfathered under the *Bipartisan Budget Act of 2015* (i.e., the site-neutral payments system).[1] Under the site-neutral payment system, which began in 2019, CMS capped the payments to hospitals for outpatient clinic visits at the same rate as physician office clinic visits.[2] CMS argued that the payment structure changes would lower copays for Medicare beneficiaries (decreasing the average copayment from $23 per visit to $9 by 2020 and saving $150 million per year in copays).[3] Further, the move was projected to cut $300 million in Medicare spending this year.[4] This new model was part of CMS's larger push to "*help lay the foundation for a patient-driven healthcare system*," and reorient the healthcare industry to be less industry-centric and more affordable for patients.[5] Prior to the 2019 change, CMS would pay more for the same type of clinic visit in the hospital outpatient setting than in the physician office setting.[6] The rule would have also been a big win for the *ambulatory surgical center* (ASC) industry, as it would have ensured that ASCs and *hospital outpatient departments* (HOPDs) receive comparable payments.[7]

Following the proposal by CMS, the AHA immediately pushed back against the rule change in a letter to the agency, stating that the proposed rule "*run[s] afoul of the law and rel[ies] on the most cursory of analyses and policy rationales. Taken together, they would have a chilling effect on beneficiary access to care and new technologies, while also dramatically increasing regulatory burden*."[8]

In December 2018, the AHA, joined by the *Association of American Medical Colleges* (AAMC) and several member hospitals, filed this lawsuit against the *U.S. Department of Health and Human Services* (HHS) over the policy to phase in reductions in payments for hospital outpatient clinic visit services furnished in off-campus provider-based departments.[9] The court ultimately sided with the AHA and AAMC, holding that:

> "*CMS believes it is paying millions of taxpayer dollars for patient services in hospital outpatient departments that could be provided at less expense in physician offices. CMS may be correct. But CMS was not authorized to ignore the statutory process for setting payment rates in the Outpatient Prospective Payment System and to lower payments only for certain services performed by certain providers*."[10]

Following the court's ruling, the associations issued a joint statement:

> "*We are pleased with the District Court's decision that the Department of Health and Human Services exceeded its statutory authority when it reduced payments for hospital outpatient services provided in grandfathered off-campus provider-based departments.*
>
> *The ruling, which will allow hospitals to maintain access to important services for patients and communities, affirmed that the cuts directly undercut the clear intent of Congress to protect hospital outpatient departments because of the many real and crucial differences between them and other sites of care. Now that the court has ruled, it is up to the agency to put forth remedies for impacted hospitals and the patients they serve*."[11]

CMS still has two options moving forward: to start over or to appeal. If CMS were to start over, it would not likely come until spring 2020, when the rulemaking cycle starts; it would then take another year for the agency to finalize it.[12] Alternatively, CMS may pursue an appeal of the decision based on the "*exhaustion*" argument and claim that the hospitals did not have to exhaust their administrative remedies.[13] The court did not order CMS to pay the challengers for payments that were withheld (as the court vacated the rule and left CMS to determine remedies[14]), but ordered the parties to submit a joint status report by October 1, 2019, to determine if additional briefing on remedies is required.[15]

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1 "AMERICAN HOSPITAL ASSOCIATION, et al., Plaintiffs, v. ALEX M. AZAR II, Sec'y of the Dep't of Health & Human Servs., Defendant., No. CV 18-2841 (RMC), 2019 WL 4451984, at *1 (D.D.C. Sept. 17, 2019).

2 "CMS Empowers Patients and Ensures Site-Neutral Payment in Proposed Rule" Centers for Medicare & Medicaid Services, July 25, 2018, https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider-Partnership-Email-Archive-Items/2018-07-25-eNews-SE.html (Accessed 9/20/19).

3 *Ibid.*

4 "Judge Tosses HHS Scheme Lowering Hospital Outpatient Payments" By Lydia Wheeler and Tony Pugh, Bloomberg Law, September 17, 2019, https://news.bloomberglaw.com/health-law-and-business/judge-tosses-hhs-scheme-lowering-hospital-outpatient-payments (Accessed 9/20/19).

5 CMS, July 25, 2018.

6 *Ibid.*

7 "42 CFR Parts 416 and 419" Department of Health and Human Services, July 31, 2018, https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-15958.pdf (Accessed 9/20/19).

8 "Re: CMS–1695–P, Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model; Proposed Rule (Vol. 83, No. 147), July 31, 2018." By Seema Verma, American Hospital Association, September 24, 2018, https://www.aha.org/system/files/2018-09/180924-comment-letter-cms-outpatient-pps-asc-proposed-rule-cy2019.pdf (Accessed 9/20/19).

9 "AHA, AAMC File Lawsuit Over Outpatient Payment Policy That Threatens Patient Access to Care" American Hospital Association, December 4, 2018, https://www.aha.org/press-releases/2018-12-04-aha-aamc-file-lawsuit-over-outpatient-payment-policy-threatens-patient (Accessed 9/20/19).
10 Sec'y of the Dep't of Health & Human Servs., (D.D.C. Sept. 17, 2019).
11 "JOINT STATEMENT ON OUTPATIENT PAYMENT POLICY COURT DECISION FROM AMERICAN HOSPITAL ASSOCIATION & ASSOCIATION OF AMERICAN MEDICAL COLLEGES" American Hospital Association, September 17,2019, https://www.aha.org/press-releases/2019-09-17-joint-statement-aha-and-aamc-outpatient-payment-policy-court-decision?utm_source=newsletter&utm_medium=email&utm_content=09182019%2Dat%2Dpub&utm_campaign=aha%2Dtoday (Accessed 9/20/19).
12 "Medicare Agency Can Start Over, Appeal Its Loss on Payment Cuts" By Lydia Wheeler and Tony Pugh, Bloomberg Law, September 19, 2019, https://www.bloomberglaw.com/product/health/document/X2IE2TD8000000?bna_news_filter=health-law-and-business&jcsearch=BNA%25200000016d4568d450a37d75ed6b2e0001#jcite (Accessed 9/20/19).
13 *Ibid.*
14 *Ibid.*
15 Sec'y of the Dep't of Health & Human Servs., (D.D.C. Sept. 17, 2019).

Proposed Stark Law Changes: Healthcare Valuation Implications

[Excerpted from the article published in October 2019.]

On October 9, 2019, the *Centers for Medicare & Medicaid Services* (CMS) issued a proposed rule to modernize and clarify the *Stark Law*.[1] The proposed rule changes were published in conjunction with the *Office of Inspector General* (OIG) of the *Department of Health and Human Services* (HHS), which published proposed rule changes to the *Anti-Kickback Statute* (AKS), and are part of the larger effort by HHS (of which CMS is part) to modernize and clarify fraud and abuse laws as part of the *Regulatory Sprint to Coordinated Care* initiative[2] and CMS's *Patients over Paperwork* initiative.[3] The initiatives are aimed at reducing regulatory barriers and accelerating the transformation of the healthcare system into one that better pays for value and promotes care coordination.[4] Recognizing the rapidly changing healthcare system, CMS is proposing new rules, and rule changes, that are more consistent with emerging *value-based* healthcare delivery and payment models, and which may allow for better coordination of care.[5]

These proposed rule changes have potentially significant implications, and may serve to create additional opportunities for healthcare valuation professionals, with CMS recognizing and confirming the close link between "*the regulated [healthcare] industry and its complementary parts, such as the health care valuation community...*"[6]

This *Health Capital Topics* article will summarize the Stark Law proposed rule in brief; discuss CMS's proposed changes to the definitions of *Fair Market Value* and *Commercial Reasonableness*; and, review the potential implications of these rule changes on healthcare valuation.

Stark Law Proposed Rule

The Stark Law governs those physicians (or their immediate family members) who have a financial relationship (i.e., an ownership investment interest or a compensation arrangement) with an entity, and prohibits those individuals from making Medicare referrals to those entities for the provision of *designated health services* (DHS).[7] Notably, the 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.[8]

The majority of the proposed changes to the Stark Law acknowledge the shift of healthcare reimbursement, from *volume-based* to *value-based* payment models.[9] Under the proposed rule, CMS seeks to establish new exceptions and new definitions, as well as provide additional flexibility to support this necessary evolution of the U.S. healthcare delivery and payment system.[10] Of note, the exceptions and definitions described herein apply only to the Stark Law; although OIG and CMS worked closely on their respective proposed rules, that guidance does not apply beyond the law at issue. For example, only the Stark Law addressed *fair market value* and *commercial reasonableness*;

consequently, those proposed definitions will not apply to agreements that are not subject to Stark.

Fair Market Value

The proposed revision of the *fair market value* definition seeks to clarify previous definitions and guidance on *fair market value*, and separate the term and definition from other intertwined terms, i.e., *general market value* and the *volume or value* standard. Historically, the Stark Law has defined *fair market value* generally (with additional modifications of the definition as applies to equipment leases and office space leases[11]), as follows:

> "*the value in arm's-length transactions, consistent with the general market value....Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals*."[12]

CMS proposes to provide three separate *fair market value* definitions: (1) generally; (2) for the rental of equipment; and, (3) for the rental of office space.[13] However, the agency emphasizes that "*the proposed structure of the definition merely reorganizes for clarity, but does not significantly differ from the [previous] statutory language...*"[14]

These three separate *fair market value* definitions are as follows:

(1) **General**: The value in an arm's-length transaction –
   (a) With like parties and under like circumstances;
   (b) Of like assets or services; and,
   (c) Consistent with the general market value of the subject transaction.

(2) **Rental of Equipment**: With respect to the rental of equipment, the value in an arm's-length transaction –
   (a) With like parties and under like circumstances;
   (b) Of rental property for general commercial purposes (not taking into account its intended use); and,
   (c) Consistent with the general market value of the subject transaction.

(3) **Rental of Office Space**: With respect to the rental of equipment, the value in an arm's-length transaction –
   (a) With like parties and under like circumstances;
   (b) Of rental property for general commercial purposes (not taking into account its intended use);
   (c) Without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee; and,

(d) Consistent with the general market value of the subject transaction.[15]

Of note, the revised definition of *fair market value* eliminates the connection to the *volume or value* standard.[16] CMS clarified that requirement that certain compensation arrangements "*not take into account the volume or value of referrals (or the volume or value of other business generated by the physician...)*" is "*separate and distinct*" from *fair market value* requirements.[17] Thus, CMS no longer believes it necessary to include the *volume or value* language (discussed separately below) as it appears in connection to the *fair market value* definition.[18]

In addition to the delineated definitions set forth above, CMS proposed a definition for *general market value*. Currently, the Stark Law requires that *fair market value* "*be consistent with the general market value*," and defines the term as:

> "*...the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement*."[19]

CMS proposed defining *general market value* separate and apart from *fair market value*, and, similar to fair market value, has different definitions depending on if it applies *generally* or to *rental of equipment or office space*,[20] as follows:

(1) **General**: "*the price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement*."[21] [Emphasis added.]

(2) **Rental of Equipment or Office Space**: "*the price that rental property would bring as the result of bona fide bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement*."[22] [Emphasis added.]

In reconciling the terms *fair market value* and *general market value*, CMS interpreted Congress's original intent behind general market value was "*to ensure that the fair market value of the remuneration...is generally consistent with the valuation that would result using accepted general market principles*."[23] In other words, CMS equates *general market value* with "*'market value,' the term uniformly used in the valuation industry*."[24] CMS states that their own research indicates that the valuation industry defines the term *market value* as "*the valuation of a planned transaction between two identified parties for identified assets or services, and intended to be consummated within a specified timeframe*,"[25] and notes that it "*is based solely on consideration of the*

economics of the subject transaction and should not include any consideration of other business the parties may have with one another."[26] CMS recognizes that the previous definition of *general market value* was "*likely at odds with general valuation principles*" and "*unconnected to the recognized valuation principle of "market value*," and states their intention that the new proposed definition is more "*consistent with the recognized principle of 'market' valuation*..."[27]

In further juxtaposing *fair market value* and *general market value* (a/k/a *market value*), CMS provided clear guidance on the relationship, as well as the interplay, between the two terms. Specifically, CMS views *fair market value* as relating to "*the value of an asset or service to hypothetical parties in a hypothetical transaction (that is, typical transactions for like assets or services, with like buyers and sellers, and under like circumstances)*" [emphasis added], while *general market value* relates to "*the value of an asset or service to the actual parties to a transaction*..."[28] To state it simply, *fair market value* regards hypothetical transactions of a similar type, while *general market value* is specific to a transaction with identified parties.

As noted above, the *fair market value* of the subject transaction must be "*consistent with the general market value*."[29] However, CMS significantly noted their understanding that the hypothetical *fair market value* and *general market value* of a transaction may not always be identical, and provided examples as to when a transaction may "*veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties to the subject...transaction*,"[30] to wit:

> "*...assume a hospital is engaged in negotiations to employ an orthopedic surgeon. Independent salary surveys indicate that compensation of $450,000 per year would be appropriate for an orthopedic surgeon in the geographic location of the hospital. However, the orthopedic surgeon with whom the hospital is negotiating is one of the top orthopedic surgeons in the entire country and is highly sought after by professional athletes with knee injuries due to his specialized techniques and success rate. Thus, although the employee compensation of a hypothetical orthopedic surgeon may be $450,000 per year, this particular physician commands a significantly higher salary and the general market value (or market value) of the transaction may, therefore, be well above $450,000...In this example, compensation substantially above $450,000 per year may be fair market value*."[31]

Commercially Reasonable

As regards the threshold of *commercial reasonableness*, CMS recognized that it has only addressed the concept once, in a 1998 proposed rule, interpreting the term "*commercially reasonable*" to mean an arrangement that appears to be

> "*...a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals*."[32]

In an effort to finally define the term, CMS proposed two alternative proposed definitions for the term *commercially reasonable*:

(1) "*the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements*"; or,

(2) "*the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty*."[33]

Simply stated, "*the key question to ask when determining whether an arrangement is commercially reasonable is...whether the arrangement makes sense as a means to accomplish the parties' goals*."[34] CMS also reiterates the agency's prior guidance that the determination of commercial reasonableness "*should be made from the perspective of the particular parties involved in the arrangement*."[35]

Significantly, CMS unequivocally noted that an arrangement may be *commercially reasonable* "*even if it does not result in profit for one or more of the parties*."[36] [Emphasis added.] CMS was compelled by commenters who identified a number of reasons why parties may enter into non-profitable transactions, e.g.:

(1) "*community need*;"

(2) "*timely access to health care services*;"

(3) "*fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA)*;"

(4) "*the provision of charity care*;" and,

(5) "*the improvement of quality and health outcomes*."[37]

Volume or Value Standard and the Other Business Generated Standard

Many Stark Law exceptions require that the compensation arrangement at issue "*not [be] determined in a manner that takes into account the volume or value of referrals by the physician...[or be] determined in a manner that takes into account other business generated between the parties*."[38] In response to commentator concerns, CMS proposed *"objective tests for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician*."[39]

CMS's proposed approach "*creates [a] bright-line rule*," such that "*only when the mathematical formula used to calculate the amount of the compensation **includes as a variable** referrals or other business generated, and the amount of the compensation **correlates** with the number or value of the physician's referrals to or the physician's generation of other business for the entity, is the compensation considered to take into account the volume or value of referrals or take into account the volume or value of other business generated*"[40] [Emphasis added.] This approach is manifested by four proposed "*special rules*" for compensation arrangements, two of which relate to the volume or value standard, and two of which relate to the other business generated standard.[41]

CMS also set forth "*the narrowly-defined circumstances under which [the agency] would consider fixed-rate compensation...to be determined in a manner that takes into account the volume or value of referrals or other business generated.*"[42] In other words, CMS would consider a fixed-rate compensation arrangement to violate the volume or value (or other business generated) standard if there was a "*predetermined, direct positive or negative correlation between the volume or value of the physician's prior referrals (or other business previously generated...) and the exact rate of compensation paid*."[43]

Perhaps the most significant statement made by CMS in this section was its discussion of these two standards in light of fraud and abuse cases, such as *United States ex rel. Drakeford v. Tuomey*, which have held that, within the context of inpatient and outpatient hospital services, any *ancillary service and technical component* (associated with a physician's professional services, i.e., a "*facility fee*") services performed in connection with personally performed services constituted an impermissible referral.[44] CMS reaffirmed its previous position that "*[w]ith respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services...are billed each time the employed physician personally performs a service*."[45] CMS then extended this guidance to personal service arrangements.[46]

New Stark Law Exceptions

In addition to these new definitions related to the Stark Law, CMS introduced a number of new exceptions to the Stark Law, the most pertinent of which are set forth below.

Value-Based Arrangements

The proposed rule would create permanent exceptions to the Stark Law for *value-based arrangements* (VBAs).[47] As part of the new exceptions, CMS introduced a number of new definitions, including those for value-based activity, VBA, value-based enterprise, value-based purpose, VBE participant, and target patient population.[48] The exceptions would only apply to compensation arrangements, but would apply to all patients, not just Medicare beneficiaries.[49] These exceptions are proposed in order to present lower (and

fewer) regulatory hurdles to providers seeking to pursue legitimate VBAs that are intended to coordinate care, improve the quality of care, and lower costs for patients.[50] Nevertheless, the proposed rule keeps in place some traditional protections against overutilization and associated harms.[51]

Significantly, CMS noted that remuneration under a VBA may not "*always involve one-to-one payments for items or services provided by a party to an arrangement*"; in fact, "*such payments are made...in consideration of the physician refraining from following his or her past patient care practices rather than for direct patient care items or services furnished by the physician*."[52] This comment recognizes that providers may sometimes be compensated for services not personally performed, or performed at all.

Also of note, CMS proposed *not* to require that remuneration associated with a VBA: (1) be consistent with *Fair Market Value*; or, (2) not take into account the volume or value of a physician's referrals or the other business generated by the physician for the entity, although the agency is soliciting comments on these points.[53]

Limited Remuneration to a Physician

CMS proposes a new exception for limited remuneration to a physician for items or services actually provided by the physician, on an "*infrequent or short-term basis*," in an aggregate amount not exceeding $3,500 per calendar year (as adjusted by inflation) if:

(1) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician;
(2) The compensation does not exceed the *Fair Market Value* of the items or services;
(3) The arrangement is *commercially reasonable*; and,
(4) Arrangements for the rental or use of office space or equipment do not violate the prohibitions on per-click and percentage-based compensation formulas.[54]

Of note, the remuneration does not need to be set in advance, and the arrangement does not need to be set forth in writing, in order to comply with this exception.[55]

Cybersecurity Exception

CMS also proposed the establishment of a new exception for donations of cybersecurity technology and related services that are "*necessary to implement, maintain, or reestablish security*."[56] For the exception to apply, a number of conditions must be met, including: (1) that the volume or value of referrals not be considered;[57] and, (2) the receipt of such technology may not be a condition of doing business with the donor.[58] CMS believes that the cybersecurity exception will be widely used by physicians because it helps address the growing threat of cyberattacks on data systems and health records.[59] CMS also proposed allowing for the donation of cybersecurity hardware, but only if that

hardware was determined to be "*reasonably necessary*" based on the donor's risk assessments of its organization, as well as of the potential donee.[60]

Price Transparency

In contrast to the above paragraphs, which discuss new exceptions, CMS did not make any proposals related to price transparency, but instead used the propose rule to solicit comments as to the pursuit of the Trump Administration's price transparency objectives[61] and whether to require *cost-of-care* information at the point of a referral for a healthcare item or service provided to patients.[62] The idea of requiring *cost-of-care* information is part of CMS's larger priority goal of *price transparency* aimed at lowering the rate of growth in healthcare costs and giving patients a better understanding of healthcare costs before embarking on a referral.[63] Any action ultimately undertaken by CMS to improve price transparency in healthcare services may have significant ramifications; according to the *Council of Economic Advisors 2019 Report*, 73% of the 100 highest-spending categories are considered to be *shoppable* by the patient (meaning that patients can schedule when they receive the services, and thus have an opportunity to price compare).[64] Should the price of healthcare items and services be easily accessible and comparable, this increased choice may serve to increase competition among providers, and apply price pressures on those healthcare organizations charging patients more for these items/services.

Implications

Historically, the application of the Stark Law (and the AKS) has, at times, been at odds with the goals of healthcare reform. Specifically, the discord between the objectives of fraud and abuse laws, and the objectives of value-based reimbursement models (e.g., VBAs) reflected the disjointed approach to healthcare reform by the numerous federal agencies tasked with regulation of the healthcare industry. For example, HHS and CMS have pushed value-based healthcare initiatives, which require provider alignment and collaboration, while the OIG and the *Department of Justice* (DOJ), have more intensely scrutinized these arrangements as they relate to the Stark Law and AKS, and their potential liability under the *False Claims Act*. Ultimately, this disjointed approach resulted in a scenario wherein the *left hand didn't know what the right hand was doing*.[65]

The proposed rule changes from CMS clearly aim to remedy this *Catch-22* situation, making it easier for providers to provide value-based care without running afoul of the Stark Law.[66] The agency has made significant strides in attempting to reduce the burden of compliance while also maintaining strong safeguards against fraud and abuse.[67]

At the same time, there remain a number of uncertainties related to the proposed rule. In some situations, numerous definitions or approaches are proposed, while, in other parts of the proposed rule, definitions seem to lack clarifying language regarding the terms used within the definitions. While CMS spends a considerable amount of verbiage defining *fair market value* (and *general*

market value), it appears that the ultimate implications of these changes may be minimal. These remaining issues render potential future ramifications of CMS's clarification indeterminate.

Perhaps the most significant takeaways from the proposed rule stem from CMS's acknowledgment that not all physicians, or compensation arrangements, are the same; and, that compensation arrangements may have qualitative benefits that outweigh quantitative costs, i.e., profitability. CMS's statement highlighting the difference between *fair market value* and *general market value* recognizes that an arrangement may have inherently *subjective, qualitative* elements, e.g., there are plausible scenarios that may require a valuation professional to deviate from industry normative benchmark data to account for the specific facts and circumstances related to a given transaction. This further demonstrates the need for valuation professionals in the healthcare industry who utilize an evidence-driven methodology that includes both *qualitative* and *quantitative* assessments of the specific facts and circumstances related to the transaction; document their consideration of these facts and circumstances; and, articulate their ultimate applicability to the transaction in support of their opinion.

HCC will continue to closely monitor and report, in future *Health Capital Topics*, the progression of these fraud and abuse law reforms, as well as the implications of these prospective changes on transactions involving healthcare enterprises, assets, and services.

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Proposed Anti-Kickback Statute Changes: Healthcare Valuation Implications

[Excerpted from the article published in October 2019.]

On October 9, 2019, the *Office of Inspector General* (OIG) of the *Department of Health and Human Services* (HHS) issued proposed rules to modernize and clarify the *Anti-Kickback Statute* (AKS).[1] The proposed rule changes were published in conjunction with the *Centers for Medicare & Medicaid Services* (CMS), which proposed rule changes to the *Stark Law*, and are part of the larger effort by HHS to modernize and clarify fraud and abuse laws as part of the *Regulatory Sprint to Coordinated Care* initiative[2] and CMS's *Patients over Paperwork* initiative.[3] The initiatives are aimed at reducing regulatory barriers and accelerating the transformation of the healthcare system into one that better pays for value and promotes care coordination.[4] Recognizing the rapidly changing healthcare system, CMS and OIG are proposing new rules, and rule changes, that are more consistent with emerging *value-based* healthcare delivery and payment models, and which may allow for better coordination of care.[5]

This *Health Capital Topics* article will summarize the AKS proposed rule, and review the new safe harbors proposed by HHS, as well as modifications to existing safe harbors.

The AKS "*provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration [directly or indirectly] to induce or reward the referral of business reimbursable under Federal health care programs*."[6] [Emphasis added.] AKS violations are punishable by up to five years in prison, criminal fines up to $25,000, or both.[7] Similar to the Stark Law, the AKS contains several *safe harbors*, which may shield an arrangement from regulatory liability if some or all of the requisite criteria is met.[8]

The OIG's proposed changes to the AKS are intended to promote coordinated care and foster improved quality, better health outcomes, and improved efficiency.[9] Among the more notable proposals related to the AKS include new safe harbors related to:

(1) *Value-Based Arrangements* – The OIG proposed three new safe harbors, aligned with those proposed by CMS (other than some formatting differences), for remuneration exchanged among participants in value-based arrangements that foster better coordinated and managed patient care:

   (a) Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency;

   (b) Value-Based Arrangements with Substantial Downside Financial Risk; and,

   (c) Value-Based Arrangements with Full Financial Risk.[10]

These safe harbors vary by the types of remuneration protected, the level of financial risk assumed by the parties, and the types of safeguards included as safe harbor conditions.

(2) *Patient Engagement* – The OIG proposed a new safe harbor for certain tools and supports (not gift cards, cash, or cash equivalents) furnished to patients to improve quality, health outcomes, and efficiency. Such items may include:

(a) Health-related technology patient health-related monitoring tools and services, such as smart watches and other wearable monitoring devices; and,

(b) Supports and services designed to identify and address a patient's social determinants of health.[11]

(3) *CMS-Sponsored Models* – The OIG proposed a new, standardized safe harbor for all payment models sponsored by CMS through the Innovation Center, negating the need for separate fraud and abuse waivers currently in place on an arrangement-by-arrangement basis.[12]

(4) *Cybersecurity Technology and Related Services* – The OIG proposed a new *safe harbor* protecting the donation of cybersecurity technology and services subject to five conditions, including that the agreement be set forth in writing and that the donation (or receipt thereof) does not directly take into account the volume or value of referrals or other business between the parties.[13]

Additionally, the OIG proposed modifying the following safe harbors currently in place:

(1) *Personal Services and Management Contracts and Outcomes-Based Payment Arrangements* – Modified to add more flexibility, e.g., by adding protections to certain outcomes-based payments.[14] Notably, OIG also proposed eliminating the requirement that aggregate compensation under these agreements be set in advance, instead requiring that the compensation *methodology* be set in advance; however, that methodology must be consistent with *Fair Market Value* and not be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties.[15]

(2) *Warranties* – Revises the definition of "*warranty*" and provides protection for bundled warranties for one or more items and related services.[16]

(3) *Local Transportation* – Expands mileage limits for rural areas and eliminates limits for patient transportation from the facility from which the patient is discharged to their home, as well as provides guidance related to ride-sharing services.[17]

(4) *Accountable Care Organization (ACO) Beneficiary Incentive Programs* – Codifies the statutory exception to the definition of

> "*remuneration*" as relates to ACO incentive payments to Medicare fee-for-service beneficiaries under the ACO Beneficiary Incentive Program, with some revisions.[18]

The proposed rule changes from the OIG, many of which changes are in alignment with those proposed by CMS in relation to the Stark Law, provide much greater certainty for healthcare providers participating in *value-based* arrangements and who are coordinating care for patients.[19] Additionally, the OIG attempted to ensure that, while reducing the burden of regulatory compliance, strong safeguards against fraud and abuse were maintained.[20]

As noted in the *Health Capital Topics* companion article in this month's issue related to the Stark Law proposed rule, the new and modified AKS safe harbors are applicable only to those arrangements that fall under the purview of the AKS, and, as noted by the agencies, OIG's AKS proposals may be more restrictive than CMS's due to the nature of the law, i.e., AKS is a criminal, intent based statute, and the Stark Law is a civil, strict liability law. Further, some AKS safe harbors (e.g., value based arrangements) differ from Stark Law exceptions. In both instances, healthcare providers will need to ensure compliance with either, or both, laws, depending on each law's applicability to the arrangement.

HCC will continue to closely monitor and report, in future *Health Capital Topics*, the progression of these fraud and abuse law reforms, as well as the implications of these prospective changes on transactions involving healthcare enterprises, assets, and services.

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Practice Loss Postulate Perpetuated by Third Circuit

[Excerpted from the article published in October 2019.]

A recent decision by the Third Circuit Court of Appeals reversed a lower court's decision; denied the motion to dismiss filed by the defendants, University of Pittsburgh Medical Center (UPMC) and its subsidiaries; and, ordered the *qui tam* action to proceed to the discovery phase of the lawsuit. This *Health Capital Topics* article will discuss the court's review and analysis of the compensation arrangements between UPMC and its neurosurgeons, and the potential implications of this case on healthcare providers.

Factual Background

UPMC is a large nonprofit healthcare system that owns a number of hospitals, medical practices, and other subsidiaries.[1] Three of the UPMC subsidiaries are also implicated in this case because they each employed one or more of the neurosurgeons who provided services to UPMC's hospitals beginning in 2006.[2] The compensation arrangements at issue were substantially similar in their methodology – each neurosurgeon had a base salary and a threshold number of work relative value units (wRVUs) that they were expected to achieve each year.[3] Should a neurosurgeon's annual productivity exceed that threshold, then UPMC paid the surgeon $45 per extra wRVU performed. On the other hand, if the surgeon did not achieve their threshold, their base salary for the subsequent year would be reduced.[4]

Judicial Analysis

In general, the court found that the relators' complaint sufficiently alleged the three elements of a Stark Law violation: (1) a referral of *designated health services* (DHS) by the neurosurgeons to the hospitals; (2) the existence of an indirect compensation arrangement (i.e., an unbroken chain of financial relationships connecting the surgeons with UPMC); and, (3) a Medicare claim for the referred service.[5] Further, the court ruled that the relators' complaint satisfied the three elements of a False Claims Act (FCA) violation: (1) "*the defendant presented or caused to be presented to an agent of the United States a claim for payment*"; (2) "*the claim was false or fraudulent*"; and, (3) "*the defendant knew the claim was false or fraudulent*."[6]

The appellate decision specifically addressed two questions:

(1) "*[W]ho bears the burden of pleading Stark Act exceptions under the False Claims Act?*" and,

(2) "*[D]o the relators offer enough facts to plausibly allege that the surgeons' pay varies with, or takes into account, their referrals?*"[7]

The court held that the answer to the first question is the defendants, asserting that the exceptions to the Stark Law function as affirmative decisions, which pleading burden resides with the defendant, i.e., UPMC.[8]

The majority of the court's opinion focused on answering the second question. In determining the answer, the court first examined whether the relators had sufficiently alleged that the surgeons' compensation varied with, or took into account, the volume and value of their referrals.[9] The court recognized the requirement that relators must show either *correlation* or *causation* between compensation and referrals, and dedicated a number of pages teasing out the difference between those two terms.[10] While this article will not focus on that (somewhat esoteric) discussion, suffice it to state that the court found that the relators sufficiently showed *both* correlation and causation (even though they were only required to show one).[11]

Second, the court examined whether the structure of the surgeons' contracts plausibly alleged correlation between their pay and referrals.[12] Of note, the court relied heavily on the reasoning in the 2013 4th Circuit case, *United States ex rel. Drakeford v. Tuomey*,[13] in finding that the relators sufficiently alleged that both the base salaries and the bonuses paid to the neurosurgeons varied with referrals.[14] The "*referrals*" made by the neurosurgeons, according to the court, constituted the surgeries or other procedures that the surgeons performed at a UPMC hospital, as the surgeons inherently referred the associated hospital claims (i.e., the *ancillary service and technical component* [ASTC]) that were provided and billed by the UPMC hospitals.[15]

Third, the court found that the neurosurgeons' suspiciously high compensation suggested causation, as "*[c]ompensation for personal services above the fair market value of those services can suggest that the compensation is really for referrals*."[16] In its reasoning on this point, the court relied upon five alleged facts that, "*viewed together, make plausible claims that the surgeons' pay exceeded their fair market value*":[17]

(1) "*[S]ome surgeons' pay exceeded their collections*" – The court found that "*at least three surgeons...were paid more than [UPMC] collected for their service*."[18] This is possibly due in part to the fact that UPMC allegedly "*credits surgeons with 100 percent of the [wRVUs] that they generate, even if [UPMC] cannot collect on all of them. So at least three surgeons (maybe more) were paid more than they [brought] in*."[19]

(2) "*[M]any surgeons' pay exceeded the 90th percentile of neurosurgeons nationwide*" – Some surgeons "*were sometimes paid two or three times more than the 90th percentile*"; in fact, one surgeon's 2011 bonus, by itself, "*exceeded the 90th percentile of total compensation in some surveys*."[20] It is worth noting, however, that the court did not identify the industry surveys to which they compared the UPMC surgeons' pay or productivity.

(3) "*[M]any generated [wRVUs] far above industry norms*" – "*[A]ll but one of the surgeons reported [wRVUs] above the 90th percentile in 2006 and 2007...A few even seemed 'super human,' racking up <u>two to three times</u> the 90th percentile*."[21] [Emphasis in original.]

(4) "*[T]he surgeons' bonus per [wRVU] exceeded what the defendants collected on most of those [wRVUs]*" – The neurosurgeons were paid a bonus of $45 per wRVU in excess of their wRVU threshold,[22] which is more than the Medicare reimbursement rate of approximately $35,[23] i.e., their bonuses exceeded the Medicare reimbursement rate. The majority reasoned that because "'*the majority of all claims submitted by [UPMC]...were submitted to federal health insurance programs such as Medicare and Medicaid'...we cannot assume that private payments [i.e., money from commercial insurers] suffice to make up the difference*," i.e., mitigate the difference between the bonus payment for and the Medicare reimbursement for each wRVU.[24] In other words, they claim, while paying bonuses that are more than the Medicare rate per wRVU is not enough by itself, more than 50% of UPMC's payor mix was comprised of Medicare and Medicaid, so it was improbable, if not impossible, for private insurance to have made up that difference such that UPMC was not incurring a loss in these bonus payments to the surgeons.

(5) "*[T]he government alleged in its settlement agreement that [UPMC] had fraudulently inflated the surgeons' [wRVUs]*" – The court focused on the fact that "*the Neurosurgery Department as a whole realized astounding 'annual growth rates of [wRVUs] of 20.3%, 57.1% and 20.0%' in 2007, 2008, and 2009*"[25] – in fact, "'*[t]wo of the surgeons more than doubled their output in just a few years" allegedly by "'artificially inflat[ing] the number of [wRVUs]...*'"[26] The majority also seemed to place great weight on the government's comments related to the part of this case that was settled. The government alleged a "*fudging [of] the numbers*" in its settlement agreement, asserting that surgeons claimed to have served as surgery assistants when they did not, and to have billed more expensive surgeries than they actually performed.[27] The court found the government's choice to intervene in part of the lawsuit, and its allegations in the settlement agreement, to be "*cause for suspicion*," rendering plausible claims sufficient to pass this stage of judicial scrutiny.[28]

Concurring Opinion

The concurring judge, although in agreement with the majority as to most of their legal conclusions, raised the practical concern that this ruling could open the floodgates of litigation. Specifically, he worried that the court is "*sending signals to hospitals throughout the Third Circuit, and the nation, that their routine business practices are somehow shady or suspicious and could leave them vulnerable to significant litigation*"[29]; that "*any hospital that pays its affiliated physicians according to some metric of the work they personally perform at the hospital falls under suspicion of violating the Stark Act...*"[30]; and, that "*top hospitals that offer doctors performance bonuses...could be sued and [be] forced to suffer through discovery or to settle.*"[31] In fact, "*many of the factors the majority points to as suspicious and indicating causation would*

likely be present in many cases where nothing untoward has occurred."[32] The judge then concluded that "*the only way to evade suspicion [of violating the Stark Act] altogether...would be to pay those doctors a flat annual salary – and a modest one at that*."[33] The majority's reply to this concern was that, pursuant to the *Granston Memorandum*, the federal government has the power to dismiss frivolous *qui tam* (a/k/a whistleblower) suits (over relators' objections) when warranted[34] – however, as noted by a national health law firm, this assurance "*affords the [healthcare] industry cold comfort in light of the fact that the government has exercised this authority in relatively few cases*."[35]

The concurring judge specifically took issue with the majority's focus on the wRVU bonus payments exceeding the Medicare reimbursement rate. The concurrence points out that the "*$45/wRVU rate is actually **below the national average** compensation per wRVU*."[36] [Emphasis added.] It follows, the judge reasons, that "*it is clear enough that $45 per wRVU is not aberrantly high*."[37]

Implications for Healthcare Providers

Despite the potentially significant implications of this case on hospitals, health systems, and physicians, it is important to note at the outset that the standard of review in this case was at the motion to dismiss stage (i.e., an early stage) of the lawsuit. At this stage, the standard of review is simply whether "*the complaint states a plausible claim to relief...[and p]lausible does not mean possible*."[38] As specifically relates to this case, does "*the complaint sufficiently allege[] referrals and a compensation arrangement*"?[39]

Notwithstanding the standard of review at this early stage of litigation, some of the court's reasoning within its opinion serves as an eye-opening, key development in the progression of the *Practice Loss Postulate* (PLP),[40] the concept that a financial arrangement that operates at a "*book financial loss*," is, in and of itself, dispositive evidence of a hospital's payment of consideration based on the volume and/or value of referrals.[41] The court's opinion specifically relied upon the 4th Circuit's reasoning in the *Tuomey* case, one of the first cases to rely on the PLP in its reasoning, and a milestone in a series of costly judgments and settlements against vertically integrated health systems for allegedly violating the Stark Law.[42] In *Tuomey*, a private, non-profit community hospital in South Carolina was found to have violated the Stark Law when it entered into more than fifteen employment agreements, all of which allegedly were designed to induce and maintain referral relationships.[43] Specifically, the relator alleged that Tuomey Healthcare System entered into compensation contracts with area physicians, conferring salary and benefits to those physicians in excess of the net collections received from their professional practices.[44] Tuomey would then bill Medicare for the ASTC associated with these physicians' professional services (i.e., a "*facility fee*"), because Tuomey provided the space, nurses, equipment, and other items required for the delivery of those services.[45] The court relied upon considered the testimony of the relator and the Department of Justice's expert witness, who, after the 4th Circuit issued its opinion, noted:

> "*Case documents I examined and the testimony I reviewed shows that Tuomey took into account the value and volume of anticipated physician referrals by…Acknowledging that the hospital's technical and facility fees earned each time the physicians performed an outpatient surgery are reasonable 'off-sets' for its $1.5 [million] annual operating losses. Notably because Tuomey's technical and facilities earned [sic] are deemed to be the physicians' patient referrals.*"[46] [Emphasis Added]

Similarly, in this case, a majority of three federal judges directly articulated judicial support for the validity of the inference that a "*financial hit*" or "*loss*" generated by a vertically integrated physician or physician practice may signal the payment of compensation, remuneration, and consideration to physicians as an inducement of legally impermissible referrals from physicians.[47]

Further, as noted by the concurring judge, such a threshold, i.e., wherein any amount paid to a physician must be less than he or she collected from Medicare in order to ensure legal permissibility, does not reflect the realities of the healthcare delivery system. As the concurrence stated, the bonus amount paid per wRVU was below the national average compensation per wRVU; thus, the court's reasoning on this topic indicates that hospitals with more challenging payor mixes (i.e., treating larger Medicare and/or Medicaid populations) cannot pay their physicians as much in compensation for fear of exceeding the Medicare reimbursement rate per wRVU, a significant potential detriment to hospitals seeking to recruit physicians to provide services to more indigent, older, and/or higher acuity patients (e.g., at safety-net hospitals and Disproportionate Share Hospitals (DSH)).[48] Further, the court fails to take into account for other realities within the healthcare delivery, such as the requirements of nonprofit hospitals that must fulfill their charitable mission, as well as hospitals that serve as trauma centers (which require staffing of certain specialties).

Conclusion

Despite the low pleading standard required to proceed past this stage of the lawsuit, the 3rd Circuit's opinion in this case is nevertheless a concerning continuation of the idea that an employment arrangement wherein an employed physician is compensated more than the employer hospital collects for the physician's component of a given procedure may be legally impermissible. As addressed by the concurring judge, such a low standard (although it may not survive the latter stages of litigation) may open the floodgates of litigation, and expose hospitals to additional costly lawsuits on which they must expend substantial resources in order to defend.

However, this ruling may be short lived, in light of the recently proposed changes to the Stark Law, wherein the *Centers for Medicare and Medicaid Services* (CMS) challenged some of these judicial reasoning, e.g., stating that "*a productivity bonus will not take into account the volume or value of the*

physician's referrals solely because corresponding hospital services...are billed each time the employed physician personally performs a service."[49] In fact, subsequent to the publication of this proposed rule, UPMC filed a *Petition for Panel Rehearing or Rehearing En Banc*, requesting that the case be reheard by the original four judges, or the entirety of the 3rd Circuit Court of Appeals, the reasoning for which request was based heavily on the proposed rule language.[50] Depending on the outcome of this ruling, the 3rd Circuit's original ruling will be overturned, or the case will be affirmed, and ordered to proceed to discovery. Hospitals, health systems, and physicians would be well-served to monitor the developments in this case, especially at the motion for summary judgment stage, wherein the court will likely reconsider these facts, but at a much higher standard of review.

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1 "United States of America ex rel. J. William Bookwalter, III, MD, et al. v. UPMC, et al." No. 18-1693 (3rd Cir. Sept. 17, 2019), p. 7.
2 *Ibid*, p. 7, 36.
3 *Ibid*, p. 7.
4 *Ibid*, p. 8.
5 *Ibid*, p. 14.
6 *Ibid*, p. 34 (citing "False Claims" 31 U.S.C. § 3729(a)(1)).
7 It is important to note that part of this original lawsuit was settled by UPMC and the Department of Justice in 2016, as relates to the claims for physician services; the government declined to intervene on the claims regarding the hospital services, which is the focus of this current action on appeal. *Ibid*, p. 6.
8 *Ibid.*
9 *Ibid*, p. 18.
10 *Ibid*, p. 18-22.
11 *Ibid*, p. 22.
12 *Ibid*, p. 3.
13 "United States ex rel. Drakeford v. Tuomey" 976 F. Supp. 2d 776 (D.S.C. 2013). For more information regarding this case, see "Increasing Scrutiny of Healthcare Fraud and Abuse Laws" Health Capital Topics, Vol. 7, Issue 2 (February 2014), https://www.healthcapital.com/hcc/newsletter/02_14/HTML/EMBOLDENING/7.2_emboldening_part_3_2.27.php (Accessed 10/21/19).
14 "United States of America ex rel. J. William Bookwalter, III, MD, et al. v. UPMC, et al." No. 18-1693 (3rd Cir. Sept. 17, 2019), p. 24-25.
15 *Ibid*, p. 15.
16 *Ibid*, p. 25.
17 *Ibid*, p. 27.
18 *Ibid.*
19 *Ibid.*
20 *Ibid*, p. 28.
21 *Ibid*.
22 *Ibid*, p. 29.
23 *Ibid*.
24 *Ibid.* (citing App. 193 ¶ 233).
25 *Ibid*, p. 30 (citing App. 171 ¶¶ 127-28).
26 *Ibid*, p. 30 (citing App. 171 ¶¶ 127-28).
27 *Ibid*, p. 30-31.
28 *Ibid*.
29 *Ibid*, concurring op., p. 2.
30 *Ibid*, concurring op., p. 11.
31 *Ibid*, p. 39.

32 *Ibid*, concurring op., p. 3.
33 *Ibid*, concurring op., p. 12.
34 "Memorandum: Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)" Michael D. Granston, U.S. Department of Justice, January 10, 2018, p. 1.
35 "Third Circuit Perpetuates Tuomey's Controversial Stark Law "Volume or Value" Standard" By Tony Maida, et al., McDermott Will & Emery, October 2, 2019, https://www.mwe.com/insights/third-circuit-perpetuates-tuomeys-controversial-stark-law-volume-or-value-standard/ (Accessed 10/18/19).
36 "United States of America ex rel. J. William Bookwalter, III, MD, et al. v. UPMC, et al," concurring op., p. 3 (citing Appellee's Brief, p. 49).
37 *Ibid*, concurring op., p. 3.
38 *Ibid*, p. 10.
39 *Ibid*, p. 14-15.
40 For more information on the PLP, see "Practice Loss Postulate (PLP) Regulatory Trend Misapplies Economic Theory to Healthcare Integration" Health Capital Topics, Vol. 9, Issue 6 (June 2016), https://www.healthcapital.com/hcc/newsletter/06_16/HTML/PHP/9.6_hc_topics_june_16_plp_abstract_6.22.php (Accessed 10/21/19).
41 *See, e.g.*, "United States ex rel. Drakeford v. Tuomey Healthcare System, Inc." 675 F.3d 394, 407 (4th Cir. 2012); "United States ex rel. Parikh v. Citizens Medical Center" Case No. 6:10-cv-00064, (S.D. TX. September 20, 2013), Memorandum and Order, p. 27-28; "United States ex rel. Reilly v. North Broward Hospital District, et al.," Case No. 10-60590-CV (S.D.Fla. September 11, 2012), Relator's Third Amended Complaint Under Federal False Claims Act, p. 31; "United States ex rel. Payne et al. v. Adventist Health System et al.," Case No. 3:12cv856-W (W.D.N.C. February 13, 2013), Relator's Amended Complaint, p. 56.
42 *See, e.g.*, "United States ex rel. Parikh v. Citizens Medical Center" Case No. 6:10-cv-00064, (S.D. TX. September 20, 2013), Memorandum and Order, p. 27-28; "United States ex rel. Reilly v. North Broward Hospital District, et al.," Case No. 10-60590-CV (S.D.Fla. September 11, 2012), Relator's Third Amended Complaint Under Federal False Claims Act, p. 31; "United States ex rel. Payne et al. v. Adventist Health System et al.," Case No. 3:12cv856-W (W.D.N.C. February 13, 2013), Relator's Amended Complaint, p. 56.
43 "United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc." 675 F.3d 394, 399 (4th Cir. 2012).
44 *Ibid*.
45 *Ibid*.
46 *Ibid*, Supplement to Expert and Rebuttal Reports, By Kathleen McNamara, p. 15.
47 "United States of America ex rel. J. William Bookwalter, III, MD, et al. v. UPMC, et al." No. 18-1693 (3rd Cir. Sept. 17, 2019), p. 29, 39.
48 *Ibid*, concurring op., p. 3 (citing Appellee's Brief, p. 49).
49 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55795. For more information on this topic, see the article entitled "Proposed Stark Law Changes: Healthcare Valuation Implications" in this month's issue of *Health Capital Topics*.
50 "Petition for Panel Rehearing or Rehearing En Banc" United States of America ex rel. J. William Bookwalter, III, MD, et al. v. UPMC, et al., No. 18-1693 (3rd Cir. October 15, 2019).

Trump Administration Brings Transparency to Healthcare

[Excerpted from the article published in November 2019.]

On November 15, 2019, the *Centers for Medicare & Medicaid Services* (CMS) finalized requirements that certain healthcare service and item prices be posted publicly by all hospitals in a "*consumer-friendly manner*."[1] This anticipated final rule stems from President Donald Trump's executive order to "*Improv[e] Price and Quality Transparency*",[2] and the Patient Protection and Affordable Care Act (ACA), which directed "*[e]ach hospital operating within the United States...[to] establish (and update) and make public...a list of the hospital's standard charges for items and services provided by the hospital...*"[3] This article will discuss the impetus for this latest policy push and review the most pertinent requirements of the final rule.

The *Rational Actor Theory* posits that rational consumers will choose, among a number of options, that option which maximizes their utility, based upon "*extensive information, a coherent preference ordering, and a commitment to the principles of self-interest...*"[4] For most consumer products and services in the U.S., the buyer (consumer) of those products and services is aware of the actual price, which allows them to competently assess their options and make an educated decision. However, the U.S. healthcare system does not operate under these principles, because prices for healthcare services are not typically known to the consumer (i.e., the patient). The consequences of this information asymmetry are numerous. First, patients often pay more out of pocket when they are not provided with price information sufficient to comparison shop.[5] Second, information asymmetry leads patients to accept medical care that is often unnecessary and to not seek the care that is necessary; this cycle of uninformed patients demanding unnecessary treatments due to a lack of information consequently leads to market failure.[6] While increasing healthcare choice and competition may provide a remedy to this market failure, the opaque nature of pricing in healthcare prevents consumers from being able to make an educated choice, which could subsequently enhance competition.

The Council of Economic Advisors estimates that 43% of healthcare services are "*shoppable*,"[7] wherein "*patients can schedule when they will receive care, compare and choose between multiple providers based on price and quality, and determine where they will receive services*."[8] Informing patients as to the price structure of their healthcare services could allow more patients to knowledgeably shop for their medical expenditures, which may subsequently drive down prices, foster high-value healthcare, and increase competition in the healthcare marketplace.[9] The hypothesis that price transparency may lead to positive market outcomes is substantiated by a study of New Hampshire's price transparency efforts, which found not only that patients who utilized the state's website comparison tool to compare medical imaging procedure prices paid less out of pocket, but also that the price transparency led to lower prices for *all* patients (even those who did not utilize the website).[10] This New Hampshire case study is corroborated by economic analysis which indicates that if

healthcare consumers have pricing information, providers face pressure to lower prices or provide better quality healthcare.[11]

CMS is seeking to act on the findings of these studies by making healthcare service prices transparent, and providing patients with the ability to competently comparison shop for their healthcare in order to increase healthcare quality and lower prices through open competition.

The hospital price transparency final rule compels all non-federally operated, licensed hospitals to publicly provide: (1) all standard charges and (2) negotiated charges and discounted cash prices for 300 "*shoppable*" services.

The first requirement directs hospitals to post their "*standard charges*," which includes:

(1) Gross Charges – "*the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts*";

(2) Payor-Specific Negotiated Charges – "*the charge that a hospital has negotiated with a third party payer for an item or service*";

(3) De-Identified Minimum Negotiated Charges – "*the lowest charge that a hospital has negotiated with all third party payers for an item or service*";

(4) De-Identified Maximum Negotiated Charges – "*the highest charge that a hospital has negotiated with all third party payers for an item or service*"; and,

(5) Discounted Cash Prices – "*the charge that applies to an individual who pays cash (or cash equivalent) for a hospital item or service*."[12]

These standard charges must be made available (and annually updated) in a machine-readable format.[13]

The second requirement directs hospitals to post online its (1) payor-specific negotiated charges; (2) discounted cash prices; (3) de-identified minimum negotiated charges; and, (4) de-identified maximum negotiated charges, for at least 300 "*shoppable*" services, defined as "*service[s] that can be scheduled by a healthcare consumer in advance*."[14] These services may comprise a "*package*" of services, such as professional and ancillary services (drugs, operating rooms, room and board, radiology, etc.).[15] Of these 300 services, 70 of the services are specifically identified and required by CMS to be posted; the other 230 services can be chosen by the hospital,[16] but CMS specifies that these services should be selected based on utilization (so that services commonly provided to the hospital's patient population will be represented).[17] CMS emphasizes throughout the final rule that the information posted by hospitals must be in a "*consumer-friendly*" format and easily searchable, in order to allow patients "*to make apples-to-apples comparisons of payer-specific negotiated charges across healthcare settings*."[18]

CMS estimates that the total burden for hospitals to compile and publish this information will be 150 hours, totaling $11,898.60, per hospital, in the first year.[19] The agency approximates the burden in subsequent years to be reduced

to 46 hours, totaling $3,610.88, per hospital.[20] Hospitals may be fined up to $300 per day if they do not comply with the rule.[21] In an acknowledgement of this burden on hospitals, CMS delayed the effective date of the final rule until January 2021.[22]

Subsequent to the issuance of the final rule, the *American Hospital Association* (AHA), *Association of American Medical Colleges* (AAMC), *Children's Hospital Association* (CHA) and *Federation of American Hospitals* (FAH) issued a joint statement claiming that the rule would "*introduce widespread confusion, accelerate anticompetitive behavior among health insurers, and stymie innovations in value-based care delivery.*"[23] Additionally, the organizations assert that the rule will not actually help patients understand out-of-pocket cost information and will instead confuse patients.[24] They conclude the joint statement by announcing their intent to file a legal challenge on the grounds that the rule "*exceeds the Administration's authority*."[25] The possible legal claims that the organizations may make in challenging the final rule may include infringement of hospitals' First Amendment rights and illegal interference in confidential and proprietary information. Additionally, the final rule may be susceptible to arguments that the agency has exceeded its regulatory authority.[26]

This latest regulatory development seeking to ease the rising costs of healthcare follows the Trump Administration's requirement earlier this year that drug makers include prices in their advertisements.[27] However, the pharmaceutical industry won a court ruling blocking the initiative, with the court finding that the rule exceeded the authority granted to the *Department of Health and Human Services* (HHS);[28] the agency is currently appealing the decision.[29] Whether the hospital industry will be as successful in the courts as the pharmaceutical industry remains to be seen. Nevertheless, the Trump Administration appears determined to increase transparency in healthcare costs.

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at the same price as good cars since it is impossible for a buyer to tell the difference...only the seller knows." "When Healthcare is a "Lemon": Asymmetric Information and Market Failure" By David W. Johnson, March 3, 2015, 4sightHealth, https://www.4sighthealth.com/when-healthcare-is-a-lemon-asymmetric-information-and-market-failure/ (Accessed 11/18/19) (finding that George Akerlof's "lemon" theory applies to healthcare markets due to a lack of information on the part of patients and health insurance companies (i.e., adverse selection)). For more information on the "lemon" theory, refer to: "The Market for "Lemons": Quality Uncertainty and the Market Mechanism" By George Akerlof, The Quarterly Journal of Economics, Vol. 84, No. 3 (August 1970), available at: https://www2.bc.edu/thomas-chemmanur/phdfincorp/MF891%20papers/Ackerlof%201970.pdf (Accessed 11/20/19).

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11 "Shopping For Price in Healthcare" By Paul B. Ginsburg, Health Affairs, Vol. 26, No. 2 (February 6, 2007), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.26.2.w208 (Accessed 11/21/19), p. w209.

12 "Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates; Price Transparency Requirements for Hospitals to Make Standard Charges Public" Health and Human Services Department, unpublished rule filed on 11/15/19, available at: https://www.federalregister.gov/documents/2019/11/27/2019-24931/medicare-and-medicaid-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and (Accessed 11/21/19), p. 73, 109, 118, 124.

13 *Ibid*, p. 126-127.

14 *Ibid*, p. 200-201

15 *Ibid*, p. 171-172.

16 *Ibid*, p. 313.

17 *Ibid*, p. 175.

18 *Ibid*, p. 6.; Centers for Medicare & Medicaid Services, November 15, 2019.

19 Health and Human Services Department, unpublished rule filed on 11/15/19, p. 6-7.

20 *Ibid*.

21 *Ibid*, p. 255-256.

22 *Ibid*, p. 240.

23 "Hospital and Health System Groups on Public Disclosure of Privately Negotiated Rates Final Rule" American Hospital Association, November 15, 2019, https://www.aha.org/press-releases/2019-11-15-joint-statement-national-hospital-and-health-system-groups-public (Accessed 11/18/19).

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25 *Ibid.*

26 CMS cites its regulatory authority as stemming from the Public Health Services Act, specifically Section 2718(e).

27 "HHS Finalizes Rule Requiring Manufacturers Disclose Drug Prices in TV Ads to Increase Drug Pricing Transparency" U.S. Department of Health & Human Services, May 8, 2019, https://www.hhs.gov/about/news/2019/05/08/hhs-finalizes-rule-requiring-manufacturers-disclose-drug-prices-in-tv-ads.html (Accessed 11/18/19).

28 "Merck & Co. v. United States Department of Health & Human Services" 385 F. Supp. 3d 81, 98 (D.D.C. 2019).

29 Merck & Co., Inc., et al. v. U.S. Department of Health and Human Services, et al., 2019 WL 5106949 (C.A.D.C.).

ACA Individual Mandate Ruled Unconstitutional

[Excerpted from the article published in December 2019.]

On December 19, 2019, the U.S. Court of Appeals for the Fifth Circuit ruled that the central provision of the *Patient Protection and Affordable Care Act* (ACA) – the *Individual Mandate* (requiring Americans to have health insurance) – is unconstitutional.[1] However, the court did not decide whether the unconstitutionality of the Individual Mandate invalidated the rest of the ACA; instead, the Fifth Circuit sent the case back to the district court for further review and determination of which ACA provisions could survive without the mandate.[2]

Judge Jennifer Elrod, writing for the Fifth Circuit majority, commenced the decision by remarking on the many policy arguments made before the court, both in favor and against, the highly controversial law.[3] However, the court clarifies that their decision addresses "*questions of law, not of policy*."[4] The court instead addressed the four pertinent questions before them:

> "*First, is there a live case or controversy before us even though the federal defendants have conceded many aspects of the dispute; and, relatedly, do the intervenor-defendant states and the U.S. House of Representatives have standing to appeal? Second, do the plaintiffs have standing? Third, if they do, is the individual mandate unconstitutional? Fourth, if it is, how much of the rest of the Act is inseverable from the individual mandate?*"[5]

As to the first question, the court concluded that there is a live case or controversy and the intervenor-defendant states have standing to appeal.[6] Second, the court found that the plaintiffs have standing to bring the challenge to the ACA.[7]

In answering the third question, the court held that when the U.S. Congress, through the *Tax Cuts and Jobs Act of 2017* (TCJA),[8] set the individual health insurance penalty (the tax that individuals had to pay if they did not comply with the Individual Mandate) to zero dollars,[9] it effectively rendered the Individual Mandate unconstitutional.[10] In its consideration of this question, the court reviewed one of the seminal ACA challenges, *National Federation of Independent Business (NFIB) v. Sebelius*. The 2012 Supreme Court case found in part that the Individual Mandate, while a violation of the Constitution's commerce clause, was a constitutional exercise of Congress's federal taxing power.[11]

Based on the Supreme Court's reasoning in the 2012 NFIB decision, the Fifth Circuit reasoned that the actions of Congress, wherein they essentially eliminated the penalty for not having health insurance (by virtue of making the penalty zero), do not allow the mandate to be construed as a tax any longer.[12] The Individual Mandate, without any monetary penalty, "*is only cognizable as a command*," thus rendering the mandate unconstitutional because "*there is no*

other constitutional provision that justifies this exercise of congressional power."[13]

The majority opinion criticized the lower court's severability analysis as flawed and incomplete due to the court's lack of consideration regarding the congressional intent behind the passage of the TCJA.[14] The Fifth Circuit also stated that there was not a proper explanation by the lower court as to why the newer provisions of the ACA are "*inextricably linked*" to the Individual Mandate.[15] Importantly, the court made no conclusive decision on whether any (or all) of the ACA can be severed from the Individual Mandate, stating:

> "*It may still be that none of the ACA is severable from the individual mandate, even after this inquiry is concluded. It may be that all of the ACA is severable from the individual mandate. It may also be that some of the ACA is severable from the individual mandate, and some is not*."[16]

The Fifth Circuit's instruction to the lower court to consider the congressional intent related to the TCJA is surprising, as previous Supreme Court decisions have lamented the "*nebulous inquiry into hypothetical congressional intent*."[17] However, the court found that the lower court's analysis needed to include congressional intent in 2010 (when the ACA was passed) and 2017 (when the Individual Mandate tax was eliminated) to be proper.[18]

Of note, Judge Carol King dissented from the majority, rebuking the standing of the suit to wit:

> "*Without any enforcement mechanism to speak of, questions about the legality of the individual "mandate" are purely academic, and people can purchase insurance—or not—as they please. No more need be said; it has long been settled that the federal courts deal in cases and controversies, not academic curiosities*."[19]

Over the past decade, the ACA has survived numerous attacks from congressional Republicans attempting to repeal the monumental (but controversial) legislation.[20] However, one of the largest impediments to the effectiveness of the ACA to date has been the elimination of the Individual Mandate penalty, which led to increases in the number of uninsured Americans.[21] The rate of uninsured Americans, for the second year in a row, increased by 500,000 people in 2018.[22] Nearly 28 million Americans remained uninsured, up by 1.2 million from the historic lows reached in 2016.[23] In addition to the elimination of the mandate, many Americans chose[24] not to purchase health insurance in 2018 due to large increases in premiums for the individual market.[25] These increases are largely due to the reinstatement of the health insurance tax (which is discussed further in another article in this month's issue regarding 2018 healthcare spending)[26] and the termination of federal cost-sharing reduction payments.[27] These factors, coupled with the limited expansion of Medicaid in many states, have led to increasing numbers of Americans remaining uninsured.[28]

For now, key popular provisions, such as the protection for those with pre-existing conditions, of the ACA remain preserved, although there is significant concern that this may not last.[29] The Fifth Circuit's ruling remands the law on the point of severability, meaning that the case returns to the same court that invalidated the entire law for further proceedings.[30] There are many potential conclusions with regard to severability – (1) one or more additional portions of ACA may be ruled unconstitutional; (2) all of the ACA is declared unconstitutional; or, (3) the rest of the ACA is found to be severable from the Individual Mandate, and remains in place.[31] The future of the ACA and health coverage for millions of Americans, and the timeline in which these questions are answered, remains to be seen.

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2 *Ibid*, p. 60.
3 *Ibid*, p. 2.
4 *Ibid.*
5 *Ibid*, p. 2-3.
6 *Ibid*, p. 3.
7 *Ibid*.
8 "BUDGET FISCAL YEAR, 2018 (a.k.a. Tax Cuts and Jobs Act of 2017)" Pub. L. No. 115-97, 131 Stat 2054 (December 22, 2017).
9 "Requirement to maintain minimum essential coverage" 26 U.S.C. § 5000A.
10 Case No. 19-10011 (5th Cir. Dec. 18, 2019), p. 3.
11 "National Federation of Independent Business v. Sebelius" 567 U.S. 519 (2012).
12 Case No. 19-10011 (5th Cir. Dec. 18, 2019), p. 3.
13 *Ibid*, p. 3, 44.
14 *Ibid*, p. 56-60.
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16 *Ibid*, p. 60.
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Hospitals Sue to Keep Prices Secret

[Excerpted from the article published in December 2019.]

On December 4, 2019, the nation's largest hospital groups united to commence a lawsuit against the Trump Administration related to the recently-finalized federal rule that requires hospitals to disclose negotiated prices starting in 2021.[1] The complaint was filed in U.S. District Court in Washington D.C. by the *American Hospital Association* (AHA), the *Federation of American Hospitals* (FAH), the *Association of American Medical Colleges* (AAMC), the *Children's Hospital Association*, and three hospitals in Nebraska, California, and Missouri.[2]

As discussed more fully in the November 2019 *Health Capital Topics* article entitled, "*Trump Administration Brings Transparency to Healthcare*," the *Centers for Medicare & Medicaid Services* (CMS) finalized requirements that certain healthcare service and item prices be posted publicly by all hospitals in a "*consumer-friendly manner*."[3] The rule requires hospitals to post online its (1) payor-specific negotiated charges; (2) discounted cash prices; (3) de-identified minimum negotiated charges; and, (4) de-identified maximum negotiated charges, for at least 300 "*shoppable*" services, defined as "*service[s] that can be scheduled by a healthcare consumer in advance*."[4]

The hospital plaintiffs first argue that the CMS rule violates the First Amendment by compelling speech. Second, they assert that the rule's requirements reach beyond both the *Patient Protection and Affordable Care Act* (ACA) mandate for transparency of standard charges and the statutory authority delegated by the ACA to CMS to carry out that mandate.[5] The groups claim it is "*obvious*" that:

> "*negotiated charges are not 'standard charges.' They are the opposite of standard, in fact, because they reflect the non-standard amount negotiated privately between a hospital and commercial health insurer*."[6]

The hospital groups assert that the "*rates negotiated between hospitals and commercial health insurers do not reliably predict the patient's out-of-pocket costs*," but lack any fundamental factual basis to bolster that assertion.[7]

The complaint also asserts claims of business confidentiality and the proprietary nature of negotiated prices as reasons for keeping the information secret.[8] The hospital groups state that the rule language would eliminate hospitals' "*ability to negotiate pricing with insurers at arms' length*."[9] Importantly, the hospital groups boldly assert that the disclosure of negotiated rates would "*undermine competition*."[10] At face value, this statement appears to be counterintuitive, but the hospital groups argue that competition would be would harmed because health insurers would not be incentivized to pursue innovative payment arrangements that could potentially lower costs and increase quality.[11] CMS's response to this argument will likely stem from its statements in the Final Rule, i.e., that part of the rationale for the rule is the

current trend of large employers utilizing price transparency to implement innovative approaches to healthcare payment.[12] Further, the hospital groups' claim that insurers would not be incentivized to increase quality is flawed in two ways: (1) health insurers already recognize the inherent need for better patient outcomes and healthier patients to sustain the health insurance business model, which incentives insurers to improve healthcare service quality;[13] and, (2) most reputable research on price transparency has shown a link between increased quality and the implementation of price transparency in healthcare.[14]

Third, the hospital groups asserted that the Final Rule is an arbitrary and capricious agency action:

> "*The Final Rule is arbitrary and capricious and lacks any rational basis. The agency's explanation for the Final Rule runs counter to both logic and evidence. In fact, it is belied by the agency's own research regarding what patients care about most from a pricing standpoint when selecting a hospital: their own out-of-pocket costs. The agency's justification for the Final Rule therefore does not stand up to even the barest of scrutiny. That is the epitome of arbitrary and capricious agency action.*"[15]

The groups are requesting an expedited decision in order to circumvent any preparations for the rule, which is expected to take effect in 2021.[16] The hospital groups cite concerns such as the significant personnel and financial resources that would be drained from other pressing healthcare needs.[17] The Final Rule estimated that the total burden for hospitals to review and post standard charges for the first year would be $11,898.60 per hospital.[18]

The strongest argument the plaintiff hospital groups make against the implementation of the Final Rule is that CMS has exceeded its statutory authority by broadly interpreting the meaning of "*standard charges*" in the hospital services context.[19] The hospitals rely on legal reasoning pointing to the meaning of the term as the hospital's usual or customary chargemaster charges.[20] The hospital groups cite *Webster County Memorial Hospital v. United Mine Works of America Welfare & Retirement Fund of 1950* and *Lefler v. United Healthcare of Utah, Inc.*, both of which cases clearly favor the hospital groups' more narrow interpretation of "*standard charges*" over the broader interpretation by CMS.[21]

The core of the Trump Administration's efforts to reduce healthcare costs for Americans lies in tackling rising hospital costs. Hospital inpatient prices have increased by 42% from 2007 to 2014,[22] and have now outpaced physician costs.[23] A recent *Health Affairs* study related to the increase in hospital prices concluded that healthcare spending reduction efforts should be "*primarily focused on addressing growth in hospital rather than physician prices*."[24] Seema Verma, the administrator for CMS, promoted the administration's efforts to increase price transparency in an op-ed published in *The Chicago Tribune*, wherein she states:

> "*The decadeslong [sic] norm of price obscurity is just fine for those who get to set the prices with little accountability and reap the profits, but that stale and broken status quo is bleeding patients dry. The price transparency delivered by these rules will put downward pressure on prices and restore patients to their rightful place at the center of American health care*."[25]

Verma titled her op-ed "*You wouldn't buy a car without knowing the price. So why are health care prices hidden?*"[26] It appears that the hospital groups have chosen to answer this question via the court system.

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3 "Trump Administration Brings Transparency to Healthcare" Health Capital Topics, Vol. 12, Issue 11 (November 2019), https://www.healthcapital.com/hcc/newsletter/11_19/HTML/CHARGE/convert_charge-disclosure_hc_topics_draft-11.21.19.php#_ednref14 (Accessed 12/16/19).
4 Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals To Make Standard Charges Public, Federal Register, Vol. 84, No. 229 (November 27, 2019), p. 65604.
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8 *Ibid*.
9 *Ibid*.
10 *Ibid*, p. 5.
11 *Ibid*, p. 4-5.
12 Finding self-insured employers are using price transparency in contracting. "Self-Insured Employers Are Using Price Transparency To Improve Contracting With Health Care Providers: The Indiana Experience" By Gloria Sachdev, Chapin White, Ge Bai, Health Affairs, October 7, 2019, https://www.healthaffairs.org/do/10.1377/hblog20191003.778513/full/ (Accessed 12/16/19); Federal Register, Vol. 84, No. 229 (November 27, 2019), p. 65550.
13 Finding the private health insurance plan sector has led the way in adopting strategies to improve the value of health care by using medical evidence to enhance both quality and affordability. "Leadership Commitments to Improve Value in Healthcare: Finding Common Ground: Workshop Summary" By John W. Rowe, LeighAnne Olsen, W. Alexander Goolsby, and J. Michael McGinnis, The Institute of Medicine of the National Academies, 2009, p. 273-274.
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15 Secretary of Health & Human Services, (D.D.C. December 4, 2019), p. 5.
16 *Ibid*, p. 6.
17 *Ibid*.
18 Federal Register, Vol. 84, No. 229 (November 27, 2019), p. 65525.

19 Secretary of Health & Human Services, (D.D.C. December 4, 2019), p. 16-18.
20 *Ibid*.
21 Differentiating between negotiated charges and standard charges. Webster Cty. Mem'l Hosp., Inc. v. United Mine Workers of Am. Welfare & Ret. Fund of 1950, 536 F.2d 419, 419–20 (D.C. Cir. 1976); Finding standard charges are discounted further to find negotiated charges for insurers. Lefler v. United Healthcare of Utah, Inc., 72 F. App'x 818, 821 (10th Cir. 2003); Secretary of Health & Human Services, (D.D.C. December 4, 2019), p. 17.
22 "Hospital Prices Grew Substantially Faster Than Physician Prices For Hospital-Based Care In 2007-14" By Zack Cooper, Stuart Craig, Martin Gaynor, Nir J. Harish, Harlan M. Krumholz, and John Van Reenen, Health Affairs, Vol. 38, No. 2 (February 2019), p. 184.
23 Finding hospital pricing and physician costs are not as intimately connected as previously though with hospital prices growing substantially faster than physician costs between 2007-2014. Cooper, Craig, Gaynor, Harish, Krumholz, Van Reenen, (February 2019), p. 184.
24 Cooper, Craig, Gaynor, Harish, Krumholz, Van Reenen, (February 2019), p. 184.
25 "Commentary: You wouldn't buy a car without knowing the price. So why are health care prices hidden?" By Seema Verma, The Chicago Tribune, December 3, 2019, https://www.chicagotribune.com/opinion/commentary/ct-opinion-health-care-prices-20191203-mpphzha4ofhwhftwid3od4mxoi-story.html (Accessed 12/7/19).
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Valuation Firms at Center of False Claims Act Lawsuit

[Excerpted from the article published in January 2020.]

On January 6, 2020, the *U.S. Department of Justice* (DOJ) intervened in a whistleblower *False Claims Act* (FCA) lawsuit premised on violations of the *Stark Law*.[1] Indianapolis-based *Community Health Network* (CHN), an integrated healthcare system,[2] is alleged to have violated the Stark Law by participating in above *fair market value* (FMV) compensation structures that were partly established on the referrals that the physicians made to the hospital system.[3] The complaint places at the focal point of the alleged violations of the Stark Law (and subsequent FCA violations) the involved valuation firms' statements to CHN, valuation techniques, and professional opinions to CHN.[4] This *Health Capital Topics* article will review CHN's allegedly illegal compensation arrangements with its specialists and its incentive compensation structure, as well as the role of the valuation firms in the fact pattern set forth by the government.

The Stark Law governs those physicians (or their immediate family members) who have a financial relationship (i.e., an ownership investment interest or a compensation arrangement) with an entity, and prohibits those individuals from making Medicare referrals to those entities for the provision of *designated health services* (DHS).[5] Notably, the 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.[6] Most of these exceptions require in part that compensation not exceed FMV.[7] In litigation, these exceptions often function as an affirmative defense(s) for the defendant.

Significantly, a violation of the Stark Law can trigger a violation of the FCA.[8] FCA imposes liability on any person who *knowingly* submits a false or fraudulent claim or uses false records to induce payment from the U.S. government.[9] The FCA also allows for private individual whistleblowers, called *qui tam relators*, to enforce FCA violations.[10] The government may seek to intervene in FCA *qui tam* cases.[11]

CHN is accused of recruiting and then paying breast surgeons, cardiovascular specialists, and neurosurgeons sizeable compensation amounts that often exceeded FMV.[12] The compensation amounts were intended to facilitate the integration of these providers into CHN's health network.[13] The complaint claims that the salaries provided to physicians were significantly higher than what the physicians were previously receiving when they operated as private practices;[14] for example, the complaint asserts that CHN employment compensation arrangements "*essentially doubled the salaries of all cardiovascular specialists*."[15]

The complaint places valuation firms at the forefront of the fact pattern. Upper-level management at CHN allegedly knew of the high compensation levels and was instructed to utilize professional valuation firms to obtain justification for

the payment amounts.[16] CHN is accused of having "*shopped around*" for favorable valuation opinions and then allegedly provided false information to the selected valuation firms in order to induce a favorable FMV opinion.[17] However, according to the complaint, the valuation firms routinely communicated to CHN that the majority of the compensation structures were far above FMV (describing the compensation structures as "*staggering*" and "*astounding*").[18]

The complaint purports that compensation and integration strategies were intended to prevent the "*leakage*" of referrals from physicians to competing hospitals.[19] One such example is CHN's 2009 breast cancer surgeon integration.[20] The complaint states that the integration was premised and financed from breast surgeon referrals for ancillary services.[21] The complaint quotes an internal document from CHN explaining that the compensation structure of the breast cancer surgeons would be partially based on the "*reimbursement differential*," i.e., the difference between what Medicare would pay the physicians for an ancillary service (such as imaging and radiation oncology) and what Medicare would pay the hospital.[22] In other words, the "*reimbursement differential*" is alleged to have been used to "*fund the integration and pay the physicians their salaries*."[23]

In describing the breast cancer surgeon integration, the complaint details the FMV analysis process.[24] The complaint quotes the valuation report in forming the basis of its allegations relating to the integration.[25] The valuation firm found the proposed physician compensation to be at the 97th percentile of industry market data, in the 84th percentile based on *work relative value units* (wRVUs), and in the 56th percentile based on a per collections ratio.[26] Ultimately, the valuation firm could only find CHN's proposed compensation to be reasonable for a one-year period.[27] Importantly, the FMV opinion was predicated on data provided to the valuation firm by CHN,[28] which data the complaint alleges was intentionally erroneous and contained ancillary and technical services, in addition to the personally performed professional services.[29]

The complaint asserts other violations of Stark Law, such as CHN's 2009 integration of cardiovascular specialists.[30] CHN allegedly paid 34 specialists at the 90th percentile of national industry market data.[31] The complaint directly quotes an internal communication between CHN's CFO and CEO purporting the central role that the cardiovascular testing referrals would play in "*funding the venture.*"[32] The internal communications paint the picture that CHN strongly considered (and based the compensation amounts on) the volume and value of the cardiovascular physicians' referrals when designing and implementing their compensation structures.[33] In fact, the 10% higher compensation rate for the cardiologists (over the vascular surgeons) is alleged to be based on the higher "*outpatient technical net revenues*," according to quoted internal documents. [34]

Similar to the breast surgeon integration transaction, the complaint looked to the role of the valuation firms in this cardiovascular integration. Quoting internal emails, the complaint asserts that the CHN upper-level management

specifically avoided certain valuation firms due to their perceived "*conservative*" valuation methodology, which might have resulted in an unfavorable opinion for CHN.[35] Valuation firm selection, according to internal emails quoted, appears to have been made on the basis of the firm's perceived leniency with a willingness to state that higher compensation amounts were FMV and whether they "*appear[ed] to have physician eligibility requirements for purposes of a physician qualifying for the 90th percentile*."[36] CHN allegedly engaged a valuation firm for a preliminary opinion on the basis of the valuation firm's perceived leniency, but apparently did not receive the opinion they sought.[37]

CHN then allegedly engaged a second valuation firm in hopes of receiving a favorable opinion; however, the second valuation firm stated in their draft analysis that "*This [compensation program] is well beyond any professional standard that [the valuation firm] would use for this assessment.*"[38] According to the second firm's valuation report, the compensation for at least 27 of the 34 cardiovascular specialists exceeded FMV under the firm's "*traditional analysis*."[39] However, the valuation report noted that the compensation may still be warranted on the basis of "*more lenient*" criteria, i.e., (1) satisfaction of certain "*business judgment factors*"[40] and (2) meeting certain (slightly higher) industry normative benchmark thresholds.[41] The valuation firm admitted that such criteria were "*outside the generally accepted standards*" and were to be applied only "*on an exception basis.*"[42] However, 23 of the 34 cardiovascular specialists still did not satisfy these additional, exceptional benchmark thresholds; therefore, the valuation firm did not analyze the "*business judgment factors*" of those proposed compensation arrangements.[43] The valuation opinion stated that "*the majority of the cardiologists and for all of the cardiovascular surgeons do not meet the criteria...as [a] measure of...FMV*."[44] Nevertheless, CHN's compensation committee allegedly approved the compensation plan despite (1) not receiving a favorable FMV opinion and (2) the stated concerns of the CHN Board of Directors that the salaries were excessive.[45]

Four years later, supposedly due to the concern from CHN's upper-level management regarding the high compensation levels, a third valuation firm was engaged to conduct a physician benchmarking analysis, which analysis found that the cardiovascular specialists' compensation was high and CHN was "*paying the physicians more per wRVU than what is being collected*."[46]

In addition to each of the compensation arrangements with specific specialists, the complaint asserts (on a more general level) that the incentive compensation structure of CHN was in violation of the Stark Law.[47] Part of the incentive compensation was allegedly conditioned on "*hospital downstream revenue specific to the physician*."[48] The complaint alleges that by "*conditioning incentive compensation on the physicians meeting a target of revenues from their referrals to CHN*," the incentive compensation structure took "*into account the volume or value of their referrals*."[49] Based on this presumption,

the complaint asserts that the incentive compensation structure violated the Stark Law.[50]

The allegations, if true, represent a clear pattern of compensation agreements being structured in accordance with "*downstream referrals*." The prominent role of valuation firms throughout the complaint exemplifies the important part that valuation firms play in ensuring compliance with federal and state fraud and abuse laws. Since the 2015 *Tuomey* case,[51] there has been increased pressure on healthcare organizations to justify their compensation arrangements according to FMV, a fact acknowledged by CHN according to the complaint.[52] The DOJ's complaint illustrates the importance of the documentation surrounding proposed compensation arrangements – not just the board minutes discussing the arrangements, and the valuation opinions submitted for the organization's consideration, but also the communications related to this documentation, which can be utilized to prove knowledge and scienter[53] by whistleblowers. Additionally, valuation firms must acknowledge the possibility that their reports and client communications may be used in litigation, while still maintaining the candidness and professionalism necessary for effective engagements and safeguarding the valuation professional's compliance with industry standards to reduce regulatory risk.

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1 "U.S. ex rel. Fischer v. Community Health Network, Inc., et al." Case No. 1:14-cv-1215 (S.D. Ind. January 6, 2020), United States' Complaint in Intervention, p. 1. Note that the government only intervened in part, and not in all of the allegations made by the whistleblower. "United States files False Claims Act complaint against Community Health Network" U.S. Department of Justice, January 7, 2020, https://www.justice.gov/usao-sdin/pr/united-states-files-false-claims-act-complaint-against-community-health-network (Accessed 1/13/20).

2 "About Community Health Network" Community Health Network, 2020, https://www.ecommunity.com/about (Accessed 1/14/20).

3 United States' Complaint in Intervention, p. 1.

4 *Ibid*, p. 15-30, 36-44, 46-54, 67.

5 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a).

6 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn.

7 *See* "Exceptions to the referral prohibition related to compensation arrangements" 42 C.F.R. § 411.357.

8 "False Claims" 31 U.S.C. § 3729.

9 *Ibid.*

10 "Civil actions for false claims" 31 U.S.C. § 3730.

11 *Ibid.*

12 Because the allegations regarding the neurosurgeons' compensation is so similar to those of the other specialists, this article will not discuss those arrangements. United States' Complaint in Intervention, p. 25-26.

13 United States' Complaint in Intervention, p. 17-20, 31-35, 51-53.

14 *Ibid*, p. 14.

15 *Ibid.*

16 *Ibid*, p. 15.

17 *Ibid*, p. 16.

18 *Ibid*, p. 15-16.

19 *Ibid*, p. 18.

20 *Ibid*, p. 17-31.

21 *Ibid*, p. 18.
22 There is a reimbursement differential for certain ancillary services because hospitals receive a higher reimbursement compared to physician practices for those services. "*Ibid*, p. 19.
23 This is significant because the Stark Law prohibits compensating hospital-based physicians for the referral of patients to ancillary services (e.g., diagnostic imaging), save for the personally performed professional component (if applicable). *Ibid*, p. 20.
24 *Ibid*, p. 25.
25 *Ibid.*
26 *Ibid*, p. 25-26.
27 *Ibid*, p. 25-27.
28 *Ibid*, p. 28.
29 *Ibid.*
30 *Ibid*, p. 33.
31 *Ibid.*
32 *Ibid*, p. 34.
33 *Ibid*, p. 35.
34 *Ibid.*
35 *Ibid*, p. 37.
36 *Ibid.*
37 *Ibid*, p. 39.
38 *Ibid*, p. 40.
39 This "traditional analysis," which is described more fully in the complaint, consisted of the following considerations: (1) total cash compensation (TCC) not in excess of the 75th percentile; and, (2) TCC per wRVU not in excess of the 60th percentile. *Ibid*, p. 41-42.
40 Such factors included: strategic importance of service line, community need, clinical outcomes achieved, financial performance of service line, recruitment or retention difficulties, individual accomplishments, leadership/business skills, grant dollars received, name recognition, individual training, historical compensation, offer letters from competitors, temporary compensation during physician shortages, and exceptional work effort. *Ibid*, p. 42-43.
41 These benchmark conditions (both of which had to be met) were: (1) TCC exceeding "the 75th percentile of the market, and clinical cash compensation to productivity ratios...between the 60th...and the 75th percentile of the market, particularly if based on wRVUS [sic], **and** non-clinical hourly pay rates...do not exceed the 75th percentile"; and, (2) "Total compensation exceeds the 7th percentile of the market due to benefit levels that are between the 50th...and the 75th percentile of the market." *Ibid*, p. 41-42.
42 *Ibid*, p. 42.
43 *Ibid*, p. 43.
44 *Ibid*, p. 44.
45 *Ibid*, p. 44-45.
46 *Ibid*, p. 48. This threshold is sometimes termed the "*Tuomey cap*." United States ex rel. Drakeford v. Tuomey Healthcare System, Inc, 92 F.3d 364 (4th Cir. 2015).
47 *Ibid*, p. 61-62.
48 *Ibid*, p. 62.
49 *Ibid*, p. 63.
50 *Ibid.*
51 United States ex rel. Drakeford v. Tuomey Healthcare System, Inc, 92 F.3d 364 (4th Cir. 2015). The government successfully alleged that the healthcare system had physician compensation agreements in excess of FMV, which resulted in a large payout by the hospital.
52 United States' Complaint in Intervention, p. 49.
53 Scienter is a legal term of art defined as "a mental state in fraud (as securities fraud) that is characterized by an intent to deceive, manipulate, or defraud." "Scienter" Merriam-Webster, https://www.merriam-webster.com/legal/scienter (Accessed 1/23/20).

DOJ Recovers Over $3 Billion in False Claims Act Cases

[Excerpted from the article published in March 2020.]

On January 9, 2020, the *U.S. Department of Justice* (DOJ) announced their recovery of more than $3 billion in settlements and judgments from civil cases involving fraud and false claims for *fiscal year* (FY) 2019.[1] Approximately $2.6 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.[2] This figure is slightly higher than healthcare-related recoveries during FY 2018, which totaled over $2.5 billion.[3] Settlements received from the healthcare industry (over 85% of the total recovery amount) far outstripped the $252.2 million recovered from defense contractor companies and the $196.8 million obtained from other industries such as banking.[4] In addition to the $2.6 billion recovered for federal losses, the DOJ also recovered millions of dollars for state and Medicaid programs for FY 2019.[5]

As seen in years past, the largest healthcare recoveries were obtained from the drug and medical device industry. Two of the largest settlements within the healthcare industry, in 2019, involved opioid manufacturers. According to the DOJ's press release, these recoveries reflect "*the department's commitment to holding drug companies accountable for their role in the opioid crisis.*"[6] One recovery involved multinational consumer goods manufacturer, Reckitt Benckiser Group paid $1.4 billion to settle civil and potential criminal liability pertaining to the marketing of their opioid addiction treatment drug, Suboxone.[7] The drug, designed to reduce withdrawal symptoms while users receive addiction treatment, and its active ingredient buprenorphine are "*powerful and addictive opioids*."[8] This settlement is the largest recovery in a case pertaining to opioid drugs and is one of the five largest healthcare settlements of the past decade.[9]

Additional legal action was brought by the DOJ against other drug manufacturers. In 2019, seven pharmaceutical manufacturers paid a total of $624 million in settlements. These manufacturers, including Actelion Pharmaceuticals US Inc., Amgen Inc., Astellas Pharma US Inc., Alexion Pharmaceuticals, Inc., Jazz Pharmaceuticals, Inc., Lundbeck LLC, and US Worldmeds LLC, paid to settle allegations of paying patient copays for their company's drugs through seemingly independent charitable foundations – a violation of the Anti-Kickback Statute.[10]

The DOJ also pursued cases involving several other sectors within the healthcare industry during FY 2019, including private physician practices, health systems, laboratory service providers, and medical supplies and technology companies, resulting in large recoupments.[11] The most noteworthy of these actions included the $48 million recovery received from Encompass Health Corporation (f/k/a HealthSouth Corporation), the largest inpatient rehabilitation facility (IRF) operator in the U.S., to settle allegations of Medicare fraud.[12] The IRF operator allegedly provided misinformation to

Medicare in order to receive a higher reimbursement rate and admitted some patients to its IRFs unnecessarily.[13] This settlement comes only a decade after the company, under its former name HealthSouth Corporation, paid a $325 million settlement under the *False Claims Act* (FCA) for fraudulent Medicare billing in 2009.[14]

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").[15]

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.[16] Since 1986, recoveries made under civil FCA suits total more than $62 billion.[17] Over the past five years, there has been a significant number of FCA suits brought on by both *whistleblowers* (also known as *qui tam* lawsuits) and the DOJ, with 636 qui tam cases and 146 non qui tam cases initiated in FY 2019 alone (both of which numbers are substantially similar to FY 2018 figures).[18] Despite the Trump Administration's actions to deregulate the healthcare industry during the past three years, the number of new cases enforcing healthcare fraud and abuse laws in 2019 appears to be on par with figures from previous years,[19] suggesting that FCA enforcement will remain high going forward.

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Piedmont Pays $16 Million to Settle Kickback and Overbilling Allegations

[Excerpted from the article published in July 2020.]

On June 25, 2020 Atlanta's *Piedmont Healthcare, Inc.* agreed to pay $16 million to the federal government to resolve two *False Claims Act* (FCA) allegations of kickbacks and overbilling.[1] The relator, a former Piedmont physician, alleged *Stark Law* and *Anti-Kickback Statute* (and subsequent FCA) violations of paying an amount that was above *fair market value* (FMV) and commercially unreasonable in Piedmont's 2007 acquisition of *Atlanta Cardiology Group* (ACG).[2] Additionally, Piedmont's payments settle allegations that the hospital admitted patients without medical necessity in order to bill Medicare and Medicaid for inpatient procedures that were recommended to be performed at the less expensive outpatient or observation settings.[3]

The FCA imposes civil monetary penalties in an amount between $5,000 to $10,000 per claim, as well as treble damages, upon any individual who knowingly submits a false or fraudulent claim to, or uses false records to induce payment from, the U.S. government.[4] 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.[5]

A violation of the FCA can be triggered by violations of the Stark Law and/or Anti-Kickback Statute.[6] The Stark Law governs those physicians (or their immediate family members) who have a financial relationship (i.e., an ownership interest, investment interest, or compensation arrangement) with an entity, and prohibits those individuals from making Medicare referrals to those entities for the provision of *designated health services* (DHS), unless the referral is protected by one or more of the numerous exceptions delineated by the statute.[7] Notable to the allegations against Piedmont, *group practice arrangements with a hospital* is one of the financial relationships protected by the Stark Law exceptions.[8] However, this exception requires that compensation for such an arrangement: (1) be consistent with FMV; (2) be *commercially reasonable*; and, (3) not *take into account the value or volume of any referrals* provided by the group-practice physicians.[9]

The lawsuit alleges that Piedmont paid an above-FMV and commercially unreasonable amount for the acquisition of ACG and an affiliated, ACG-physician-owned, cardiac cath lab, *CSA of Atlanta*.[10] At the time of acquisition, ACG was the largest cardiologist group in Georgia and was affiliated with Atlanta's *Saint Joseph's Hospital*.[11] Upon acquisition, ACG severed ties with Saint Joseph's and 32 of ACG's 34 physicians became employed by Piedmont.[12] Per the terms of the acquisition, Piedmont paid over $15 million for the acquisition of ACG and its affiliated cath lab and agreed to compensate each of the employed physicians a salary of $750,000 per year (plus productivity bonuses) for five years.[13]

To support their claims of Stark Law violations, the relator alleged that the over $15 million paid for the acquisition of ACG was an inflated and excessive amount.[14] Similarly, the complaint alleges that the agreed-upon salary for the ACG physicians was above FMV, as evidenced by compensation packages that were: (1) greater than the total dollar value of service performed; (2) hundreds of thousands of dollars greater than those received by similarly-skilled physicians employed in the months following the ACG acquisition; and (3) not reflective of their productivity when compared to high-performing physicians in their practices.[15] The complaint claims that the payments (comprised of salary and productivity bonuses) made to ACG cardiologists, interventional cardiologists, vascular surgeons, cardiac surgeons, and thoracic surgeons, in nearly all cases, exceeded the dollar value of the performed physician services before or after acquisition.[16] Additionally, in approximately nine months following the ACG acquisition, Piedmont acquired cardiology groups *Cardiology of Georgia* and *Cardiac Disease Specialists*.[17] The complaint alleges that 35 of the 37 physicians employed as a result of the additional group acquisitions were paid salaries "*hundreds of thousands of dollars less than the ACG physicians for comparable skills and services*" as a result of the inflated ACG-physician compensation agreements.[18] The relator asserts that the ACG physicians' compensation packages were not a result of higher levels of productivity, claiming that many of the highly compensated physicians' *relative value units* (RVUs) were repeatedly 40% to 60% less than their high-performing colleagues.[19]

Piedmont allegedly structured the terms of the ACG acquisition so that in exchange for above-FMV compensation, ACG physicians would be incentivized to refer patients for medically unnecessary, inpatient, interventional diagnostic and therapeutic cardiac and vascular procedures at Piedmont Hospital and Piedmont's cath lab, violating the Anti-Kickback Statute.[20] The payment of these kickbacks is related to the second FCA allegation resolved by Piedmont's settlement, i.e., that Piedmont billed Medicare and Medicaid for medically unnecessary hospital admissions so that procedures could be reimbursed at the more expensive, inpatient level of care.[21] The complaint asserts that Piedmont placed pressure on above-FMV-compensated ACG physicians to refer patients to receive inpatient cardiac procedures at Piedmont, even when the procedures could be performed in an outpatient setting, resulting in Medicare reimbursement to Piedmont that was 300% to 400% higher.[22]

While Piedmont denies any wrongdoing, the entity determined that it was in their best interest to settle with the government in order to avoid further litigation.[23] Piedmont, in a statement to the press, emphasized that the "*decision to settle is not an admission of liability*" and that "*in all cases, [Piedmont] doctors and nurses made their decisions based on the best interest and health of their patients—just like they always have and always will*."[24]

Piedmont Pays $16 Million to Settle Kickback and Overbilling Allegations

As mentioned in the March 2020 *Health Capital Topics* article entitled, "*DOJ Recovers Over $3 Billion in False Claims Act Cases*," there has been a significant number of FCA suits brought by whistleblowers, as well as by the *Department of Justice* (DOJ), in recent years.[25] Despite the Trump Administration's actions to deregulate the healthcare industry during the last three years, the number of new healthcare fraud and abuse enforcement actions suggest that regulatory scrutiny of healthcare transactions will remain high going forward.

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Executive Order Expands Telemedicine and Eases Burden on Rural Providers

[Excerpted from the article published in August 2020.]

On August 3, 2020, President Donald Trump signed an executive order aimed at expanding access to care through two avenues: telemedicine and eased financial burdens on rural providers.[1] This *Health Capital Topics* article will discuss the executive rule and the subsequent agency actions on these fronts.

The August 3rd executive order builds on President Trump's original expansion of coverage for telemedicine services in early March 2020, an order which was praised by the *American Telehealth Association* (ATA) and *American Medical Association* (AMA) for swiftly responding to the growing healthcare crisis.[2] The new order allows some of the 135 services that were originally waived on a temporary basis to be permanently delivered via telemedicine technology going forward.[3]

For both patients and providers, the stakes of continuing to provide, and have access to, telemedicine care are high, and the permanent expansion of reimbursement for such services has been long sought by groups such as the *American College of Physicians* (ACP), which has been lobbying the *Centers for Medicare & Medicaid Services* (CMS) since June 2020 to allow certain measures to remain in place after the COVID-19 *public health emergency* (PHE) is over.[4] ACP's request focused on the importance of continuing facility fee payments, maintaining flexibility in physician direct supervision, lifting restrictions based on geographical site, allowing physicians to practice telemedicine across state lines, continuing pay parity between telemedicine and in-person *evaluation and management* (E/M) and other visits, expanding *remote patient monitoring* (RPM) codes, and allowing physicians to reduce or waive cost-sharing for telemedicine.[5]

Telemedicine has quickly become routine for Medicare beneficiaries since the start of the PHE. Only 14,000 Medicare beneficiaries used telemedicine per week at the start of 2020, but from March to early July, the number of beneficiaries who have received care through telemedicine has soared to over 10 million.[6] As relates to primary care, only 0.1% of Medicare primary care visits were conducted via telemedicine prior to February 2020, compared with 43.5% in April 2020.[7] There is evidence that both primary and specialty care physicians have experienced increases in the number of telemedicine visits, and even the state with the lowest rate of telemedicine use, Nebraska, saw increases in telemedicine primary care visits, up to 22% of all primary care visits.[8] The *Department of Health and Human Services* (HHS), as well as CMS, have touted this technology for its greater efficiency of care and as a way to stay safe and avoid unnecessary exposures.[9] HHS is largely responsible for this rapid expansion of telemedicine, due to its emergency declaration allowing beneficiaries to receive care wherever they were located – even across state lines – and its decision to not impose *Health Insurance Portability and Accountability Act* (HIPAA) penalties for providers who committed a privacy

violation by using unencrypted video programs such has Skype or FaceTime to conduct telemedicine visits (but who had acted in good faith).[10] Telemedicine's growing importance, as well as input from healthcare stakeholders such as the AMA and the ACP, seem to have impacted CMS's decision-making process in its 2021 updates to the *Medicare Physician Fee Schedule* (MPFS) and *Quality Payment Program* (QPP). These rules are discussed in this month's Health Capital Topics article entitled, "2021 Physician Fee Schedule & Quality Payment Program Proposed Rules Released."

Rural providers have often not been able to take advantage of the opportunities provided by telemedicine to the same extent as those in urban areas,[11] but President Trump's executive order also directly addresses these rural providers, signaling for dramatic functional and reimbursement changes for them and the 57 million Americans they serve.[12] The order highlights opportunities in technological infrastructure investment for rural areas.[13] As telemedicine becomes a greater part of the healthcare delivery system, access will be an important issue for patients in rural areas who may not have the requisite Internet technology or bandwidth in place to support telemedicine. The order also calls on HHS to develop a new payment model with increased flexibility, more predictable payments, and incentives for quality of care for rural hospitals.[14] Some healthcare executives believe that such a payment model would greatly aid and incentivize rural systems that are prepared to transition to value-based care.[15] COVID-19 has hit rural hospitals especially hard, with a dozen closing in the first half of 2020[16] and nearly a quarter in danger of bankruptcy.[17] This new executive order may provide some much-needed relief for struggling rural providers and increase quality and access to care for Americans living in these rural areas.

On August 11, 2020, approximately one week after the publication of President Trump's executive order, CMS released a new payment model for rural providers – the *Community Health Access and Rural Transformation* (CHART) model.[18] Citing disproportionate health burdens faced by rural populations in the U.S., this model aims to reduce costs to rural providers while improving access to quality healthcare through:

(1) Making up-front investments and capitated payments based on quality and patient outcomes;

(2) Lessening regulatory burdens to give rural providers greater flexibility; and,

(3) Ensuring financial stability for providers, in order to allow them to offer services that address social determinants of health.[19]

The CHART model will achieve these ends through two value-based reimbursement "*tracks*": (1) the *Community Transformation Track* and (2) the *Accountable Care Organizations (ACO) Transformation Track*.[20] The *Community Transformation Track* will consist of 15 "Lead Organizations," e.g., state Medicaid agencies, local public health departments, and academic medical centers, which organizations will represent a rural community (defined

as one or multiple continuous counties or census tracts) and work with community partners to facilitate value-based payment and viability.[21] Lead Organizations will receive upfront funding of $2 million upon acceptance into the program and an additional $3 million throughout the five-year program to coordinate community efforts.[22] CMS will also set an annual *capitated payment amount* (CPA), so that participating rural hospitals will receive stable revenue.[23] CMS will also decrease some regulatory burdens, by allowing participating hospitals to waive cost sharing, provide transportation for Medicare beneficiaries, and offer incentives for Chronic Disease Management Programs.[24] CMS will offer other benefits as well, including continuing telemedicine expansion post-COVID-19 and waiving the required 3-day inpatient stay prior to a skilled nursing facility (SNF) admission.[25] The 15 Lead Organizations will be chosen in Spring 2021 with the performance period set to begin July 2022.[26]

Similarly, the *ACO Transformation Track* will consist of up to 20 ACOs with a majority of providers or suppliers in rural areas, which ACOs will be required to join the *Medicare Shared Savings Program* (MSSP).[27] For a five-year period, the selected ACOs would each receive: (1) a minimum, one-time payment of $200,000 plus $36 per beneficiary served; and, (2) prospective payments of at least $8 per Medicare beneficiary per month for up to two years.[28] ACOs will also be enrolled in the *Beneficiary Incentive Program*, enjoy telemedicine coverage expansion beyond COVID-19, and be waived from the three-day inpatient stay requirement prior to a SNF admission.[29] Applications for this track will open in Spring 2021 with selection of participating ACOs in Fall 2021; the performance period would begin in January 2022.[30]

Since March 2020, the Trump Administration has released numerous executive orders and other mandates to expand healthcare services and support providers in the midst of the COVID-19 pandemic. President Trump's August 3rd executive order, together with CMS's 2021 *Physician Fee Schedule* and *Quality Payment Program* proposed rules highlight the administration's belief that telemedicine will continue to play a permanent, significant role through the end of the COVID-19 crisis and into the future. As CMS Administrator Seema Verma said in a statement following the release of the proposed rules: "*Telehealth can never fully replace in-person care, but it can complement and enhance in-person care by…[increasing] access and choices for America's seniors*."[31] Further, this executive order, and CMS's proposed CHART model, may serve to expand healthcare access and protect providers in struggling rural areas. The Trump Administration hopes that these two measures will lead to better health outcomes for patients in rural areas and future sustainability for rural providers.[32]

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IV. COMPETITION TOPICS

Healthcare "Disrupters" Continue to Attract Capital

[Excerpted from the article published in February 2020.]

On January 30, 2020, *1Life Healthcare, Inc*. (*One Medical)*[1] went public, opening at $14 per share, and closing at $22.07 per share.[2] The innovative San Francisco-based direct primary care organization more closely resembles a technology start-up than a traditional healthcare organization.[3] The membership model service provides "*seamless access*" to primary care services at "*calming offices*," 24/7 virtual care, and 21st century technology (e.g., a mobile application that allows patients to schedule appointments and message their provider).[4] One Medical's initial public offering (IPO) may be indicative of a trend of capital gravitating toward industry disruptors instead of the "*old guard*." The successful IPO (during which One Medical sold 17.5 million shares, raising $245 million) values One Medical at $2.7 billion,[5] and is well above the $1.5 billion valuation in the last round of funding (less than six months) prior to going public.[6]

Anything but Typical

Unlike many organizations in the healthcare industry, One Medical is backed by major high profile investors. One such investor is the private equity Carlyle Group, which invested $350 million in 2018.[7] The Carlyle Group is known for its high-profile investments in exceedingly successful brands such as Dunkin' Brands.[8] Other prominent investors of One Medical include J.P. Morgan, GV (formerly known as Google Ventures), Maverick Ventures, Benchmark, and DAG Ventures.[9] These investors are known for identifying disruptive companies that recreate entire industry segments. One Medical's IPO more than repays its investors, especially early investors.[10] For example, based upon the results of the recent IPO, the value of the Carlyle Group's equity position has doubled in value since its summer 2019 investment.[11] Notably, the strong IPO comes on the heels of broader market headwinds, such as, concerns over the impact of a global pandemic related to the coronavirus, instability in international trade arising from trade wars, and political uncertainties resulting from the upcoming U.S. Presidential Election, and the impeachment of Donald Trump, among other factors.[12]

One Medical's revenue grew by 29% to $200 million in the first nine months of last year.[13] However, losses also grew by nearly 27%, with net income declining to -$33 million over the nine-month period.[14] The loss increase is expected for an early-stage company in the rapid growth phase, and losses have deepened for the company as it has been aggressively pursuing new patients.[15]

New Approach

Tom Lee, MD, a Harvard-trained internist, founded One Medical in 2007, seeking to change the way medical care was delivered, and make it more convenient for patients.[16] Lee served as an executive at UnitedHealth Group and CEO of Stanford Health Care before ultimately founding One Medical and serving as CEO until 2017.[17]

As noted above, One Medical operates as a direct primary care provider organization,[18] which model aims to address both physician and patient concerns related to primary care delivery.[19] The company charges an annual fee of $199 and bills the patient's insurance company for the provided healthcare services.[20] The membership allows patients to text their providers, schedule same-day appointments, and utilize the company's patient portal.[21] One Medical intentionally targeted the lucrative demographic of employer-sponsored insured, working-age urban adults in cities such as New York and San Francisco.[22] More than 95% of One Medical's patients have commercial insurance.[23] Importantly, as One Medical has grown, the targeting of employees has become more strategic. One Medical has started to operate on-site clinics at some employers, such as Alphabet Inc. (d/b/a Google);[24] in fact, 10% of One Medical's net revenue in 2018 was generated from Alphabet's on-site clinics.[25] Currently, One Medical has over 6,000 enterprise clients.[26] The company asserts that employers using One Medical as an enterprise solution have seen 41% reductions in emergency room visits and total employer cost savings of over 8%.[27]

One Medical has maintained customer-centric focus in the delivery of its healthcare services. The company opens clinics in convenient locations such as close to patients' work or home instead of on hospital campuses.[28] Often, the offices are small and furnished in a "*contemporary interior design*" more typical of an upscale living room than a physician's office.[29]

One Medical's use of technology is prolific. The company uses technology to allow patients to access care 24/7 using the One Medical mobile phone application.[30] A patient can use the application for a video visit or to message a provider.[31] Members can also rate their providers after the conclusion of a video visit.[32] The company also proactively reaches out to patients regarding health situations utilizing the mobile phone application.[33] One Medical reports that 47% of its members interact with the mobile application monthly.[34]

As noted above, One Medical's model aims to address physician burnout concerns by allowing flexible work schedules and paying providers on a salary basis with no connection to the fees collected or their productivity.[35] One Medical hopes that this compensation structure encourages providers to focus on providing medical care and prevent burnout.[36] One Medical claims to have reduced the administrative burden on providers significantly (it claims that its providers perform 44% fewer electronic health records (EHR) tasks compared to the rest of the healthcare industry) by simplifying the EHR system for its providers.[37] The company also asserts that the support from virtual medical teams, along with the salaried compensation structure, reduces any effect of financial incentives on clinical decision-making.[38]

One Medical has received a number of awards for its approach to providing primary care services. Its EHR won the *EHR Innovation Award* from *MedTech Breakthrough*, an organization that recognizes the top companies in healthcare.[39] The award is telling of the company's Silicon Valley roots and technology focus. The patient-centric approach is evidenced by One Medical's

recent accolades, such as being named the #1 *Most Customer Centric Company in Healthcare* by Forbes[40] and the *Most Innovative Health Company* in 2019 by Fast Company.[41] The hype around One Medical's IPO was likely partially induced from the selection of the company for placement on the *CB Insights* (a prominent machine intelligence platform of start-ups) *2019 Digital Health Unicorn Startups* list.[42] In addition to these (relatively subjective) accolades, One Medical provides empirically high-quality care; it is in the 90th percentile rankings on key primary care *Healthcare Effectiveness Data and Information Set* (HEDIS) quality metrics.[43]

According to the January 2020 registration filing, One Medical has over 397,000 members and 77 locations nationwide.[44] It predicts that it could more than double its market footprint by expanding from its nine current markets to the 50 largest metropolitan markets.[45]

Capital Flowing to Primary Care

The U.S. has not traditionally prioritized primary care services, which makes up only 5% to 7% of the $3.6 trillion in total healthcare spending, as it has focused more healthcare spending on high-cost fee-for-service specialty care services.[46] The lack of spending is contrasted with other *Organisation for Economic Co-operation and Development* (OECD) countries, which spend, on average, 14%.[47] Over the past decade, the federal government implemented regulatory and reimbursement policies to shift the focus toward primary care services to keep utilization rates of more expensive care settings, such as emergency rooms or hospital outpatient departments, lower. On average, for every $1 spent on primary care, an estimated $13 is saved on costs in other parts of the healthcare delivery system.[48]

Healthcare capital investments are looking to invest in primary care practices,[49] as many investors and large companies believe there is room for cost-cutting in primary care, as the specialty has not yet been optimized. Major insurers and pharmacies are also starting to open primary care service clinics.[50] CVS Health, Humana, and Walgreens all now operate hundreds of primary care clinics.[51] Humana has over 230 primary care centers or joint ventures.[52] CVS Health operates 50 HealthHubs that provide primary care services nationwide.[53] Anthem has discussed buying or operating primary care clinics.[54] Even Walmart operates a full-service clinic in Georgia.[55] Other prominent start-up primary care clinics such as Iora Health seek to redefine primary care by reorienting the payment and care delivery system, and are attracting the capital, recently closing on a $126 million funding round.[56]

The distrust of healthcare's "*old guard*" is not only felt by investors, but by patients, 81% of whom have reported dissatisfaction with their healthcare experience.[57] Many patients may welcome the new entrants into a primary care industry that has, for years, been dominated by traditional healthcare organizations acquiring independent physician offices. Significantly, the new entrants may prove that primary care clinics do not have to be "*loss leaders*," as traditionally believed by many in the healthcare industry. These less

traditional strategies may suggest that the healthcare industry is ripe for changes to the primary care delivery system.

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New Vertical Merger Guidance Could Implicate Healthcare M&A

[Excerpted from the article published in February 2020.]

On January 10, 2020, the *U.S. Department of Justice* (DOJ) and the *Federal Trade Commission* (FTC) jointly published draft guidelines clarifying antitrust enforcement policies relating to vertical mergers.[1] The guideline changes, which are rare, reflect the "*accumulation of experience at the Agencies*"[2] and provide insight and guidance concerning vertical merger antitrust enforcement policy. The new guidelines supersede the *1984 Merger Guidelines*,[3] which are now withdrawn in their entirety.[4]

Federal antitrust agencies define vertical mergers as mergers that combine firms that operate at different stages of the supply chain.[5] An example of a vertical merger could be a retailer acquiring the manufacturer of the products it sells (an "*upstream*" vertical merger) or a manufacturer acquiring the firm that sells it parts (a "*downstream*" vertical merger).[6] Two recent vertical merger transactions in healthcare are those of *CVS Health* with *Aetna*, and *Cigna* with *Express Scripts*.[7] Vertical mergers can be appealing to many firms because it may allow for increased savings in costs gained through increased production (i.e., *economies of scale*).[8] Moreover, firms may be enticed by a vertical merger because it may result in a greater control over supply costs or downstream prices increasing profit margins.[9] Healthcare organizations can be particularly attracted to vertical mergers as a solution to changing reimbursement models and increased demand for integrated delivery systems.[10] In healthcare, the perceived efficiency gains of vertical mergers are twofold: (1) increased profits and (2) improved quality of healthcare for patients.[11]

The DOJ/FTC vertical merger guidelines focused on five areas of potential adverse competitive effects: *related products, market share, unilateral competitive effects, coordinated competitive effects,* and *efficiencies*.[12] Each are discussed below.

Related Products

The guidelines state that federal regulators will be employing a market definition of "*related products*" when analyzing vertical mergers.[13] When identifying competitive concerns in a *relevant market*,[14] agencies will be specifying the *related products* in the market.[15] *Related products* are products or services supplied by a merged firm that are vertically related to products or services in the *relevant market* and affect competition in the *relevant market*.[16] The guidelines proceed to give examples of *related products*, such as "*an input, a means of distribution, or access to a set of customers*."[17] These broad examples indicate that federal regulators will analyze a wide array of related products in the *relevant market*.

Market Share

The guidelines identify the market share threshold required for increased federal antitrust scrutiny of a vertical merger. Regulators are unlikely to challenge vertical mergers where the parties have less than 20% market share in the *relevant market*.[18] Further, a challenge is unlikely in cases where the parties' *related products* are used in less than 20% of the *relevant market*.[19] However, there may be exceptions to this *safe harbor*, such as in circumstances where the *relevant product's "share of use in the relevant market is rapidly growing.*"[20] Finally, the guidelines clarify that simply having a 20% market share or more does not alone indicate an inference that the vertical merger will likely lessen competition because more factors must be analyzed.[21] As previously noted in the *Horizontal Merger Guidelines*,[22] market share merely provides a way to identify mergers that *may* raise competitive concerns.[23]

Unilateral Competitive Effects

Parts of the draft vertical merger guidelines rely heavily on the 2010 *Horizontal Merger Guidelines*.[24] For example, evidence of adverse competitive effects in vertical mergers adopt many of the types of evidence described in Section 2.1 of the *Horizontal Merger Guidelines*, such as "*actual effects observed in consummated mergers, direct comparisons based on experience, and evidence about the disruptive role of a merging party*."[25] Moreover, regulators will use the same types of documentation used in a horizontal merger analysis to prove adverse competitive effects in vertical mergers.[26]

Regulators identify two ways in which a vertically merged firm's control of a *related product* may adversely impact competition in the *relevant market*. First, a vertical merger may foreclose a competitor from accessing a *related product* or raise the rival's cost of the *related product* to a point where consumers of the *related product* are harmed.[27] The merged firm could also refuse to supply the rival with the related products altogether resulting in "*foreclosure*."[28] Alternatively, a vertical merger may increase the ability of the merged firm to decrease the quality of its rivals' products or services.[29] Second, the merged firm's control of a *relevant product* could allow the firm access to competitively sensitive information of *downstream* competitors, which may allow the merged firm to moderate its competitive response to rival's competitive actions to preempt or react quickly to procompetitive business actions.[30] These actions may adversely impact competition because rivals may see less competitive value in taking procompetitive actions, or the rivals may refrain from doing business with the merged firm out of fear competitively sensitive business information will be used adversely.[31] These effects may result in rivals becoming less effective competitors because they may lack competitive pricing options from other trading partners.[32]

Coordinated Competitive Effects

Regulators identify the possibility for a vertical merger to allow anticompetitive behaviors such as overt or tacit coordination by competitors to eliminate or competitively harm upstart "*maverick*" firms.[33] Vertically merging parties

could harm the ability of a non-merging *maverick* in the *relevant market* from effectively competing against the merged firm and increase the likelihood of coordination between the merged firm and other rivals.[34] The change in market structure and access to confidential information may allow for tacit agreements among market participants, detecting cheating in the agreements, and then punishing firms who cheat.[35] These illegal agreements[36] result in locking out *maverick* firms from effectively competing.[37]

Efficiencies

The draft guidelines state that regulators will analyze if the perceived efficiencies from a proposed vertical merger will result in lower prices to downstream consumers.[38] Further, the guidelines recognize efficiencies such as combining economic functions and eliminating the need for contracting functions, which may create unnecessary costs that may ultimately be passed along to downstream consumers.[39] Finally, regulators state that approaches to evaluating efficiencies will be drawn from the *Horizontal Merger Guidelines*.[40]

Healthcare Missing

Despite being the first update to the *1984 Merger Guidelines* in 34 years, the draft guidelines are surprisingly short and do not expound on a number of questions from antitrust experts relating to vertical merger antitrust enforcement. Significantly, there are no references to healthcare or any examples of vertical mergers in healthcare. The draft contains no discussion of the standards that agencies will utilize to evaluate the ability of merging firms to cut off the supply of downstream products to rivals. This is significant to healthcare because vertically merging healthcare organizations may make it more difficult or costly for competitors to obtain physician services. The omission of any reference to healthcare is surprising given the FTC's involvement in the healthcare industry over the past year, including: (1) its 2019 intervention in the vertical merger of *UnitedHealthGroup's* acquisition of *DaVita Medical Group*;[41] and, (2) the Eighth Circuit's 2019 ruling in favor of the FTC when it blocked the proposed acquisition of *Mid Dakota Clinic* by *Sanford Health*.[42] Finally, the guidelines do not mention any potential remedies. Due to the nature of vertical deals not containing any overlapping products, the only potential remedy that exists other than an injunction would be behavioral remedies administered by a federal court.

Healthcare providers continue to view vertical mergers as perceived increased efficiency solutions; however, the evidence of such results is scarce and ambiguous.[43] Moreover, the evidence that does exist indicates that hospital acquisition of physician practices has minimal impact on increasing care quality.[44] In addition, increased market concentration is strongly associated with reduced patient satisfaction scores.[45] Finally, it has been established that there is a significant increase in spending on healthcare services when they are delivered in hospital-owned settings versus the physician office setting.[46] Merger activity in healthcare may threaten competition in local markets, which may force regulators to focus on vertical mergers to ensure high quality and affordable costs for healthcare consumers.

Despite these potential red flags, vertical integration in healthcare has, nevertheless, continued, and even accelerated, with hospital-acquired medical practices increasing from 35,700 in 2012 to 80,000 in January 2018.[47] Antitrust law appears to still be playing catch-up to healthcare's new economic realities. Vertical mergers are still largely perceived as inherently efficient, with the harm to competition outweighed by the gained efficiency. However, research indicates that this perception may hold true as regards the healthcare industry. The recently proposed guidelines offer a more comprehensive vertical merger antitrust analysis, but it is still unclear if these updates will ultimately result in increased antitrust enforcement of vertical mergers.

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How Will COVID-19 Change Healthcare Delivery?

[Excerpted from the article published in April 2020.]

Spurred by how unprepared the American healthcare system was for a pandemic, the current COVID-19 emergency may present the conditions necessary to commence a healthcare delivery model paradigm shift.[1] In response to the public health emergency, the federal government, which has a record of reducing regulatory "*burdens*" under the Trump Administration,[2] has taken aggressive actions to create regulatory flexibilities for healthcare providers and suppliers.[3] At least some of the various actions taken to reduce provider burden as they treat COVID-19 patients are likely to stay intact following the end of this pandemic, potentially revising the fundamental tenets of U.S. healthcare delivery. This *Health Capital Topics* article will discuss some of the ways in which the pandemic may change the healthcare delivery landscape going forward.

Accelerated Shift to Outpatient Settings

Healthcare delivery has been shifting toward the outpatient setting over the past two decades for several reasons, including patient convenience and lower cost of care (and not necessarily in that order). The *Centers for Medicare & Medicaid Services* (CMS) has promulgated agency regulations and guidance to incentivize the provision of care in these lower-cost settings; this shift may well be accelerated as a result of the pandemic.

Ambulatory surgery centers (ASCs) are uniquely capable of handling surgical overflow from hospitals, a characteristic that healthcare organizations may find more valuable post-crisis.[4] During the pandemic, ASCs have been allowed to coordinate with local hospitals to provide hospital services.[5] If these partnerships are successful, hospitals are likely to remember this coordinated response when making future transactional decisions. The post-COVID-19 transactional arena may consist of healthcare organizations with deeper interests in non-traditional sites of care, including ASCs, urgent care centers, or telemedicine companies, as these business lines may provide a way for healthcare organizations to diversify their revenue.

Further, the proliferation of concierge medicine, i.e., primary care providers who usually receive annual or monthly fees in exchange for providing patients 24/7 access, has gained significant momentum during the pandemic due to the desire to obtain treatment and testing outside of hospitals. Consumers may become accustomed to the priority treatment received from concierge providers, leading to growth in this form of outpatient treatment. Technologically-inclined concierge providers, such as *One Medical*, are ideally positioned to succeed because they had a strong telemedicine infrastructure in place pre-COVID-19.[6] In contrast, many traditional primary care providers will not survive the COVID-19 crisis because of the closures of physician offices due to stay-at-home orders; the wariness of patients entering a medical facility during a pandemic; and, the non-emergent nature of many primary care

appointments.[7] Further, most primary care providers, who tend to have fewer technological and financial resources,[8] are unprepared to add telemedicine services to their practices; only 22% of family physicians used video visits in 2019.[9] Without massive support from the government, many primary care practices will not survive the pandemic,[10] providing an opportunity for concierge providers to gain significant market share. Healthcare organizations seeking to expand their outpatient footprint may find failing primary care facilities or successful concierge providers as attractive acquisition targets.

Expansion of Telemedicine Services

While relaxed regulations related to telemedicine across all aspects of healthcare, from hospice to primary care, were intended to be temporary when established, these regulatory changes may permanently shift how medical care is delivered and reimbursed. CMS has loosened site limitations and expanded the number of covered telemedicine procedures to 80, and is paying for these services at the same rate as their in-person counterparts.[11] Some Medicare COVID-19 reimbursement changes, e.g., allowing providers to see patients without a previously-established relationship and allowing patients to receive telehealth services regardless of the patient's or provider's location, may be allowed continue going forward.[12] In fact, on April 15, 2020, CMS Administrator Seema Verma announced that CMS is exploring how it can make the emergency telehealth regulation changes permanent once the pandemic is over,[13] and will be working with Congress to expand telehealth access to all Medicare beneficiaries post-COVID-19.[14]

In addition to Medicare, private insurers have also expanded their telehealth policies, with most shifting to cover telehealth visits of all kinds since the start of the crisis.[15] Multiple insurers, including Anthem, Cigna, UnitedHealthcare, and Aetna, are waiving any cost sharing for telehealth visits[16] and/or reimbursing for telemedicine services at the same rate as in-person visits.[17] Significantly, several insurers own telemedicine services (e.g., Anthem's LiveHealth Online), which compete directly with providers.[18] Health insurers may be able to establish themselves as telehealth providers for their subscribers during this crisis, creating a competitive advantage post-COVID-19. Moreover, commercially-insured patients will likely become much more accustomed to telehealth services as a result of having to use the technology during the crisis,[19] Patients may consequently opt to continue receiving medical services in this manner post-crisis, which means that providers who do not offer telehealth services may find it difficult to convince commercially-insured patients to come into the office for visits that can be provided virtually. This reliance on commercial reimbursement is primarily because of the significant price discrepancy between Medicare payments and commercial insurance payments; on average commercial insurance reimburses hospitals at 241% of Medicare rates.[20]

From a broader policy perspective, this forced overnight shift to telemedicine is more efficient for the healthcare delivery and payment system overall. Increased utilization of telemedicine will reduce unnecessary (and costly)

emergency room visits and help physicians prioritize patients with complex conditions, including allowing them to spend more in-person time with those patients and more frequently monitor their conditions through telemedicine technology. Thus, those providers who choose not to adapt to this healthcare delivery "*sea change*" may jeopardize revenue and market share.

Increased Delivery of Healthcare in the Home

As alluded to above, the COVID-19 crisis has not just shifted services to the outpatient setting, but is also shifting certain services from being provided by a physician in the hospital to being provided by a nurse in the patient's home.[21] While this trend toward providing more care in the patient's home began in earnest over the past couple of years due to the CMS expansion of payment for home healthcare services[22] and the overall shift to value-based reimbursement, this change may become much more prevalent, as the expansion of these services during the crisis are affirming that some services do not, in fact, need to be performed by physicians or in a hospital setting. Because patients treated in the comfort of their own homes require less testing, have fewer readmissions, and report higher satisfaction with the care received,[23] taking certain services out of the hospital setting will not just reduce long-term costs for insurers, but will also reduce healthcare costs for patients. Going forward, hospitals may face significant pushback from patients if providers insist the services received in the home during the crisis must now be returned to the hospital setting, especially if the patient was satisfied with the care received in-home. This shift may allow home health providers to capitalize on the newfound need for home healthcare post-COVID-19.[24]

The Final Blow to Rural Providers

Rural hospitals were already in a precarious position pre-crisis, with many rural providers teetering on the brink of closure with "*razor-thin*" operating margins.[25] COVID-19 has changed the risk of closure into a reality – seven rural hospitals have closed since the beginning of the pandemic.[26] Before the crisis, approximately 25% of rural hospitals were at risk of closing unless financial conditions improved.[27] The elimination of elective procedures will further negatively affect the long-term viability of many rural providers, as evidenced by the *American Hospital Association* (AHA) requesting additional emergency funding for that very reason.[28]

Pre-crisis, rural hospitals were already a victim of their circumstances, due to an older and less healthy patient population,[29] rural outmigration, payor-mix degradation,[30] clinician shortages, and an overall lack of capital.[31] The current pandemic may be the final blow. The federal stimulus efforts, in their current form, are likely not sufficient to prop up rural hospitals for the duration of the public health crisis.[32] Closures of rural hospitals could significantly change the healthcare delivery landscape in much of the country. This may force the expedited adoption of telehealth in rural regions at a time when broadband networks, even in rural America, appear to have sufficiently handled the surge in traffic from the pandemic, indicating that rural broadband networks can support the use of telehealth in rural areas post-COVID-19.[33]

Ameliorated Healthcare Worker Shortages

The critical state of the physician workforce shortage has been highlighted by the pandemic, compelling the relaxation of Medicare licensing restrictions that has allowed for an influx of physicians and other healthcare clinicians.[34] Regulations loosened by the *Department of Health & Human Services* (HHS) include allowing hospitals to use non-physician providers (NPPs) to the fullest extent possible.[35] Current Medicare standards of care regulations, which require Medicare patients to be under the care of a physician, have been waived for the duration of the crisis.[36] Other changes related to NPPs include the following:

(1) The *Coronavirus Aid, Relief, and Economic Security (CARES) Act* permanently authorizes NPs and physician assistants (PAs) to order home healthcare services for Medicare patients;[37]

(2) CMS waivers allow all providers to practice across state lines (via telehealth technology) at the top of their license authority;[38]

(3) CMS waivers allow NPPs to perform some medical exams at skilled nursing facilities;[39] and,

(4) A number of those states that do not currently allow full practice authority have relaxed their scope of practice standards.[40]

These expansions in NPP scope of authority and state licensure could theoretically remain in place going forward with minimal adverse consequences. Such changes may serve to alleviate physician manpower shortages not just during a public health crisis, but over the next few decades, as the aging *Baby Boomers* population will require more healthcare services than the current physician population can provide. Because CMS has shown a willingness in the past to expand NPP practice authority, more states have been expanding NPP scope of practice,[41] and the federal government has explicitly endorsed expanding NPP practice authority,[42] there is a strong possibility that at least some of these changes related to NPP practice authority will become permanent.

In addition to expanding NPP practice authority, many states have also substantially decreased licensing requirements for foreign physicians and medical students, which may further alleviate physician shortage problems long term.[43] Foreign physicians (who are already living in the U.S.) will likely stay in the U.S. post-crisis due to the higher physician salaries,[44] which would significantly increase the supply of physicians.[45] Additionally, many states have allowed nearly-graduated medical students to commence practicing immediately.[46] Thousands of medical students have joined the ranks to fight COVID-19, with some in special services roles, but many through early residency start.[47] The push to graduate medical students early could finally move medical schools in the direction of graduating more medical students based on *competency-based medical education* (wherein students are judged on competency, not on years in medical school), which would significantly reduce physician shortage problems in the long run because many medical

students could graduate after three years, in contrast to the current four-year curriculum.[48]

The Future is Still Unwritten

As the ultimate impact of COVID-19 is unknown, it will likely take a significant amount of time before healthcare consumer behavior returns to previous trends, if ever. Moreover, what characteristics will define the "*new normal*" of healthcare consumer behavior remain tentative at best. Health policy experts have argued that this unprecedented moment in the nation's history is the ideal time for Congress to transform the U.S. healthcare delivery system.[49] However, policy experts may overestimate the appetite of congressional lawmakers for bipartisan healthcare reform, especially considering the impending presidential election. While Congress has acted swiftly and cooperatively thus far to alleviate the economic and healthcare crisis, further bipartisan agreement on contentious healthcare issues seems improbable.[50] While healthcare crises such as COVID-19 may highlight the inadequacies of the healthcare delivery and payment system, and accordingly spark healthcare reform conversations, the reality is that Americans traditionally have only had the appetite for small incremental changes to the healthcare system. Although a wholesale change of the healthcare system appears improbable, the changes highlighted above, such as patient care settings shifting away from traditional settings and the utilization of technology and other clinicians to increase healthcare access, could, in aggregate, result in the next paradigm shift in the U.S. healthcare delivery system.

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Post-Coronavirus Physician Practice Acquisitions: Proceed with Caution

[Excerpted from the article published in June 2020.]

As the coronavirus (COVID-19) global pandemic has wreaked havoc on the U.S. economy generally, and the healthcare industry specifically, the previously-active healthcare transactional environment has been largely stunted. Despite (or perhaps because of) this economic turbulence, stakeholders expect that merger and acquisition (M&A) activity will soon resume with a vengeance.[1] This potential opportunity, however, is not without pitfalls, due in part to the concern from stakeholders and regulators that well-capitalized entities may use this economic and public health crisis to prey on debilitated physician practices.[2] This concern was highlighted in the *Federal Trade Commission's* (FTC's) May 2020 announcement that it will continue its enforcement of competitive market practices and, post-COVID-19, will pay close attention to opportunistic healthcare consolidation.[3]

Over the past few decades, one of the most prevalent trends in the U.S. healthcare industry has been the consolidation of independent physician practices. Between 2016 and 2018, hospitals acquired 8,000 medical practices, and 14,000 physicians left private practice to work in hospitals.[4] However, physician practice acquirers are not relegated to just hospitals – both large insurers and private equity (PE) firms have entered the space as well.[5] In fact, the number of PE-acquired physician practices has grown dramatically, with the number of deals more than doubling between 2013 and 2016,[6] and, in 2018, such deals totaled 855, with $100 billion in capital invested.[7] Similarly, healthcare M&A activity at the beginning of 2020 was off to a strong start until the COVID-19 pandemic brought the U.S. economy to an abrupt halt.[8]

As noted above, the pandemic has caused widespread economic destruction, officially resulting in the U.S. entering an economic recession in February 2020, after a record 128 months of expansion.[9] The double-digit unemployment rate[10] and plunging economic output has not skipped the healthcare sector. The uncertainty of COVID-19 transmission and larger economic headwinds have caused investors to pause, delay, or cancel planned transactions.[11] This impact is illustrated by the total number of M&A transactions as of first quarter 2020, with only 366 healthcare deals closing,[12] a 10% decrease compared to the same quarter in 2019.[13] Additionally, recent trends show that April and May both had the lowest monthly totals of transactions in 2020, at 106 each.[14] Although health systems and other healthcare industry providers seem to have currently paused their M&A activity, transactions are expected to remain relatively strong throughout the remainder of 2020.[15]

The anticipated growth in M&A activity during the latter half of 2020 is expected to engender strict regulatory scrutiny, as demonstrated by the FTC's May 2020 announcement.[16] Physician groups that have been financially devastated by COVID-19 may rush to join larger organizations such as hospital

systems, national healthcare companies, and large platform groups backed by PE firms,[17] while hospitals and health systems may seek to grow and diversify their service lines (in order to prevent the revenue drops experienced in the early months of the pandemic) through acquisitions and other arrangements.[18] Regulators and lawmakers are specifically concerned that there could be a heightened probability of predatory consolidation resulting from the billions of dollars that financially-healthy providers received in federal aid to offset COVID-19 losses.[19] The $175 billion in grants allocated to the *Department of Health and Human Services'* (HHS's) *Public Health and Social Services Emergency Fund* to financially sustain healthcare providers during the pandemic could help large, well-capitalized companies buy smaller practices that were weakened financially by COVID-19's induced economic recession.[20] Moreover, the FTC's earnest proactive affirmation of healthcare M&A oversight indicates that the agency has an elevated concern that these larger organizations will pounce at the opportunity to add undervalued assets to their operations via vertical merger and/or horizontal consolidation.[21]

The FTC's statutory authority for fostering a competitive marketplace stems from three key federal antitrust laws: the *Sherman Act*, the *Clayton Act*, and the *Federal Trade Commission Act* (FTCA).[22] Section 1 of the *Sherman Act* prohibits contracts, combinations, and conspiracies "*in restraint of trade*,"[23] which, in healthcare, is likely to appear in contracts between providers and insurers.[24] Section 2 of the Sherman Act prohibits monopolization, attempted monopolization, or conspiracy to monopolize.[25] Section 7 of the *Clayton Act* prohibits mergers and acquisitions that may substantially lessen competition or tend to create a monopoly.[26] Lastly, Section 5 of the FTCA prohibits "*unfair methods of competition*," which include all violations of the Sherman Act and Clayton Act, as well as "*unfair or deceptive acts and practices*."[27] These federal antitrust laws work in concert with applicable state laws to thwart anticompetitive practices.

The "*failing firm defense*" has become commonly used by merging parties that attempt to elude the FTC's review of anticompetitive consolidation practices. This defense posits that the weaker firm is failing, and thus has no other option but to be absorbed by the larger acquiring firm.[28] The hope is, if the "*failing firm defense*" can meet all of the elements,[29] the FTC and/or state attorneys general will approve the horizontal merger because it is preferable to have the assets in the hands of the acquirer than to see the assets exit the market completely. The FTC is predicting a possible wave of these failing firm claims in consideration of the current state of the economy, which may support the acquiring firm's defense.

With over 90% of U.S. hospital markets considered highly concentrated, and 60% of overall healthcare dollars paid to short-term acute care hospitals, physicians, and other healthcare professionals, the FTC's proactive approach to stymie predatory transactions seems practical.[30] Despite 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

(especially among hospitals) lead to increased pricing due to more negotiation leverage,[31] as well as poorer outcomes (higher rates of mortality, higher readmission rates, etc.).[32] Because of the increasing M&A activity over the past few years, researchers have suggested that increased antitrust enforcement may address such price and quality issues by preventing harmful consolidations that could dominate the market.[33] The FTC's May 2020 announcement indicates that it has been listening to such concerns, and may be more forthright in deeming such potentially predatory deals anticompetitive and rejecting them.[34]

Healthcare providers may have a myriad of reasons for entering into a transaction or other arrangement once the COVID-19 pandemic slows down. Some providers may not have the requisite resources to survive, and seek out an acquirer for their practice. Other providers (particularly hospitals and large, multispecialty groups) may wish to diversify their service lines going forward in order to prevent any cash flow issues exposed by the pandemic. Still others may have been well-positioned for such a crisis and may consequently come out on the other side of the pandemic in a stronger position, which position they may utilize to acquire those distressed providers. No matter the motivation, providers may want to proceed with caution, given that the federal government has made it clear that they will be scrutinizing transactions that stem from COVID-19. Specifically, providers may want to be cautious of the following:

- That the seller conducted a sufficient search for, and analysis and selection of, a buyer, as "*the most financially challenged firm must do more than window shop the* assets;"[35]
- That the acquirer can support the assertion that they are the only available purchaser;[36]
- That the seller has documented, if applicable, where they "*lack[] sufficient reserves to make identified capital improvements, resulting in declines in its competitive significance*;"[37] and,
- That the transaction does not implicate any other federal healthcare laws, such as the Stark Law or the Anti-Kickback Statute.

Proceeding with a physician practice acquisition in 2020 will inevitably have its own set of challenges. Despite the current unique circumstances surrounding the healthcare industry, providers will be well-served to proceed cautiously with transactions, and be mindful of the fact that the COVID-19 pandemic is not a "*get out of jail free*" card.

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New Index Ranks Hospitals' Community Benefit

[Excerpted from the article published in July 2020.]

On July 7, 2020, the Lown Institute, a nonpartisan think tank,[1] announced the initial release of its new ranking system for hospitals.[2] Called the "*Hospitals Index*," this ranking analyzes not just the quality of care and patient outcomes but also the hospital's civic leadership and avoidance of overuse,[3] ideas that harken back to the core mission and vision of the Lown Institute itself. Founded in 1973, the Institute advocates for a healthcare system that "*rejects low-value care, incentivizes healing over profits, promotes health equity, and honors the value of the clinician-patient relationship*."[4] This vision came from the Institute's founder, cardiologist and 1985 Nobel Peace Prize winner[5] Bernard Lown, MD, who was instrumental in developing the direct current defibrillator and in understanding the psychological factors of heart diseases.[6] Today, the Institute addresses issues such as medical overuse/underuse, health equity, and the cost of care[4] through publications, conferences, data, and tool development;[7] the Institute also founded *Right Care Alliance*, an advocacy organization focusing on healthcare as a human right.[8] The Institute's priorities are reflected in the *Lown Institute Hospitals Index*, which examines factors such as inclusivity, use of low-value care, and community benefit in ranking the best hospitals in the country.[9] In its *Washington Monthly* article, the Institute made parallels between its new ranking system and reports such as *U.S. News & World Report*'s "*America's Best Hospitals*" list and IBM Watson Health's "*Top 100 Hospitals*," but concluded that these rankings fall short because they do not examine whether hospitals use their resources wisely and "*to provide quality care to everyone in their communities*."[10]

In order to create its rankings, the Lown Institute analyzed three main components – quality of care, civic leadership, and value of care, weighted at 50%, 30%, and 20%, respectively – which components contained subsections including pay equity, community benefit, inclusivity, overuse, clinical outcomes, patient safety, and patient satisfaction.[11] The Institute ranked 3,282 hospitals in its system, assigning to each an overall letter grade, as well as letter grades for each category.[12] Each hospital and health system was also given a percentile score for each component and a star rating for the subsections of each component.[13] The Institute principally used data from the 2015-2017 time period, and aggregated the information from multiple sources, including the *Centers for Medicare & Medicaid Services* (CMS), the *American Hospital Association* (AHA), the U.S. Census Bureau's *American Community Survey*, *Internal Revenue Service* (IRS) 990 forms, the *Securities and Exchange Commission* (SEC), and the *Bureau of Labor Statistics* (BLS).[14] Hospitals were excluded from the rankings if they: (1) were classified as a non-acute care hospital, federally-owned hospital, Medicare Advantage program, or specialty hospital; (2) were located outside of the 50 U.S. states or Washington, D.C.; (3) were closed by 2019; or, (4) had missing data.[15]

The top five hospitals in the *Lown Institute Hospitals Index* are (in ranking order):

(1) JPS Health Network in Fort Worth, Texas;
(2) Marshall Medical Center in Placerville, California;
(3) UPMC McKeesport in McKeesport, Pennsylvania;
(4) Seton Northwest Hospital in Austin, Texas; and,
(5) Mercy Health-West Hospital in Cincinnati, Ohio.[16]

All of these hospitals scored component scores of at least *A*-, with the exception of Mercy, who scored a *B* in their Civic Leadership category.[17] Surprisingly, many of the renowned, and often well-ranked, hospitals did not earn top spots in Lown's ranking system: for example, University of Washington Medical Center, Massachusetts General Hospital, Cleveland Clinic, and Mayo Clinic in Jacksonville, Florida,[18] were ranked at 141, 394, 1,009, and 2,047, respectively, out of 3,282.[19] Many of these hospitals' scores were dragged down by their civil leadership ratings, mostly due to high CEO salaries, which led to low scores for the pay equity criterion.[20]

The Lown Institute hopes that their report will address gaps in existing rating systems, assist hospitals in serving their communities, and help the public hold hospitals accountable.[21] The Institute asserts that "*what you measure matters*," and in order to quantify how well hospitals are serving the communities they represent, and how nonprofit hospitals are earning their tax-exempt status, measures such as patient population inclusivity, overuse of unnecessary (and even harmful) services, and community benefit should be considered.[22] Lown Institute President Vikas Saini states that community contributions and investment by hospitals are essential to patients, because life expectancy often "*depends more on your ZIP code than your genetic code*."[23] Many healthcare professionals have praised the release of this ranking system. For example, Sara Singer of Stanford University School of Medicine commended the use of a civic leadership measurement and the evaluation of overuse of low-value procedures.[24] Leah Binder, President and CEO of the Leapfrog Group (which has its own rating system that emphasizes patient safety measures), called the inclusion of a metric for low-value procedures "*a breakthrough*."[25] Binder notes that, while patients are not likely to choose a hospital based on pay equity, these civic leadership measures "*are informative about a hospital's culture*" and that "*[i]f there is anything you want out of a hospital, it's ethics*."[26]

Some who praised the report, however, also offered criticism. Singer, for example, was skeptical of the usefulness of the civic leadership measure for patients, stating that while she could see it influencing "*where you might make a charitable contribution*," she was unsure that it was as necessary for patients as quality measures.[27] As noted above, quality of care indicators in the *Lown Institute Hospitals Index* account for 50% of the hospital's composite rankings, while the criticized civic leadership indicator is weighted at 30%.[28] The AHA was vocal in its objections to the Lown rankings, calling the report "*a hodgepodge of composite score, ranking, and star ratings*" that offer no "*accurate and useful information*" to consumers and merely confuses and

misleads them.[29] Specifically, the AHA argued that the Institute's definition of community benefit was "*too narrow*" and does not recognize hospital contributions to "*medical research and professional training*."[30] The Lown Institute itself states in its methodology that it used a subset of reported community benefit spending and specifically chose not to include certain types of spending that have been criticized in research for not directly benefiting community health, including the research and health professional training measures that the AHA highlighted.[31] The Lown Institute also recognizes that the ranking data is limited, due in part to issues in hospital transparency, especially regarding community benefit spending and CEO pay,[32] an issue that other reports have previously highlighted.[33] In fact, CEO pay information was publicly unavailable for over 1,500 of the hospitals included in Lown's rankings – nearly half of the dataset.[34] Lown used a model from the half of hospitals with available data to estimate CEO pay for those hospitals with unavailable data. This model was created from almost exclusively private, nonprofit hospital information, but was extrapolated to project pay estimates for for-profit, public, and other nonprofit hospitals.[35] Further, over 20% of hospitals had incomplete wage index information for workers' wages, which were instead estimated by the Institute using BLS data.[36] Dr. John Mafi, an assistant professor at UCLA and low-value care and quality measurement researcher, expressed concern that the rankings did not indicate every time that services were actually low-value, instead opting to use categorical terminology like "*always overuse*," which he found problematic.[37] In his work, he says, he has seen a lot more "*gray area*" than the Lown measures take into account.[38]

While Saini admits that the Lown Institute's measurements are not perfect and may be flawed, he hopes that these rankings will serve to begin the discussion on the importance of what society measures and how hospitals engage and operate within their communities.[39] Hospitals need to think critically about what they are doing to advance equity in their region, he says.[40] The COVID-19 pandemic has highlighted the pertinence of the Lown Institute measures and the necessity of having a report that prioritizes these measures – with U.S. hospitals losing over $50 billion every month since March 2020 and nearly a quarter of the nation's rural hospitals in danger of closing,[41] the Lown Institute points to a troublesome system that is dependent on elective procedures, does not adequately address the conditions that produce at-risk groups, and is not transparent on important fairness and safety issues.[42] In its press release, Lown elaborated on the importance and use of their ranking system in the current COVID-19 crisis:

> "*Regardless of which class of patients they serve, hospitals are getting financially creamed because of the high costs of treating COVID-19 patients and a nationwide drop in profitable surgeries... [The initial] $100 billion in [federal] aid to hospitals…will almost certainly wind up just being a down payment. Hundreds of billions more tax dollars will be needed… [The bailout is] a chance to fundamentally rethink the nation's entire health system and the role hospitals should play in it…Taxpayers*

> *have a right to demand some accountability for all that money…[but] we first need a reliable set of metrics to hold them accountable to.*"[43]

This accountability is precisely what the Lown Institute hopes their hospital rankings will contribute to the healthcare system.

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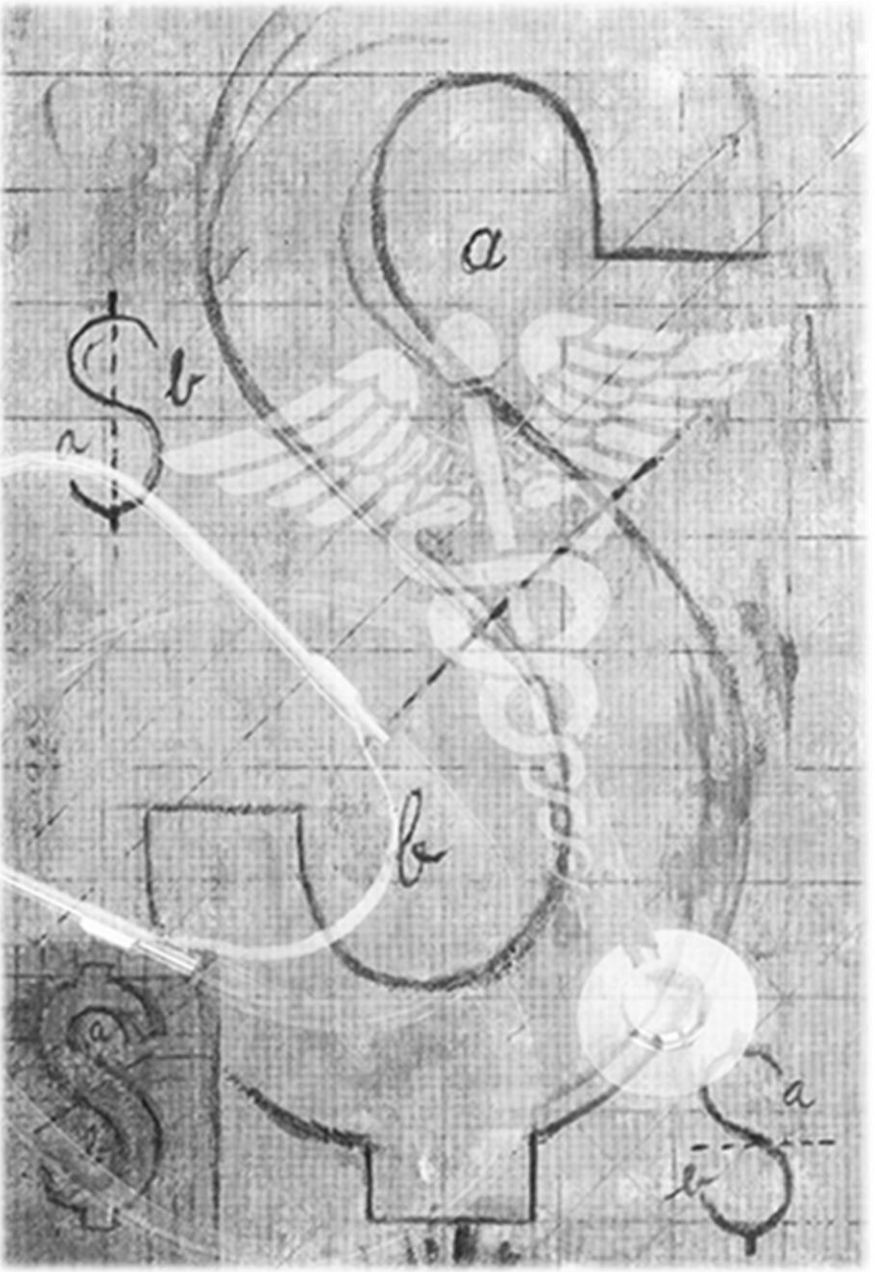
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V. TECHNOLOGY TOPICS

Corporate Solutions in Healthcare

[Excerpted from the article published in January 2020.]

With the federal government incapable of making meaningful improvements to the healthcare industry due to political impasses, and the systemic problems of: high and increasing costs; large deductibles; healthcare manpower shortages; and, delays in treatments and obtaining medications plaguing the U.S. healthcare delivery system, corporate America is stepping up to the task. While profit may be a motive for many of these corporations, they are also taking a more entrepreneurial path to problem-solving than existing healthcare organizations, which may result in higher quality, lower cost healthcare. This *Health Capital Topics* article will briefly survey some of these current private sector initiatives.

Making Specialty Medication Process Easier

CVS Health (CVS) is attempting to both reduce the time it takes for patients to obtain specialty drugs and improve patient adherence to these drugs through CVS's new specialty drug programs, *Specialty Expedite* and *Specialty Connect*.[1] Many patients utilize specialty drugs to manage complex medical conditions or chronic health conditions.[2] *Specialty Expedite* allows patients to shorten the onboarding process from multiple weeks to as little as three days.[3] The program works by gathering all of the required patient information directly from the electronic health record (EHR) system of the patient's provider, in contrast to faxing forms back and forth and conducting multiple phone calls.[4] CVS claims that the process will reduce the number of errors due to the significant reduction in paperwork.[5] Additionally, *Specialty Expedite* allows patients to receive real-time updates on the status of their specialty prescriptions via email or text.[6]

Specialty Connect, the next step of the process for patients attempting to obtain specialty prescriptions, allows patients to select how they receive their specialty prescriptions, either through a local CVS pharmacy or a mail service.[7] CVS brings further convenience and ease to the process by allowing *Specialty Connect* patients to connect with a dedicated team of specialty pharmacy experts 24/7.[8] CVS asserts that these programs give patients more "*flexibility and choice*," thus allowing patients "*to start their therapies sooner...[improving] adherence and satisfaction*."[9]

CVS's *Specialty Expedite* and *Specialty Connect* programs, which aim to control costs and improve the quality of care for better patient health outcomes,[10] are optimally timed as health insurance companies are assessing how to save money on specialty drugs, which are expected to rise both in cost and in utilization.[11] CVS's strategy may position the company as the prime choice for those health insurance companies seeking to control costs, resulting in CVS securing coverage inclusion or exclusivity for the distribution of specialty drugs.[12] Additionally, CVS claims that "*97 percent of patients successfully start[] on therapy after their first interaction at a CVS Pharmacy store*,"[13] providing further incentive for insurance companies to make CVS their

specialty pharmacy of choice, if this claim proves true. Since CVS renamed the corporation from CVS Caremark Corp. to CVS Health in 2014,[14] the corporation has shifted its focus more exclusively on healthcare. Other corporations are also stepping deeper into the healthcare service and product industry, seeking to capitalize on efforts to decrease healthcare spending.[15]

Betting Big on Healthcare

Best Buy is making a significant push into health services for aging consumers. In August 2018, they launched Best Buy Health and acquired GreatCall, a connected health services provider.[16] Chairman and CEO Hubert Joly stated in the company's Annual Report that "*[t]he integration of GreatCall into [Best Buy's] business has met, if not exceeded, our expectations*."[17] GreatCall addresses the needs of the aging population by providing senior customers with personal emergency response services, utilizing a combination of mobile products and connected devices that are specially tailored for elderly patients,[18] such as the Jitterbug, a phone designed for seniors.[19] In 2019, Best Buy further increased its market share in health monitoring services by acquiring Critical Signals Technology, a remote patient monitoring service designed to help individuals live independently.[20]

Best Buy is not limiting their ambitions of expanding in health technology to just older consumers, but rather is pursuing consumers across multiple age groups to address a variety of health needs.[21] Best Buy became the first major retailer to partner with TytoCare, an at-home self-examination telehealth device.[22] Additionally, in August 2019, Best Buy purchased BioSensics, a predictive healthcare technology business, in which technology is capable of detecting falls by seniors.[23] Best Buy has also begun partnering with Medicare Advantage plans such as Senior Whole Health of Massachusetts to provide in-home monitoring services through the utilization of GreatCall.[24] Best Buy's big bet on healthcare seems to be paying off, as Morgan Stanley recently reported that the business could add as much as $2 billion in revenue through 2025.[25] Morgan Stanley states that over the next 10 to 20 years, Best Buy could cumulatively generate between $11 billion and $46 billion in revenue from their commercial health business.[26] While Best Buy has been focusing thus far on the senior home care market, other corporations are pursuing larger systemic problems in healthcare.

Mitigating High Out-of-Pocket Costs

Sam's Club has partnered with Humana, Quest Diagnostics, and telehealth startup 98point6 for an initiative termed *Care Accelerator*.[27] The partnership's goal is to significantly lower out-of-pocket healthcare costs for healthcare consumers.[28] *Care Accelerator* will focus on bundling various services, such as primary and optical care, to lower costs.[29] There are four bundles to select from, ranging in price from $50 to $240 per year.[30] All of the bundles offer free prescriptions on certain generic medications, $1 telehealth visits, and savings on dental services, vision exams, and optical products.[31] The family bundle, priced at $240 per year, includes preventative health screenings, a 30% discount on chiropractic services, and a 10% discount on hearing aids.[32] Sam's Club will

be piloting *Care Accelerator* in Michigan, Pennsylvania, and North Carolina, and intends to make changes and add benefits to the initiative based on member feedback.[33]

Sam's Club has a patient disclaimer that clarifies its services, specifically stating: "*Care Accelerator is not a health insurance plan, but a discount health program*."[34] However, the similarities between the *Care Accelerator* discount program and health insurance are notable. Sam's Club's move to implement *Care Accelerator* came after the Kaiser Family Foundation released its annual *Employer Health Benefits Survey*, which found that the average deductible in 2019 for single coverage was $1,655, which is 41% higher than the average in 2014 and 162% higher than in 2009.[35] As healthcare costs continue to grow at a faster pace than wages,[36] *Care Accelerator* may be a beneficial proposition for many healthcare consumers (and a possible stepping stone for Sam's Club toward the operation of a full-scale "*members only*" insurance plan in the future). Walmart, the owner and operator of Sam's Club, has remained active in the healthcare space over the past several years, and *Care Accelerator* is in line with the discount brand's other forays into healthcare, one of which is described below.

Solving the Shortage of Healthcare Workers

There is a need for more than 250,000 new healthcare workers by 2020 to meet the demand for healthcare services.[37] A recent report from the *Association of American Medical Colleges* (AAMC) indicates a projected shortfall of 46,900 to 121,900 physicians by 2032.[38] Moreover, the limited capacity and high cost of education problems are significant contributing factors to the healthcare worker shortage.[39]

Walmart, which has been providing primary care services through its operation of in-store retail clinics, is pursuing an innovative means of filling their clinics with healthcare workers.[40] Through *Live Better U*, Walmart will be allowing their store associates to apply for one of seven bachelor's degrees and two career diplomas (for pharmacy technician and optician career paths) in healthcare-related fields for only $1 per day.[41] The education program will allow Walmart to place the employees across their extensive and growing network of pharmacies, vision centers, and hearing centers, as well as in their new Walmart Health center in Georgia.[42] In a statement regarding the new initiative, Walmart's Chief Medical Officer stated:

> "*Our presence in thousands of communities gives us a unique opportunity to provide access to affordable healthcare to millions of people, and we need trained associates in order to do so, as our health and wellness strategy and offerings continue to evolve, Live Better U will play a critical role in preparing our associates across the country for future work opportunities in the growing healthcare field*."[43]

As noted above, in September 2019, Walmart announced its intention to open the first Walmart Health center in Dallas, Georgia, which will provide "*primary care, labs, X-ray and EKG, counseling, dental, optical, hearing and community health education*."[44] All of these services will be provided with transparent pricing and "*regardless of customers' insurance status*."[45] The pricing for the services is relatively low, with child annual check-ups priced at $20, adult teeth cleaning at $25, and lab tests starting at $10, regardless of whether the patient has health insurance.[46] Similar to its retail strategy, Walmart's competitive pricing strategy has the potential to eat into traditional industry players' market share in the region.

Big Tech in Healthcare

Amazon, the second-largest e-commerce website in the world,[47] has launched an initiative to help patients manage their medications while maintaining compliance with the privacy provisions of the *Health Insurance Portability and Accountability Act* (HIPAA).[48] The new technological ability, available on its *Alexa* virtual assistant (which abilities are termed "*skills*" by Amazon), is the result of a collaborative effort between Amazon, Giant Eagle (a grocery store and pharmacy retailer), and Omnicell (a medication-management company).[49] Customers will be able to review prescriptions, set reminders to take medications, and request prescription refills utilizing the new Alexa skill.[50] The main goal of this initiative, spurred from a trend of customers "*using Alexa to remind them to take medications on a regular basis*," is to simplify prescription management for customers taking multiple medications.[51] Amazon will ensure security by requiring customers to verify their identity with Alexa using both their voice and a passcode.[52] To maintain HIPAA-compliant privacy policies, the interactions with the skill will be redacted in the Alexa phone application.[53] This launch positions Amazon as an actor in one of the largest healthcare consumer markets, as over half of U.S. adults report taking prescription medications.[54] Moreover, Alexa's new skill could make a significant impact in reducing one of the largest avoidable healthcare costs – patient nonadherence with suggested medication regimens.[55]

This will most likely not be the last healthcare-related skill to come from Amazon's invite-only Alexa healthcare program, in which a number of select healthcare organizations collaborate with Amazon to develop HIPAA-compliant skills.[56] Amazon announced this new program in April 2019, along with the first six skills to be initially launched as part of the program.[57] The six initially launched skills, and their associated healthcare partners, include:

(1) Express Scripts – Checking the status of prescription deliveries;

(2) Cigna Health Today – Managing health improvement goals;

(3) My Children's Enhanced Recovery After Surgery (ERAS) (Boston Children's Hospital) –Allowing ERAS program patients and their parents to provide recovery updates to care teams and receive post-operative information;

(4) Swedish Health Connect (Providence St. Joseph Health) – Finding and scheduling same-day appointments with a local urgent care center;

(5) Atrium Health – Finding and scheduling same-day appointments with a local urgent care center; and,

(6) Livongo – Querying blood sugar readings and trends and receiving personalized health information.[58]

Increasing Competition

Corporate America's recent moves into the healthcare sector may result in increased price competition, a greater variety of services, and more price transparency for patients. Walmart[59] and Best Buy[60] both prominently display their prices for their services, in stark contrast to the current opaque nature of pricing by the healthcare industry establishment. Further, Walmart's persistence in ameliorating the workplace shortage problem on its own initiative is a novel approach not comparable to any other organization. Lastly, Amazon's high-tech approach to simplifying tasks for patients could result in better health outcomes for patients. While profit seems to be a significant driver for many of these corporate initiatives, the byproduct of the private sector's pursuit of higher profits may be better, more accessible healthcare for patients.

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COVID-19 Could Solidify Telehealth's Long-Term Future

[Excerpted from the article published in March 2020.]

One of the potential beneficiaries of the ongoing coronavirus (COVID-19) pandemic may very well be telehealth technology. The significant number of actions taken over the past month to relax regulatory and reimbursement restrictions has resulted in a windfall of demand for these telehealth providers, and may be unfeasible to reverse at the conclusion of the pandemic, once patients and providers become reliant on the new technology.

On March 6, 2020, President Donald Trump signed the $8.3 billion *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*.[1] One provision of the law, entitled the *Telehealth Services During Certain Emergency Periods Act of 2020* (TSDCEPA), gives authority to the Secretary of the *Department of Health and Human Services* (HHS) to lift some telehealth delivery restrictions.[2] The goal of this policy shift is to allow providers to render telehealth services to Medicare beneficiaries in their homes and prevent those patients from entering crowded or contaminated healthcare facilities. The telehealth changes relate to all conditions, not just those related to the coronavirus, or COVID-19.[3] Telehealth, also called telemedicine,[4] refers to "*the remote delivery of health care services and clinical information*,"[5] and most often manifests as real-time "*virtual visits*" (i.e., video chats) between patients and providers.

The Act lifts the "*originating site*" requirements for telehealth services.[6] Previously, the patient receiving the telemedicine services had to be located at a healthcare facility in:

(1) A county outside of a *Metropolitan Statistical Area* (MSA); or,
(2) A rural *Health Professional Shortage Area* (HPSA) located in a rural census tract.[7]

The relaxation of the "*originating site*" restriction allows telehealth services to be provided to patients in all areas of the country across all settings, e.g., within the patient's home.[8] The added flexibility will allow many more patients to access telehealth services during the emergency period, without the risk of infecting themselves or others.[9]

Further, a range of providers will now be able to offer telehealth to their patients, including nurse practitioners, social workers, and physicians.[10] Previously, which practitioners were allowed to receive reimbursement for telehealth services were dictated by state law.[11]

Three weeks later, on March 27, 2020, President Trump signed another economic stabilization package that provides $2 trillion to individuals, businesses, and states.[12] Among a myriad of other measures, the *Coronavirus Aid, Relief and Economic Security (CARES) Act* includes a number of additional provisions related to telehealth services, including:

(1) $200 million to the *Federal Communications Commission* (FCC) for telehealth development support;
(2) A removal of the requirement that a physician must have treated a patient within the last three years to receive payment for telehealth;
(3) Allowing hospice care to be recertified via telehealth;
(4) Expanded eligibility for home dialysis patients to receive telehealth; and,
(5) Increased flexibility for federally qualified health centers (FQHCs) and rural health clinics (RHCs).[13]

Billing of telehealth services during this period are to be coded the same as if the service was furnished in-person, but should use the Place of Service (POS) code "02-Telehealth;" No specific modifiers need to be associated with telehealth services furnished during the crisis period.[14] Of note, because telehealth services are professional services, no facility fee can be charged by the provider.[15]

Medicare beneficiaries will be able to receive common office visits, mental health counseling, and preventive health screenings via telehealth technology.[16] There are three main types of virtual visits that can be provided:

(1) *Medicare telehealth visits*: New or established patients[17] may receive services from providers through an interactive audio and video communication system that permits real-time communication. The visits are considered the same as in-person visits and, significantly, are paid at the same rate as regular in-person visits[18] – previously, most insurers reimbursed telehealth visits at 50% of its in-person counterpart.[19]
(2) *Virtual check-ins*: Established patients may have a brief (five to ten minute) communication via telephone, or exchange of information through video or image, with practitioners. These check-ins (likely initiated by the patient) are intended to avoid trips to the healthcare facility for quick questions of relatively small concern. The communication cannot be related to a medical visit within the previous seven days and cannot lead to a medical visit within the next 24 hours.[20]
(3) *E-visits*: Established patients may initiate communications with providers by using their online patient portal. The patient must generate the initial inquiry, and communication can occur over seven days.[21]

In addition to the above-listed visits, the *Drug Enforcement Agency* (DEA) published guidance on March 16, 2020 stating that during the pandemic, physicians will be able to prescribe controlled substances via telemedicine, without an in-person examination.[22]

Significantly, the HHS *Office of Inspector General* (OIG) will allow providers to reduce or waive pat ient cost-sharing for telehealth visits paid by federal healthcare programs for the duration of the pandemic.[23] The HHS *Office for Civil Rights* (OCR) will also waive penalties for violations of the *Health*

Insurance Portability and Accountability Act (HIPAA) against healthcare providers that serve patients in good faith through everyday communication, such as Skype or FaceTime, for the duration of the crisis.[24]

In response to this roll-back of regulations, demand for telemedicine services has surged upwards of 10- to 20-fold, overwhelming providers.[25] A number of companies and providers have large backlogs of patients, resulting in significant delays.

Over the past two years, the Trump Administration has incrementally expanded telehealth coverage under Medicare.[26] However, the current coverage expansion is the most significant change in the coverage of telehealth benefits since Medicare began reimbursing certain telehealth services in 2001.[27] The expansion comes at a critical time for healthcare organizations overwhelmed by the COVID-19 pandemic, and allows Medicare beneficiaries to receive medical services without risking their health or the health of others. Moreover, many industry stakeholders predict that these changes could serve as a harbinger for the future of telemedicine, and remain in place after the crisis subsides,[28] if it is proven to be a successful (and cost-effective) method of delivering healthcare services to beneficiaries.

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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.

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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); *The Health Lawyer* (ABA); *Valuation Strategies; Business Appraisal Practice*; and, *NACVA QuickRead*.

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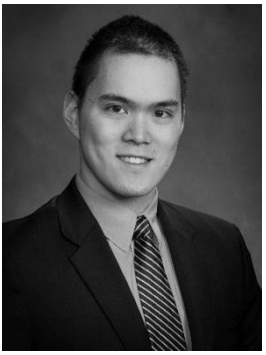

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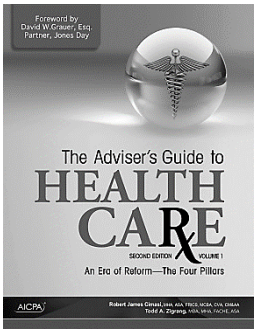

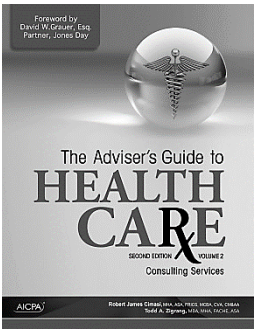

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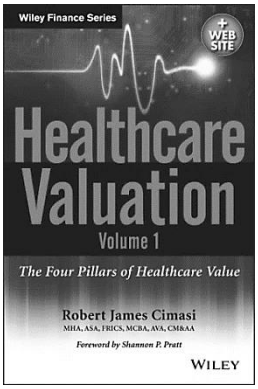

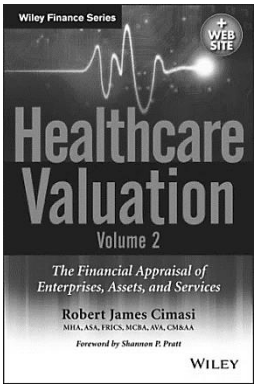

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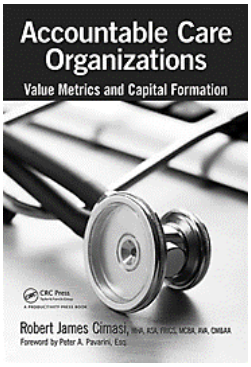

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