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DISCLAIMER

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

DEDICATION

As we celebrate our thirtieth year in service, the entire team at **HEALTH CAPITAL CONSULTANTS** *dedicates this 12th 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, ABV.

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

Janvi R. Shah, MBA, MSF, Senior Financial Analyst, has excelled in representing HCC throughout numerous healthcare client engagements, assisted with research, writing, review, and comments.

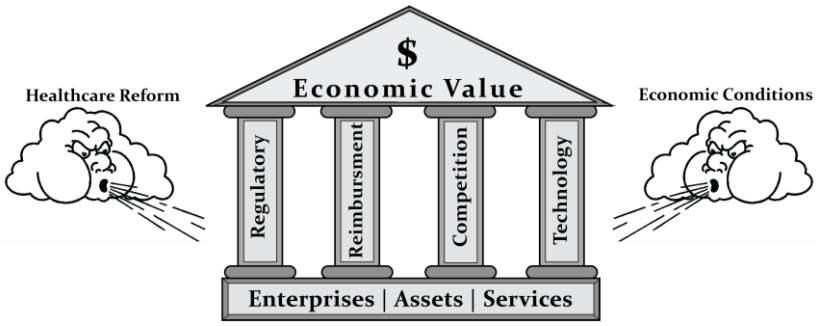
Sean J. Wallace, Director of Operations, was instrumental in the e-publishing, web archiving, and design of this book.

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

INTRODUCTION

In 2023, we at **HEALTH CAPITAL CONSULTANTS** (HCC) have witnessed, and our clients have experienced, industry changes in each of the *Four Pillars* i.e., regulatory, reimbursement, competition, and technology. See figure below.

The Four Pillars of the Healthcare Industry



Reimbursement changes, such as updates to the various Medicare payment systems and the introduction of new reimbursement models, were proposed and enacted amid the specter of continuing increases in healthcare expenditures, which are expected to surpass $7 Trillion by 2031. Many of the regulatory changes in 2023 were motivated by the end of the COVID-19 public health emergency (PHE) in May, while a highly-anticipated decision related to the False Claims Act was issued by the U.S. Supreme Court in June. Competition in healthcare has continued to be highly scrutinized, with the federal government taking steps to more closely regulate mergers and proposing to ban all non-compete clauses. Despite this emboldened enforcement, healthcare organizations continued to merge, albeit in more creative fashion and non-traditional players continued to enter the healthcare market. Technology – and related ethical considerations – came to the forefront of healthcare discussions in 2023, as AI is gaining more traction in healthcare and the industry is grappling with how to appropriately utilize the technology. This book is a selection of some of the changes mentioned above that have impacted how our clients operate and our considerations when performing valuations of healthcare enterprises, assets, and services.

INTRODUCTION *(Continued)*

At HCC, we strongly believe that 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.

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 on the previous page.

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, ABV
President

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HCC

HEALTH CAPITAL CONSULTANTS

Providing Solutions in an Era of Healthcare Reform for 30 Years

1993 - 2023

I. VALUATION TOPICS

Valuation of Remote Therapeutic Monitoring: Introduction

[This is the first article in a five-part series regarding Remote Therapeutic Monitoring This installment was published in July 2022.]

RTM, formally called Remote Therapeutic Monitoring/Treatment Management,[1] "encompasses the collection and monitoring of therapy adherence and therapy response data along with treatment management services."[2] The RTM concept was created in October 2020 by the Current Procedural Terminology (CPT) Editorial Panel.[3] RTM consists of five general medicine CPT codes, which were created in order to fill in some of the "noteworthy gaps that exist in the current coverage and delivery of [remote patient monitoring]….[and] help patients experience more consistency and quality along the continuum of care, especially in the realm of chronic disease monitoring."[4]

It is anticipated that incentivizing RTM may improve patient outcomes and reduce overall health spending as health issues may be identified earlier. This will likely become particularly pertinent for providers who participate in value-based reimbursement models. Additionally, RTM may improve data driven clinical decision making, allowing providers to construct personalized care plans to assist in achieving the best possible patient outcomes. Analyzing real-time data can also allow providers to identify trends and adjust care plans proactively. This may allow for a shorter recovery time for patients, further increasing cost effectiveness. From the provider perspective, the use of RTM has been found to result in improved workflow efficiencies, such as enhanced staff productivity and reduced administrative costs, which may lead to additional cost savings.

There are a number of similarities between RTM and remote patient (physiologic) monitoring (RPM). For example, the two services are billed at the same general rates, as the Centers for Medicare & Medicaid Services (CMS) has noted its intent to maintain payment parity between the two sets of codes.[5] The CPT codes themselves also generally mirror each other. However, RTM is different from RPM in two notable ways. First, RTM allows a greater number of provider types to order and bill for RTM (i.e., qualified healthcare practitioners who are unable to independently bill for evaluation & management services may bill for RTM). These practitioners may include physiatrists, physical therapists, occupational therapists, clinical psychologists, and dietitians.[6] Second, RTM does not monitor physiologic data such as heart rate, blood pressure, and blood sugar levels. Instead, RTM codes monitor health conditions (non-physiologic data) such as musculoskeletal system status, respiratory status, therapy/medication adherence, and therapy/medication response.[7] RTM is expected to be complementary to RPM.

RTM requires the use of a device to collect and report the non-physiologic data. Those devices must be "medical devices" (rather than a general wellness device such as an Apple Watch) as defined by the U.S. Food & Drug Administration (FDA).[8] However, the patient self-reported data may be from general wellness

devices, provided the data is collected and submitted via Software as a Medical Device, in addition to the standalone peripheral devices.[9]

One example of how RTM may be utilized in practice is as follows:

> "*An asthmatic patient is prescribed a rescue inhaler equipped with an FDA-approved medical device that monitors when the patient uses the inhaler, how many times during the day the patient uses the inhaler, how many puffs/doses the patient uses each time, and the pollen count and environmental factors that exist in the patient's location at that time. This is non-physiologic data. The data is then used by the treating practitioner to assess the patient's therapeutic response and adherence to the asthma treatment plan. This can enable the practitioner to better determine how well the patient is responding to the particular medication, what social or environmental factors affect the patient's respiratory system status, and what changes could be made to improve the patient's health*."[10]

The market for RTM may experience increasing demand in the coming years, due to an aging U.S. population and the growing prevalence of musculoskeletal and respiratory conditions. These factors may augment the number of individuals that are candidates for RTM.

In most industries, such a demand may lead to rising prices. However, in the healthcare industry, the federal government has some power to set prices through the Medicare and Medicaid programs. Further, with respect to Medicare reimbursement, the CPT codes for RTM just became effective in 2022. Consequently, there will likely be issues that arise over the next couple years that causes CMS to revise the payment amounts, or billing requirements, for RTM. Further, RTM's requisite reliance on one or more FDA-approved devices may serve as a ceiling on the swiftness with which providers can adopt and bill for RTM. Nevertheless, RTM may allow providers to streamline care and reduce costs through earlier identification of health issues and improving data-driven clinical decision making, which will prepare them for participation in value-based reimbursement models. The second installment of this five-part series will therefore cover the reimbursement environment of RTM.

Valuation of Remote Therapeutic Monitoring: Reimbursement

[This is the second article in a five-part series regarding Remote Therapeutic Monitoring
This installment was published in August 2022.]

The U.S. government is the largest payor of medical costs, through Medicare and Medicaid, and has a strong influence on physician reimbursement. In 2020, Medicare and Medicaid accounted for an estimated $829.5 billion and $671.2 billion in healthcare spending, respectively.[11] The prevalence of these public

payors in the healthcare marketplace often results in their acting as a price setter, and being used as a benchmark for private reimbursement rates.[12]

Medicare recently began paying for Remote Therapeutic Monitoring (RTM) through the Medicare Physician Fee Schedule (MPFS). MPFS payments are calculated according to Medicare's *Resource Based Relative Value Scales* (RBRVS) system, which is updated annually by the Centers for Medicare & Medicaid Services (CMS). The RBRVS system assigns relative value units (RVUs) to individual procedures based on the resources required to perform each procedure. Under this system, each procedure in the MPFS is assigned RVUs for three categories of resources:

(1) The physician work (wRVU) component, which represents the physician's contribution of time and effort to the completion of a procedure. The higher the value of the code, the more skill, time, and work it takes to complete;

(2) The practice expense (PE RVU), which is based on direct and indirect physician practice expenses involved in providing healthcare services. Direct expense categories include: clinical labor, medical supplies, and medical equipment. Indirect expenses include: administrative labor, office expenses, and all other expenses; and,

(3) The malpractice (MP RVU) expense, which corresponds to the relative malpractice practice expenses for medical procedures.[13] These values typically comprise the smallest component of the RVU, and due to the variation in malpractice costs among states and specialties, must be weighted geographically and across specialties.[14]

Once the procedure's RVUs have been modified for geographic variance, they are summed, and the total is then multiplied by a conversion factor to obtain the dollar amount of governmental reimbursement for a given service.[15]

The 2022 MPFS introduced five new general medicine Current Procedural Terminology (CPT) codes for the reimbursement of RTM, effective January 1, 2022:

(1) **98975:** Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment.

(2) **98976:** Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days.

(3) **98977:** Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days.

(4) **98980:** Remote therapeutic monitoring treatment management services, physician/other qualified healthcare professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes – base code.

(5) **98981:** Remote therapeutic monitoring treatment management services, physician/other qualified healthcare professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional add on code 20 minutes (list separately in addition to code for primary procedure).[16]

Notably, three of these codes are PE-only codes, while two include professional work (wRVUs). Also of note is that RTM requires the use of a device approved by the U.S. Food & Drug Administration (FDA), and CPT codes 98975, 98976, and 98977 require that device to monitor at least 16 days' worth of data in each 30-day period.[17] The 2022 payment rates for each of these codes are set forth below:[18]

CPT Code	2022 Non-Facility Reimbursement
98975	$19.38
98976	$55.72
98977	$55.72
98980	$50.18
98981	$40.84

For 2023, CMS proposes tweaking the RTM codes in response to stakeholder comments and CMS concern regarding who could perform certain codes. CMS suggests discontinuing payment for CPT codes 98980 and 98981; adding four new RTM codes related to monitoring and management services (as HCPCS G codes[19]); and adding a new CPT code for supplying Cognitive Behavioral Therapy Monitoring (CBTM) devices.

Specifically, CPT codes 98980 and 98981 are proposed to be eliminated and replaced with HCPCS codes GRTM1 and GRTM2,[20] which will allow the billing clinician to provide *general*, rather than *direct*, supervision, as the requirement to directly supervise staff providing RTM care management services was overburdening billing clinicians.[21] The two other new HCPCS codes proposed by CMS (GRTM 3 and GRTM 4) are for assessment services furnished by nonphysician qualified health care professionals (QHCPs) such as physical therapists, occupational therapists, and speech language pathologists.[22] Notably, these two codes are designated as "sometimes therapy" codes, which "means that the services could be billed outside a therapy plan of care" if billed by a physician or nonphysician provider, but not if the services are billed by a QHCP.[23] The new CPT code for CBTM devices, 989X6, will be a PE-only code "intended to provide reimbursement for RTM devices supplied to patients to

monitor a patients' adherence and response to a prescribed cognitive behavior therapy program."[24] This code is very similar to the device supply CPT codes 98976 and 98977 for respiratory and musculoskeletal devices under the Remote Patient Monitoring (RPM) codes.[25]

As the 2023 MPFS has not yet been finalized, there are no confirmed updates on the non-facility reimbursement rates for RTM services. Due to the newness of RTM, it is likely that CMS will continue to tweak the coverage of and payment for these services in the years to come through regulatory rulemaking. Consequently, the regulatory environment of RTM will be discussed in the next installment in this series.

Valuation of Remote Therapeutic Monitoring: Regulatory

[This is the third article in a five-part series regarding Remote Therapeutic Monitoring This installment was published in September 2022.]

Healthcare organizations and providers are increasingly seeking partnerships (often with healthcare tech companies that have developed a compatible medical device) to facilitate their provision of remote therapeutic monitoring (RTM) services to eligible patients. Because only a licensed healthcare provider can bill for RTM services, these arrangements often involve the provider compensating the device manufacturer for the devices used to perform the RTM. Such arrangements typically fall under the purview of federal fraud and abuse laws such as the Anti-Kickback Statute (AKS) and the Stark Law. This third installment of the five-part series on the valuation of RTM will discuss these regulatory hurdles.

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. Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.

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.[26] Notably, 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.[27] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, and/or

exclusion from Medicare and Medicaid as an alternative civil remedy to criminal penalties.[28] Interpretation and application of the AKS under case law has created 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 illegal remuneration.[29]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[30] In response, the law contains a number of statutory exceptions called *safe harbors*.[31] 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.[32] However, failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[33] It should be noted that, in order for a payment to meet the requirements of many AKS *safe harbors*, the compensation must not exceed the range of *Fair Market Value* and must be *commercially reasonable*.[34]

Of note, in December 2020, the Department of Health & Human Services (HHS) Office of Inspector General (OIG) released new revisions in a final rule, many of which are similar to those revisions to the Stark Law proposed by the Centers of Medicare & Medicaid Services (CMS), as discussed below.[35] Among the more notable revisions included are new safe harbors for value-based arrangements, wherein the safe harbor requirements lessen as the participants take on more financial risk. Additionally, several already-established safe harbors, such as personal services and management contracts and outcomes-based payment arrangements, were modified by this final rule.[36] These arrangements were changed to add more flexibility, e.g., by adding protections to certain outcomes-based payments.[37] Notably, the OIG also eliminated the requirement that aggregate compensation under these agreements is set in advance, instead of requiring the compensation methodology in advance; however, that methodology must be consistent with Fair Market Value and not directly take into account the volume or value of referrals or other business generated between the parties.[38]

The Stark Law prohibits physicians from referring Medicare patients to entities with which the physician or their family members have a financial relationship for the provision of *designated health services* (DHS).[39] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[40] 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 hospital services.[41]

Under the Stark Law, financial relationships include: (1) *ownership interests* through equity, debt, other means, and ownership interests in entities which then have an ownership interest in the entity that provides DHS;[42] and (2) *compensation arrangements*, which are defined as arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or in kind.[43] 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.[44] Similar to the AKS *safe harbors*, without these *exceptions*, the Stark Law may prohibit legitimate business arrangements. It must be noted that in order to meet the requirements of many *exceptions* related to compensation between physicians and other entities, compensation must: (1) not exceed the range of *Fair Market Value*; (2) not take into account the *volume* or *value of referrals* generated by the compensated physician; and, (3) be *commercially reasonable*.[45] Unlike the AKS safe harbors, an arrangement must fall within one of the *exceptions* in order to be legally permissible under the Stark Law.[46]

As noted above, in December 2020, CMS released a number of revisions to the Stark Law in a final rule, including:

(1) Revised definitions for Fair Market Value, General Market Value, and Commercial Reasonableness; and,
(2) New permanent exceptions for value-based arrangements.[47]

Importantly, the new value-based arrangements exceptions protect the following arrangements:

(1) Full financial risk arrangements: Includes capitated payments and predetermined rates or a global budget;
(2) Value-Based Arrangements with Meaningful Downside Financial Risk: Where a physician pays no less than 25% of the value of the remuneration the physician receives when he or she does not meet pre-determined benchmarks; and,
(3) Value-Based Arrangements: Applies regardless of risk level to encourage physicians to enter value-based arrangements, even if they only assume upside risk.[48]

Notably, a violation of the AKS or Stark is sufficient to state a claim under the *False Claims Act* (FCA); which prohibits individuals from knowingly submitting false claims to the government. Therefore, in addition to *civil monetary penalties* paid under the AKS and/or Stark, violation would create additional liability under the FCA, which itself carries *civil monetary penalties* of up to $25,076 plus treble damages.[49]

It is important to note that, the regulatory scrutiny of healthcare entities (especially with regard to fraud and abuse violations) has generally increased in recent years. Therefore, under current regulation, the severe penalties that may be levied against healthcare providers under the AKS, the Stark Law, and/or the FCA will likely raise a hypothetical investor's estimate of the risk of paying for RTM services.

Valuation of Remote Therapeutic Monitoring: Competition

[This is the fourth article in a five-part series regarding Remote Therapeutic Monitoring This installment was published in October 2022.]

With Medicare's recent decision to cover remote therapeutic monitoring (RTM),[50] it is anticipated that the number of providers utilizing RTM with their patient panels will significantly increase, which growth (as of now) is limited only by the supply of RTM devices (which will be discussed further in the forthcoming fifth installment in this series) and the conditions that RTM may monitor. Currently, the use of RTM is limited to musculoskeletal and respiratory conditions. Consequently, RTM demand is driven by those with chronic musculoskeletal and respiratory conditions who may benefit from the services.

Musculoskeletal conditions, also known as musculoskeletal disorders (MSDs), are diseases or injuries of the skeletal and muscular systems that may cause acute or chronic pain and interfere with daily activities.[51] MSDs occur in all major body areas, such as hands, arms, feet, and legs, and include a wide variety of conditions of the muscles, bones, and joints.[52] MSDs affect more than 50% of U.S. adults, approximately 75% of whom are 65 and older.[53] A 2017 Global Burden of Disease study indicated that MSDs were the second highest contributor to global disability, with 20-33% of people living with an MSD.[54] In 2015, more than 124 million adults (approximately 50.1 per 100 persons in the U.S.) reported having an MSD, an increase from 2005 (48.3 per 100 persons in the U.S.).[55] MSDs remain the most often reported medical condition in the U.S., exceeding the prevalence for both circulatory and respiratory diseases.[56]

MSDs can also result from chronic overuse of a particular muscle or joint, which can cause repeated *micro-traumas*, i.e., repetitive and more subtle events occurring over time, to the musculoskeletal system.[57] Such "*overuse injuries*" are generally more subtle than acute injuries, which are usually a result of *macro-trauma*, i.e., a single, traumatic event.[58] Overuse injuries are often treated with rest, ice, physical therapy (PT), and anti-inflammatory medicine;[59] however, in some cases, reconstructive surgery may be necessary in order to stabilize the joints or replace the torn ligament if the injury is severe enough.[60]

Other factors such as obesity can create additional erosion of the musculoskeletal system, not unlike the micro-trauma associated with overuse injuries. Similar to obesity, arthritis is a chronic condition that can cause significant damage to a patient's musculoskeletal system. Arthritis is one of the most common forms of MSD, and the disease is the leading cause of disability in the U.S., with approximately 91.2 million individuals in 2015 either having physician-diagnosed arthritis and/or reporting symptoms consistent with an arthritis diagnosis.[61] By 2040, it is expected that 25.9% of the U.S. adult population (78.4 million people) will have physician-diagnosed arthritis.[62] The

most common form of arthritis is *osteoarthritis* (affecting 30.8 million American adults), a degenerative or "*wear and tear*" disease that erodes the cartilage in the body's joints, such as the hands, knees, and hips, and causes pain, swelling, loss of motion, and disability.[63] As osteoarthritis worsens, bones may break down, develop growths, or chip off, causing inflammation and pain.[64] Specifically, individuals with sports injuries (both acute and overuse) are more likely to develop osteoarthritis.[65]

From 2012 to 2014, the U.S. spent over $882 billion on medical services related to MSDs.[66] Additionally, MSDs create significant indirect economic burdens on patients and the healthcare industry, accounting for nearly one-third of the injuries involving days away from work.[67] A 2013 study investigating the indirect economic costs of MSDs found that people who have "*increasing levels of difficulty [in] performing physical activities*" due to an MSD are more likely to miss work.[68] These indirect costs, e.g., lost productivity and product defects, can amount to up to five times the direct costs.[69] Another study found that the indirect cost due to earnings losses for U.S. adults with MSDs from 2012 to 2014 totaled $1,490 per person on average, or $97.5 billion in total.[70] Both direct and indirect costs due to MSDs in the U.S. represented an estimated 5.76% of the *gross domestic product* (GDP) between 2012 and 2014.[71] These figures illustrate both the loss of productivity for individuals, as well as the increased burden on government programs, caused by MSDs. It is hoped that RTM can help effectively manage these conditions, which will not just result in reduced healthcare costs, but also reduced indirect costs resulting in increased productivity.

Respiratory conditions, also known as respiratory diseases, are some of the most common non-communicable diseases in the world.[72] These conditions include, but are not limited to, chronic obstructive pulmonary disease (COPD), asthma, interstitial lung disease, silicosis, and asbestosis.[73] In 2019, respiratory disease accounted for 39.10 deaths per 100,000 in the U.S.[74]

It is estimated that over 25 million Americans have asthma; although the prevalence of asthma has increased since the 1980s, the death rate has been decreasing for the past 25 years.[75] Risk factors for asthma include family history, childhood respiratory infections, and being overweight. In 2017-2018, over 42% of Americans were classified as obese (up from 30.5% in 1999-2000),[76] which may partially explain the rise in asthma prevalence over the past four decades. While asthma affects all sexes, races, and ages, asthma morbidity and mortality rates are higher among African Americans, Puerto Ricans, Americans living below the federal poverty level, and Americans with certain workplace exposures.[77]

Further, approximately 14.8 million American adults have been diagnosed with COPD, although an additional 12 million are estimated to have COPD but have not yet been diagnosed; COPD is the 4th leading cause of death in the U.S.[78] COPD is largely caused by exposure to cigarette smoke.[79] As of 2019, approximately 34.1 million adults smoked cigarettes (14% of all American adults), a decrease from 2005 rates (20.9% of all American adults).[80] Although

the use of traditional cigarettes has decreased, electronic cigarette usage has increased. In 2018, approximately 8.1 million American adults were active e-cigarette smokers,[81] and in 2022, 2.5 million middle and high school students (approximately 1 in 10 students) were current e-cigarette smokers.[82]

The market for RTM may experience increasing demand in the coming years, due to an aging U.S. population and the growing prevalence of musculoskeletal and respiratory conditions. These factors may augment the number of individuals that are candidates for RTM. However, RTM's requisite reliance on one or more FDA-approved devices may serve as a ceiling on the swiftness with which providers can adopt and bill for RTM.

Valuation of Remote Therapeutic Monitoring: Technology

[This is the final article in a five-part series regarding Remote Therapeutic Monitoring This installment was published in November 2022.]

As discussed in the first installment in this five-part series on valuing remote therapeutic monitoring (RTM), such services require the use of a device to collect and report the non-physiologic data. Those devices must be "medical devices" (rather than a general wellness device) as defined by the U.S. Food & Drug Administration (FDA).[83] This final installment in this series will discuss the technological environment in which RTM operates.

The *Food, Drug, and Cosmetics Act* (FD&C Act) requires that a medical device be used in RTM. The FD&C Act defines "device" as:

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is…intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man...."[84]

Some examples of devices that may be utilized in RTM include:

(1) A sensor that attaches to an inhaler and sends information regarding where the inhaler is used (and links it to weather and air quality in the patient's area) and how often it is utilized (i.e., medication adherence);[85]
(2) A smart pill dispenser, which sends information regarding what drugs are dispensed and when (i.e., medication adherence);
(3) A smart-sensor shoe insole that tracks the temperature, inflammation levels, and pressure being applied to a diabetic patient's ulceration;[86] and,

(4) A digital goniometer that a patient can use at home to measure their range of motion before and after performing exercises recommended by their physical therapist.[87]

Note that wellness devices (e.g., apps that play sounds to reduce anxiety, food journal apps, FitBit and Apple watches, Apple Watch's blood oxygen sensor) are not considered medical devices by the FD&C Act. However, patients may self-report data from these devices provided they are collected and submitted via Software as a Medical Device (SaMD), in addition to the standalone peripheral devices.[88] In the RTM space, SaMD is likely the pathway through which data will be self-reported by patients, e.g., pain levels and medication adherence.[89] SaMD is defined the same as a medical device, except that the software (rather than the physical hardware) is performing that function. Further, that software can be used without being part of a hardware medical device.[90] Some examples of this are "software that allows a smartphone to view images obtained from a magnetic resonance imaging (MRI) medical device for diagnostic purposes" and "Computer-Aided Detection (CAD) software that performs image post-processing to help detect breast cancer."[91]

The market for RTM may experience increasing demand in the coming years, due to an aging U.S. population and the growing prevalence of musculoskeletal and respiratory conditions. These factors may augment the number of individuals that are candidates for RTM. However, RTM's requisite reliance on one or more FDA-approved devices may serve as a ceiling on the swiftness with which providers can adopt and bill for RTM. Nevertheless, RTM may allow providers to streamline care and reduce costs through earlier identification of health issues and improving data-driven clinical decision making, which will prepare them for participation in value-based reimbursement models. Ultimately, this could promote one of the central goals of healthcare reform, i.e., increased efficiency in healthcare and high quality care.

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Valuation of MA Plans: Introduction & Competition

[This is the first article in a three-part series regarding Valuation of MA Plans. This installment was published in March 2023.]

Medicare Advantage (MA) plans, also known as Part C plans, serve as a supplement or an alternative to Original (also called Traditional) fee-for-service (FFS) Medicare Part A and Part B coverage, but they are still part of the Medicare program.[1] Most of these plans also include Part D (drug) coverage. MA was created by Congress to offer seniors an alternative to Original Medicare – with an emphasis on treating and managing the health of the whole patient. MA plans are offered to Medicare beneficiaries by Medicare-approved private companies, known as MA Organizations (MAOs), which must follow rules set by Medicare.[2]

Under the MA program, Medicare purchases insurance coverage for Medicare beneficiaries from private MA plans. These plans can be advantageous for beneficiaries because they limit patient out-of-pocket costs for covered services (although out-of-pocket costs vary by plan) and may cover additional healthcare services (e.g., fitness programs, vision, dental, hearing) as well as other benefits (e.g., transportation to appointments, drugs/services that promote wellness).[3] Further, MA plans cannot charge more than Original Medicare for certain services like chemotherapy, dialysis, and skilled nursing facility care.[4] However, in order to manage costs, MAOs may require beneficiaries to utilize providers in the plan's network. Providers can join or leave a plan's provider network (and the network can change providers) anytime during the year.[5]

There are a number of different types of MA plans:

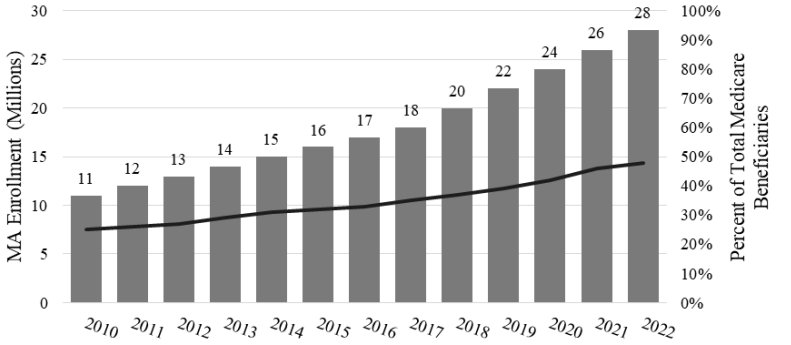
- Health Maintenance Organization (HMO): A type of plan that usually limits coverage to care from physicians who work for or contract with the HMO. It generally does not cover non-emergency out-of-network care. An HMO may require beneficiaries to live or work in its service area to be eligible for coverage. Beneficiaries are required to choose a primary care physician, and must obtain a referral to see a specialist. HMOs often provide integrated care and focus on prevention and wellness.
- Preferred Provider Organization (PPO): A type of plan where beneficiaries pay less if they use providers in the plan's network. Beneficiaries can use physicians, hospitals, and providers outside of the network without a referral for an additional cost. Beneficiaries do not have to choose a primary care physician.
- Private Fee-for-Service (PFFS) Plans: A type of plan where beneficiaries can see any of the providers in the plan's network. PFFS plans may not cover non-emergency out-of-network. Beneficiaries do not have to choose a primary care physician and do not have to obtain a referral to see a specialist.

- Special Needs Plans (SNPs): SNPs are limited to beneficiaries with specific diseases or characteristics, because those plans tailor their benefits, provider choices, and drug formularies to meet the specific needs of that patient population. All SNPs must provide drug coverage. The requirement to choose a primary care physician or whether a referral is required to see a specialist differs by plan.

There are two different categories of MA plans – local and regional. Local plans may be any of the types of plans listed above and may serve one or more counties. Regional plans, on the other hand, may only be PPOs and must serve all of a Centers for Medicare & Medicaid Services (CMS)-designated region (there are 26 regions in all), which comprise one or more states.[6] Local and regional plans are also paid differently by CMS. Enrollment in Medicare generally has increased, from 39.6 million beneficiaries in 2001 to an estimated 64 million beneficiaries in 2021.[7] This number is projected to further increase by approximately 1.5 million beneficiaries per year between 2022 and 2030, resulting in a projected 76 million Medicare enrollees by 2030.[8]

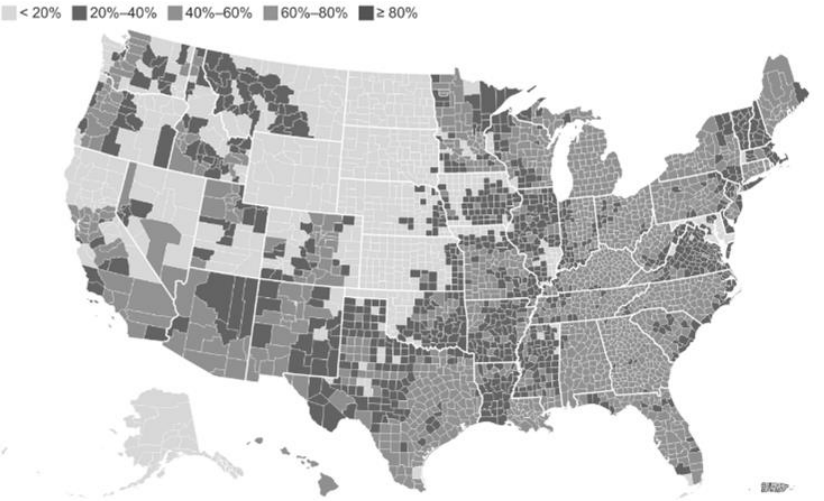
As illustrated in Exhibit 1 below, enrollment in MA plans grew much faster than overall Medicare, more than doubling between 2010 and 2020.[9] As of 2022, 28 million Americans were enrolled in an MA plan.[10]

Medicare Advantage Enrollment, 2010-2022[11]



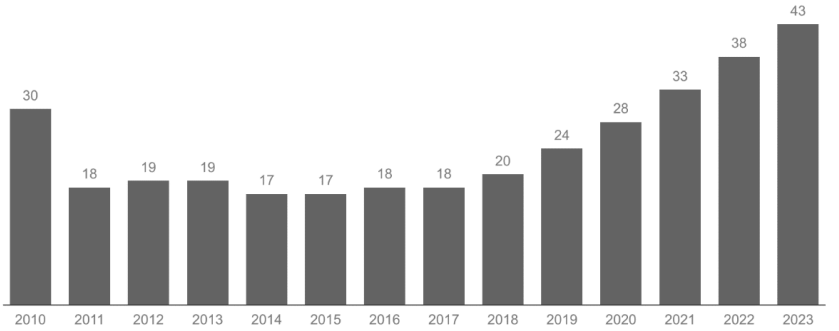
While nearly all Medicare beneficiaries have access to an MA plan,[12] it is important to note that MA enrollment is not well-distributed geographically, with the percent of Medicare beneficiaries enrolled in MA highest in the Eastern U.S.

Medicare Advantage Penetration by County, 2022[13]



Likely driven by the increasing number of Medicare enrollees, the number of MA plans has increased to 3,998 plans in 2023 (the greatest number of MA plans to date).[14] In 2023, the average Medicare beneficiary has access to 43 MA plans (more than double the 2018 number):

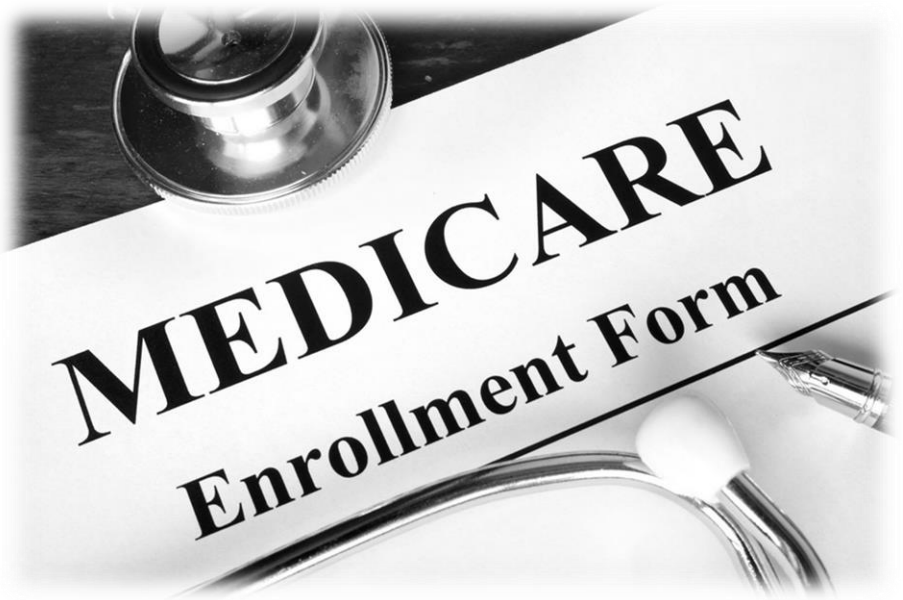
Average Number of MA Plans Available to Beneficiaries 2010-2023[15]



Due to the growing popularity of MA plans, and the number of Americans becoming Medicare eligible every year, MA is still an attractive market for insurers; in 2023, 8 insurers entered the MA market for the first time.[16] However, the market is quite concentrated, with UnitedHealthcare and Humana accounting for 46% of the market in 2022.[17] Nevertheless, industry experts report that MA competition is continuing to grow, and will have strong momentum going forward.[18] This competition is in large part due to the entry of non-traditional plan sponsors such as hospitals and non-healthcare providers. The last few years have seen the emergence of the "payvider," i.e., health

system-sponsored MA plans or MA plans jointly sponsored by payors and providers. In fact, almost 60% of health systems planned to become payviders in 2022.[19] Becoming a payvider allows health systems to diversify their risk-based payment strategy and vertically integrate "to gain control over the flow of care and better manage services delivered to members."[20] Additionally, nontraditional healthcare participants, such as Walmart and private equity (PE) firms, are entering the MA market. On September 7, 2022, Walmart and UnitedHealth Group announced a 10-year partnership, wherein jointly-branded MA plans will be offered to seniors in Georgia and Florida, near current Walmart Health locations, eventually expanding across the country to cover hundreds of thousands of beneficiaries.[21] This is not Walmart's first foray into the health plan space – in October 2020, the retail giant announced a partnership with insurer Clover Health to offer MA plans to low-income beneficiaries in Georgia.[22] In addition to Walmart, private equity firms have also been entering the MA space; as of 2021, approximately 2% of MAOs were owned by PE firms.[23] The entry of these nontraditional players may serve to disrupt the MA space, requiring current MAOs to be nimble in their provision of health services to in order to engage and maintain plan members.

Future installments in this three-part series on the valuation of MA plans will review the reimbursement and regulatory environments in which MA plans operate and the technological advancements being leveraged by MAOs to engage current members and attract new members.

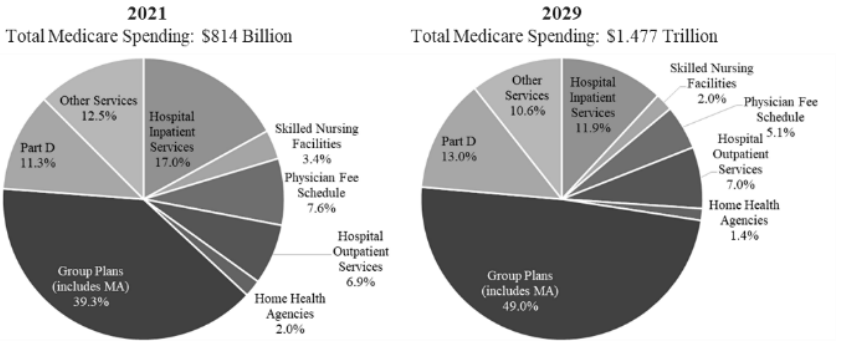


Valuation of MA Plans: Reimbursement & Technology

[This is the second article in a three-part series regarding Valuation of MA Plans. This installment was published in April 2023.]

As noted in the first installment of this three-part series on the valuation of Medicare Advantage (MA) plans, Medicare enrollment is expected to increase significantly over the next several years. As a result, Medicare spending is expected to nearly double over the same time frame.[24] As illustrated in Exhibit 1, group plans (which are largely comprised of MA plans) received 35% of all Medicare spending in 2021. That proportion is projected to grow to 49% by 2029:

Medicare Spending Categories, 2021 and 2029[25]



Medicare reimburses Local MA plans (a type of MA plan that can take a number of different forms, and serve one or more counties[26]) a fixed amount (capitated payment) per month. That amount is determined annually, based on a combination of:

(1) The plan's annual bid, in which they propose to Medicare the amount it would take to cover an average beneficiary, including administrative costs and the plan's profit;

(2) The bid is compared to the local benchmark, which looks at average fee-for-service (FFS) spending per Medicare beneficiary in each county. Plans are then assigned to a benchmark based on FFS spending in the counties at issue in the previous year (those counties with higher spending are assigned lower benchmarks);

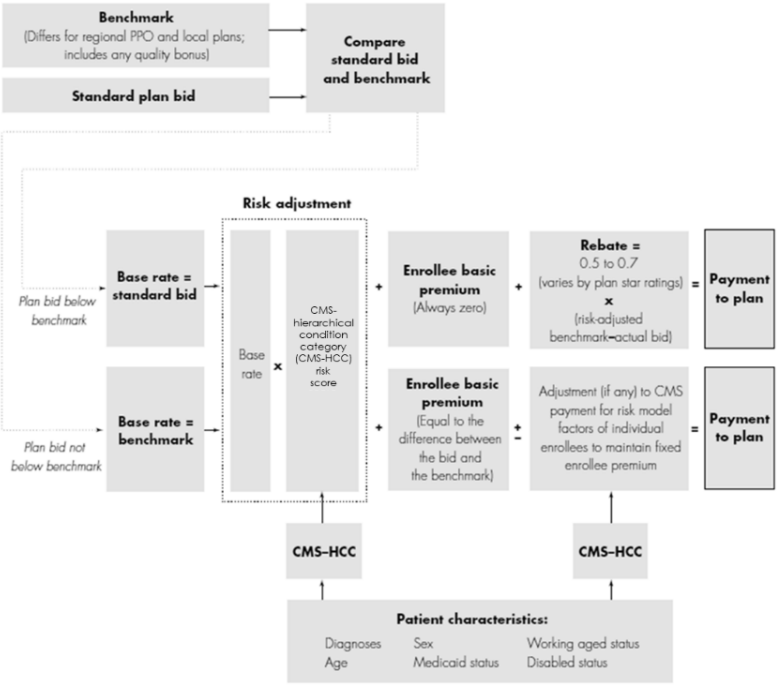
(3) The plan's Medicare star ratings; and,

(4) The plan's patient geographic and health risk characteristics.[27]

If the plan's bid is above the benchmark, "the plan receives a monthly base payment equal to the benchmark and its enrollees have to pay an additional

premium." If the plan's bid is the same as the benchmark, the plan is paid a monthly base payment equal to the benchmark. If the plan's bid is lower than the benchmark, the plan receives a monthly base rate equal to its bid, plus a "rebate" equal to a portion of the difference between the bid and the benchmark.[28]

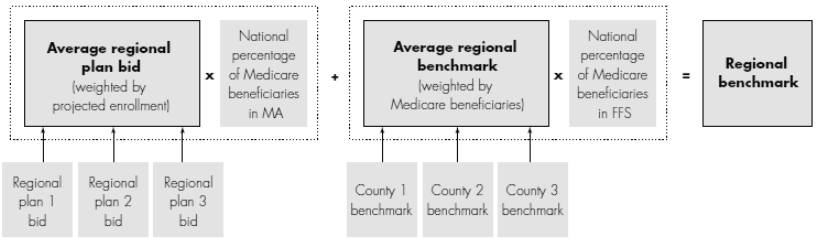
MA Payment System for Local Plans[29]



Note that this payment methodology only applies to Part A and Part B services; plans with Part D prescription drug benefits must submit a separate bid for that portion.[30]

The payment methodology for regional MA plans (preferred provider organizations that serve all of a region designated by the Centers for Medicare & Medicaid Services [CMS][31]) is more complex in that the benchmark formula includes the bids submitted by MA plans, as shown in the below schematic:

MA Payment System for Regional Plans[32]



Notably, although MA plan bids are typically cheaper than Traditional Medicare (i.e., MA plans are more cost effective), Medicare does not realize these cost savings – those cost savings are shared by the specific plans and their enrollees, in the form of extra benefits.[33] In fact, Medicare spends approximately 6% more on MA beneficiaries than on Traditional Medicare enrollees (up from a 4% in 2022), which is the antithesis of the reason for MA's establishment.[34] For that reason, the Medicare Payment Advisory Commission (MedPAC) has strongly urged CMS to apply "appropriate financial pressure similar to…providers in the traditional FFS program"[35] and even proposed specific changes to MA benchmark calculations in an effort to reduce MA payments.[36]

MA plans may be more cost effective than Traditional Medicare in part due to their leveraging of digital solutions to engage current members and attract new members. These efforts were accelerated by the COVID-19 pandemic, as MA plans sought to keep patients at home and cared for.[37] Perhaps the most important digital solution being embraced by MA plans is telehealth. A Deloitte analysis found that more MA members used telehealth in the first four months of 2020 than in all of 2019.[38] As a result of this dramatic shift toward the use of telehealth, those that do not have the technology are expected to be at a competitive disadvantage going forward. In fact, as of 2023, 97% of individual MA plans offer telehealth benefits, 75% offer remote access technologies, and 3% offer telemonitoring services.[39]

Particularly because of the patient demographics of those enrolled in MA plans (i.e., age 65 and older), plans are also ensuring that the technology is accessible. Toward that end, MA organizations (MAOs) are offering step-by-step instructions and helplines to assist members in utilizing the technology, and increasing access by providing hot spots that plan members can use to access Wi-Fi and join telehealth appointments.[40] Facilitating these efforts, CMS revised MA rules in April 2020 so that plans may now provide smartphones or other video devices (as a supplemental benefit) for members to use for their telehealth visits.[41]

As noted above, while MA plans have shown the ability to provide care more efficiently than Traditional Medicare, and plan bids are consistently chapter than Traditional Medicare, Medicare spends 6% more per MA enrollee, "a difference that translates into a projected $27 billion in 2023."[42] As a result, MedPAC has called for "a major overhaul of MA policies is urgently needed to reduce the gap between MA and FFS payment,"[43] a request that would necessitate regulatory action and increased oversight. The current state of regulatory enforcement of MA plans will be addressed in the last installment of this three-part series.

Valuation of MA Plans: Regulatory

[This is the final article in a three-part series regarding Valuation of MA Plans. This installment was published in May 2023.]

Healthcare provider organizations, including Medicare Advantage organizations (MAOs), face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. This final installment of the three-part series on the valuation of Medicare Advantage (MA) plans will review the regulatory environment in which these plans operate.

The MA Program is regulated under Title 42, Part 422 of the Code of Federal Regulations (CFR), but because MA organizations (MAOs) that wish to operate MA plans must have an insurance license in every state in which they operate, their conduct is also governed by state law. Federal law requires MA plans to offer the same benefits as Original Medicare, but they are also permitted to cover additional benefits, subject to the approval of the Centers for Medicare & Medicaid Services (CMS). Further, a plan is required to have an adequate network of providers who can offer all necessary services to the plan's beneficiaries, known as network adequacy. In order to demonstrate network adequacy, MAOs are required to file annual Health Service Delivery (HSD) tables to show the plan has enough facilities, primary care and specialty physicians, and other provider types within a certain time and distance requirement set by CMS.[44] To have proper network adequacy, an MAO must have contracts with these providers. CMS has several requirements that must be included in each provider contract between a MAO and a provider. It is then left to the two parties to negotiate a payment rate.

As MA utilization (by both MAOs and Medicare beneficiaries) has grown, so has regulatory enforcement of MA plans and organizations. In a September 2021 report, the U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG) found that MAOs were leveraging chart reviews and health risk assessments to maximize risk-adjustment payments – in other words, MA plans were fraudulently depicting their patients as sicker than they actually were in order to obtain higher payments from Medicare.[45] Subsequently, in April 2022, the OIG issued a report finding that 15 of the largest MAOs "have at times denied or delayed beneficiary access to care and provider payment requests for services that met Medicare coverage and MAO billing rules."[46] As a result, the OIG recommended that CMS:

(1) "Issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews";
(2) "Update its audit protocols to address the issues identified in this report, such as MAO use of clinical criteria, and/or examine particular service types"; and,

(3) "Direct MAOs to take additional steps to identify and address vulnerabilities that can lead to manual review errors and system errors."[47]

CMS concurred with all three of these OIG recommendations,[48] indicating that additional MA regulation may be forthcoming.

In addition to additional regulations aimed at MAOs, the U.S. Department of Justice (DOJ) has been active over the past decade in regulatory enforcement, largely by pursuing fraud actions against MAOs. A recent New York Times review of "dozens of fraud lawsuits, inspector general audits and investigations by watchdogs" found that 9 of the top 10 MAOs have been accused of fraud, largely in the form of overbilling, which has resulted in overpayments from Medicare totaling billions of dollars.[49] As recently as 2022, the DOJ has made clear in press releases that one of its priorities is "investigating and litigating a growing number of matters related to the Medicare Advantage program."[50]

MAOs are expected to face increased enforcement and scrutiny going forward, as MA grows in terms of enrollment and federal spending.[51] Enforcement actions against MAOs have largely focused on violations of the False Claims Act (FCA), and has primarily involved risk adjustment activities.[52] Allegations, which vary among MAOs, include:

(1) Adding unsupported diagnosis codes;
(2) Conducting "one-sided" reviews of patient charts to identify codes (but not deleting them);
(3) Developing data mining software to identify missed diagnosis codes, and using addenda to retroactively add them;
(4) Using vendors to identify diagnosis codes through in-home assessments of patients; and
(5) Failing to delete diagnosis codes that are not supported.[53]

In a 2022 report, the HHS OIG criticized MAOs for using prior authorization to deny their members access to services that were medically necessary, and to deny payments to providers for these services.[54] The OIG is also expected to increase enforcement actions against MAOs for denial of services that are deemed medically necessary.[55]

On April 5, 2023, CMS released a final rule that would increase the oversight of MA plans, and align them more with Original Medicare plans.[56] This ruling would:

- Access gaps in behavioral health services;
- Further streamline the prior authorization process;
- Establish additional health plan utilization management oversight processes to include required annual reviews of MA plan policies;
- Establish reviews of coverage denial reviews by healthcare professionals with relevant expertise;
- Tighten MA marketing rules to protect beneficiaries from misleading advertisements and pressure tactics;

- Expand requirements for MA plans to provide culturally and linguistically appropriate services; and
- Make changes to MA star ratings to address social determinants of health.[57]

The various government actions described above, with the most recent final rule from CMS, indicate that the federal government may continue its relatively intense regulatory scrutiny of MA plans in the future. CMS, which regulates MAOs, has been urged by MedPAC, the OIG, and the U.S. House of Representatives, among others, to increase oversight and enforcement of MA plans.[58] Whether it will heed these urgings, and further intensify MA scrutiny, remains to be seen.

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Valuation of Clinical Laboratories: Introduction and Competitive Environment

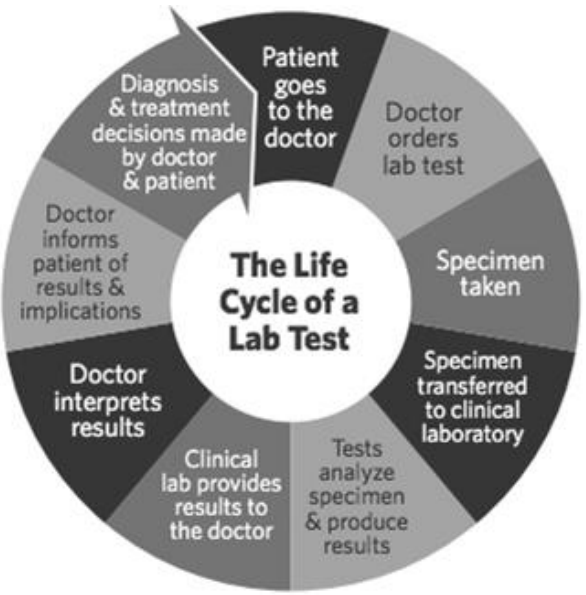
[This is the first article in a three-part series regarding Valuation of Clinical Laboratories. This installment was published in December 2022.]

Clinical laboratories (referred to in shorthand as "clinical labs") are healthcare facilities wherein healthcare professionals such as pathologists and laboratory technologists extract and/or analyze samples of biological specimens collected from patients, typically bodily fluids (e.g., blood, urine, cerebrospinal fluid) and tissues, to help diagnose conditions.[1] Clinical labs are usually located in hospitals, in physician offices, or in an independent setting.[2] Further, these laboratories can generalize and provide common diagnostic laboratory tests or they can specialize in certain disease-specific diagnostic and confirmatory tests or certain types of tests, including:

- Clinical Chemistry;
- Clinical Microbiology;
- Hematology;
- Blood Banking and Serology (a/k/a transfusion medicine);
- Clinical Microscopy;
- Histopathology and Cytopathology;
- Molecular Biology; and,
- Public Health (e.g., water analysis, testing for environmental substances, other tests related to public and environmental health).[3]

The typical process for a lab test is set forth below in Exhibit 1.

Exhibit 1: Lab Test Life Cycle [4]



Several types of facilities may provide clinical lab testing, including: hospitals, physician offices, and independent laboratory providers. Recently, independent medical laboratories have gained market share, accounting for 42% of the U.S. medical laboratory testing market (hospitals account for approximately 55% and physician offices for about 4%).[5] Over the past half-decade, the industry has seen increased competition from hospital outreach programs and physician insourcing.[6] However, the increasing demand for clinical lab testing is anticipated to result in a shortage of clinical lab services, negating any competitive concerns among providers.

Clinical labs are integral to the healthcare sector, as approximately 70% of medical decisions depend on laboratory test results.[7] The principal demand driver for this industry is the aging Baby Boomer population and their high prevalence of chronic illnesses (approximately 78% of Americans age 55+ have one or more chronic illnesses[8]), which require frequent testing and routine monitoring.[9]

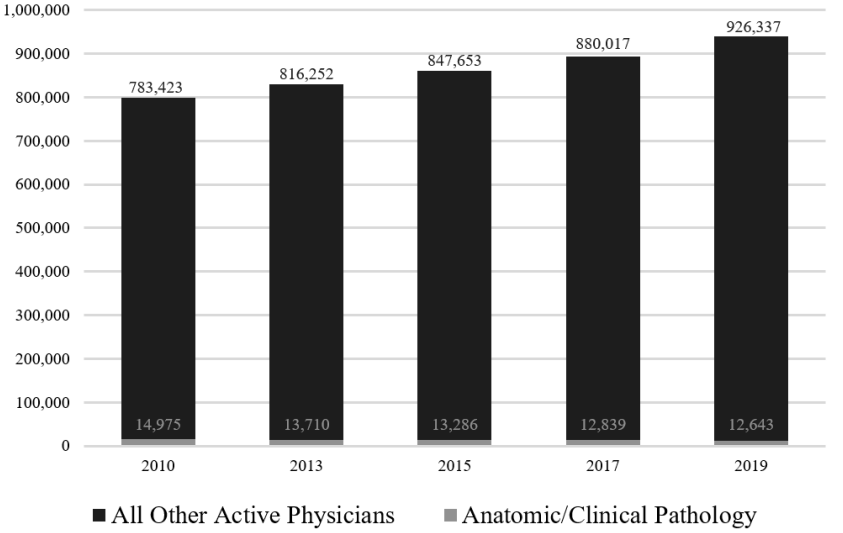
These labs have experienced increased demand from the COVID-19 pandemic, wherein testing was vital to controlling the virus's spread.[10] While the frequency of testing has receded, the demand for COVID-19 testing may continue as various businesses require COVID-19 testing to return to work upon experiencing symptoms and for patients prior to undergoing medical procedures. Further, with the increasing prevalence of other respiratory viruses (e.g., influenza and RSV),[11] clinical labs may play a significant role in testing for these viruses as well. However, the potential for these labs to expand and meet this demand will likely be restricted by the amount of staff available to analyze the tests.

According to the Centers for Medicare & Medicaid Services (CMS), there are approximately 279,000 CLIA-certified laboratories in the U.S.[12] Industry revenue grew at an annual rate of 1.6% between 2017 and 2022, and industry analysts expect revenue to grow between 2.5% and 6.4% annually over the next few years.[13] Further, industry consolidation has bolstered profitability in the industry as laboratories have collaborated with hospitals that lack in-house testing.[14] This increased demand has surpassed the supply of skilled laboratory employees, as the aging workforce has caused a shortage in the sector coupled with fewer individuals pursuing these healthcare professions.[15] The National Accrediting Agency for Clinical Laboratory Sciences reports that an estimated 7,000 new laboratory jobs are needed annually, but only 6,000 new graduates are entering the industry each year, resulting in an estimated shortage of 1,000 laboratory professionals each year.[16] Moreover, the U.S. Department of Labor reports that only a third of these professionals are being trained, exacerbating the shortage.[17]

As demand for clinical lab testing rises, the need for pathologists – physicians specialized in disease diagnosis utilizing laboratory analysis – is likely to also increase. As set forth in the below exhibit, the number of pathologists practicing in the U.S. has decreased 1.9% per year since 2010, despite the number of active

physicians in general increasing 1.9% annually.[18] Nevertheless, pathology remains the 17th most popular specialty of all physicians.[19]

Exhibit 2: Physician Supply by Self-Designated Specialization, 2010-2019[20]



Compounding the issue of the declining pathology workforce is the proportion of the current pathology workforce nearing retirement – as of 2020, over two thirds of pathologists were age 55 or older.[21] According to a physician workforce analysis published by the *Association of American Medical Colleges* (AAMC) in March 2016, physicians typically retire at the age of 67.[22] Accordingly, over half of the pathology workforce may retire in the next 10 years.

One factor that may contribute to a potential shortage of pathologists is the lack of available residency positions in the specialty. In 2022, 994 medical students competed for just 631 pathology residency positions.[23] If the current trend of new entrants remains stable, then the next ten years may see more pathologists retiring than entering the workforce, causing the total supply to shrink while demand continues to grow, which may result in a shortage.

Considering the seemingly inevitable gap between supply and demand, clinical labs may face some challenges in the coming years. With the growth in the Baby Boomer population, a significant portion of whom have one or more chronic conditions, clinical labs may greatly benefit from the potential associated rise in demand. However, a clinical lab's ability to meet this demand may be hindered by the shortage of pathologists and other laboratory professionals. Therefore, clinical labs that are positioned to adopt rapidly-advancing technology may be able to utilize technology to automate some manual work in order to thwart any workforce shortage. Further, in some industries, a gap between supply and demand may lead to increased prices, but

with the U.S. healthcare system's third-party payor system, in which the government has an outsized influence, the typical supply-demand dynamic does not affect prices. The next installment of this two-part series will cover the reimbursement and technological environments for clinical labs.

Valuation of Clinical Laboratories: Technology & Reimbursement Environment

[This is the second article in a three-part series regarding Valuation of Clinical Laboratories. This installment was published in January 2023.]

As discussed in the first installment of this three part series on the valuation of clinical laboratories, services provided by these labs rely on common diagnostic laboratory tests and disease-specific diagnostics to diagnose medical conditions. Medical advancements and technological innovation have brought new tests and equipment, as well as new techniques, which have allowed greater efficiency and automation. Clinical lab technology is expected to play a crucial role in the delivery of future healthcare services, especially given that healthcare reimbursement for clinical lab services (as discussed below) does not rise and fall to meet supply and demand.[24]

The U.S. government is the largest payor of medical costs, through Medicare and Medicaid, and has a strong influence on laboratory reimbursement. In 2021, Medicare and Medicaid accounted for an estimated $900.8 billion and $734 billion in healthcare spending, respectively.[25] The prevalence of these public payors in the healthcare marketplace often results in their acting as a price setter, and being used as a benchmark for private reimbursement rates.[26]

Medicare Part B provides coverage for clinical lab services that are "medically reasonable and necessary… [and must be] ordered by a physician or a qualified nonphysician practitioner."[27] Notably, during the COVID-19 public health emergency, these requirements have been relaxed so that additional healthcare professionals can order diagnostic tests; this is likely to be rescinded at the end of the public health emergency (PHE).[28] Most clinical lab services are paid under the Clinical Lab Fee Schedule (CLFS), although some services that require physician input (e.g., surgical pathology) are paid under the Medicare Physician Fee Schedule (MPFS).[29] There are over 1,600 Healthcare Common Procedure Coding System (HCPCS) codes that are reimbursed under the CLFS.[30]

Effective 2018, the Protecting Access to Medicare Act (PAMA) required CLFS payment rates to be "based on the weighted median of private payer rates."[31] This weighted median for each HCPCS code is calculated annually by CMS and has been slowly phased in to ensure payment rates are not significantly reduced. Between 2022 and 2024, payment rates for any service cannot be

reduced more than 15% from year to year.[32] Notably, unlike most Medicare payment systems, CLFS rates do not vary geographically and are not updated annually based on inflation; there is one CLFS payment rate for all facilities, and most payment rates are in effect for at least three years at a time.[33]

Because COVID-19 tests did not exist before the pandemic, the reimbursement rates for these tests had to be determined by CMS outside of the annual CLFS update. Currently, CMS reimburses clinical labs $100 per COVID-19 test (when ordered by a physician or other healthcare practitioner) if the test is turned around within two calendar days; however, if a laboratory takes longer than two days, CMS only reimburses $75 per test.[34] Notably, the regulations dictating this reimbursement is only effective for the term of the PHE.[35] Once the PHE expires, it is unclear whether CMS will continue reimbursing for COVID-19 tests and, if so, whether the reimbursement amount will remain the same.

An important driver in the changing marketplace of clinical labs has been automation. There are stages to automation within a laboratory, which occur in three parts.[36] The first stage, the pre-analytic stage, begins with test ordering through computer systems to help assist in turnaround times of results. For hospital settings, cylinder tube delivery systems may be utilized to receive samples, and for independent labs, couriers are utilized. Specimens are then collected and analyzed by laboratory staff to ensure the minimum specific amount and appropriate tubing is used. Specimens are often labelled with barcodes to further automate the diagnostic process, and processes like specimen handling or preparation can even be automated. While some clinical lab tests are manually evaluated, most are performed using technically advanced instrumentation. There is still potential for additional automation, particularly in preanalytic processes (e.g., specimen collection, labeling, transfer, and preparation).[37]

The second stage, the analytic stage, begins with automation. Over the past few years, there have been major technological advancements in laboratory medicine's analytic phases, which have significantly improved clinical lab diagnostics and monitoring.[38] For example, laboratory automation has proliferated in recent years, by way of devices such as the Robot Chemist, which automated historically manual analytical steps.[39] Development in the area of automation has allowed for "improved efficiency, higher throughput, larger assay menus, and reduced errors."[40]

The third and final stage begins with the use of computer programs to deliver results and can be expected to reduce costs that are incurred through fax and phone usage. Laboratory staff can assist providers in further evaluating results of tests; however, this final step allows for the care of patients to revert back in to the hands of a provider. Other parts of this stage can include the routine maintenance of equipment within the laboratory.[41]

Additionally, the concurrent development of artificial intelligence (AI) "may pave the way for an era of precision and personalized medicine, adding significant value to the critical role of the laboratory within healthcare

provision."[42] AI is utilized in medical labs through identifying health problems by lab samples from patients and comparing it to other results in a database. Additionally, pathologists have begun to use it to reduce the possibility of medical errors.[43] While AI is currently used in only a minority of clinical labs, those who do utilize AI largely believe it to be valuable or extremely valuable, and apply it in disease diagnosis, patient risk profile review, preempting rapid response solutions, and transmittal of laboratory results.[44]

While technological advancements may increase patient access to testing, these advancements may also pose a competitive threat to clinical labs going forward.[45] For example, point-of-care testing, such as at-home COVID-19 tests, can be completed without the input of a clinical lab.[46] Nevertheless, such advancements may ameliorate the workforce shortage in clinical labs. For example, the Abbott ID NOW COVID-19 assay, has equipped hospitals, physician offices, and urgent care clinics all over the nation to detect positive COVID-19 results in five minutes or less. This device, which was approved under the Food and Drug Administration's (FDA) Emergency Use Authorization, can use nasal, throat, and nasopharyngeal swabs.[47] The company has also manufactured devices that address other illnesses such as strep, respiratory viruses, and both types of influenza, allowing quick on-site turnarounds for testing without the input of a clinical lab.

Considering the trends discussed in this series, clinical labs may face some additional challenges in the coming years. As noted in the first installment in this series, the growth in the Baby Boomer population, a significant portion of whom have one or more chronic conditions, may create significant demand that greatly benefit clinical labs. However, a clinical lab's ability to meet this demand may be tempered by the shortage of pathologists and other laboratory professionals. While ensuring their workforce does not dwindle during periods of high demand, clinical labs will also need to adhere to federal and state law to avoid regulatory scrutiny, as discussed in the next installment of this series. Additionally, as discussed in this installment, clinical labs that are positioned to adopt rapidly-advancing technology may be able to utilize technology to automate some manual work in order to thwart any workforce shortage.

The last installment in this three-part series will discuss the regulatory environment in which clinical labs operate.

Valuation of Clinical Laboratories: Regulatory Environment

[This is the final article in a three-part series regarding Valuation of Clinical Laboratories. This installment was published in February 2023.]

Clinical laboratories face a range of federal and state legal and regulatory constraints that 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 greatest impact on the operations of healthcare providers. Further, clinical labs must adhere to regulations mandating minimum quality control standards, most notably federal requirements under the Clinical Laboratory Improvement Amendments (CLIA). The last installment in this three-part series on the valuation of clinical labs will discuss the regulatory environment in which these organizations operate.

Federal Fraud and Abuse Laws

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.[48] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[49]

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,[50] even if only one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[51] Notably, 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,[52] only an awareness that the conduct in question is "*generally unlawful*."[53] Further, a violation of the AKS is sufficient to state a claim under the *False Claims Act* (FCA).[54]

Criminal violations of the AKS are punishable by up to ten years in prison, criminal fines up to $100,000, or both, and civil violations can result in administrative penalties, including exclusion from federal healthcare programs, and civil monetary penalties plus treble damages (or three times the illegal remuneration).[55] In addition to the civil monetary penalties paid under the AKS, if the AKS violation triggers liability under the FCA, defendants can incur

additional civil monetary penalties of $13,508 to $27,018 per violation, plus treble damages.[56]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[57] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to the U.S. Department of Health & Human Services (HHS) to protect certain business arrangements by means of promulgating several *safe harbors*.[58] 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.[59] Failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[60] It should be noted that, in order for a payment to meet the requirements of many AKS *safe harbors*, the compensation must not exceed the range of *fair market value* and must be *commercially reasonable*.

Of note, in a December 2020 final rule, the HHS Office of Inspector General (OIG) released several revisions to the AKS, many of which are similar to those revisions to the Stark Law proposed by the Centers for Medicare & Medicaid Services (CMS), as discussed below.[61] Among the more notable revisions are new safe harbors for value-based arrangements (the safe harbor requirements for which arrangements lessen as the participants take on more financial risk) and revisions to existing safe harbors.[62]

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).[63] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[64] For the purposes of this article, DHS include, but are not limited to, clinical lab services and inpatient and outpatient hospital services.[65]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities also have an ownership interest in the entity that provides DHS.[66] 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.[67]

Civil penalties under the Stark Law include overpayment or refund obligations, a potential civil monetary penalty of $15,000 for each service, plus treble damages, and exclusion from Medicare and Medicaid programs.[68] Further, similar to the AKS, violation of the Stark Law can also trigger a violation of the FCA.[69]

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.[70] Similar to the AKS safe harbors, without these exceptions, the Stark Law may prohibit legitimate business arrangements. It must be noted that in order to meet the requirements of many exceptions

related to compensation between physicians and other entities, compensation must: (1) not exceed the range of fair market value; (2) not take into account the volume or value of referrals generated by the compensated physician; and, (3) be commercially reasonable. Unlike the AKS safe harbors, an arrangement must fully fall within one of the exceptions in order to be shielded from enforcement of the Stark Law.[71]

As noted above, in December 2020, CMS released a number of revisions to the Stark Law in a final rule, including:

(1) Revised definitions for Fair Market Value, General Market Value, and Commercial Reasonableness; and,
(2) New permanent exceptions for value-based arrangements.[72]

Importantly, the new value-based arrangements exceptions protect the following arrangements:

(1) Full Financial Risk Arrangements: Includes capitated payments and predetermined rates or a global budget;
(2) Value-Based Arrangements with Meaningful Downside Financial Risk: Where a physician pays no less than 25% of the value of the remuneration the physician receives when he or she does not meet pre-determined benchmarks; and,
(3) Value-Based Arrangements: Applies regardless of risk level to encourage physicians to enter value-based arrangements, even if they only assume upside risk.[73]

It is important to note that, the regulatory scrutiny of healthcare entities (especially with regard to fraud and abuse violations) has generally increased over the past two decades. Therefore, under current regulation, the severe penalties that may be levied against healthcare providers under the AKS, the Stark Law, and/or the FCA will likely raise a hypothetical investor's estimate of the risk related to clinical lab services.

Clinical lab Improvement Amendments (CLIA)

Prior to 1988, only independent and hospital laboratories were subject to federal regulation under the *Medicare, Medicaid, and Clinical labs Improvement Act of 1967*.[74] Following a public outcry after numerous reports of inaccurate Pap smear results, Congress passed the *Clinical lab Improvement Amendments* (CLIA), and its subsequent amendments, in order to improve the quality of laboratory test results.[75] Three agencies – CMS, the Food & Drug Administration (FDA), and the U.S. Centers for Disease Control and Prevention (CDC) – possess regulatory authority over clinical labs under CLIA.[76] CMS is charged with regulating healthcare providers who perform laboratory testing on patient specimens in order to ensure accurate and reliable test results.[77] Laboratory testing performed for forensic purposes; on human specimens without patient specific results; or, drug testing by *Substance Abuse and Mental Health Service Administration* (SAMHSA) laboratories are exempted from CLIA's requirements.[78]

CLIA regulations categorize laboratory testing procedures by complexity, assigning each test to a waived, moderate, or high level.[79] A test's category is determined by assessing its complexity, on a scale of 1 to 3, based on seven distinct areas:

(1) The level of scientific and technical knowledge required to perform the test;
(2) The level of training and experience required for the three pre-analytic, peri-analytic, and post-analytic phases of the test;
(3) The stability and reliability of the materials needed for the test;
(4) The relative ease or difficulty of each step of the testing process;
(5) The calibration, control, and proficiency of the testing materials;
(6) The relative ease or difficulty of maintaining or troubleshooting the testing system; and,
(7) The amount of interpretation and judgment needed during the three phases of the test.[80]

Laboratories only performing the lowest level complexity tests, known as "*waived tests*," must enroll in CLIA, pay applicable fees, and follow specific manufacturing instructions as well as standards related to cytology tests.[81] Laboratories performing moderate and high level complexity tests are subject to more stringent rules that set minimum qualifications for individuals who perform or supervise testing procedures. Laboratories performing moderate and high level complexity tests must satisfy quality standards related to: (1) proficiency testing; (2) patient test management; (3) quality control; and, (4) personnel training.[82] Penalties for non-compliance include: *"(A) Use of intermediate sanctions; (B) Suspension, limitation, or revocation of the certificate of a laboratory that is out of compliance with one or more requirements for a certificate; and, (C) Civil suit to enjoin any laboratory activity that constitutes a significant hazard to the public health."*[83]

COVID-19 Testing Enforcement

During 2020, the first year of the COVID-19 pandemic in which COVID-19 tests were available, Medicare spent approximately $1.5 billion on COVID-19 tests alone.[84] The federal government also issued a number of regulatory "flexibilities" to ease provider burden during the public health emergency (PHE). For example, during the PHE, Medicare beneficiaries may obtain their first COVID-19 test without a physician/practitioner order, but must obtain an order for subsequent tests. Additionally, some documentation and recordkeeping requirements for COVID-19 test orders were removed. However, CMS has made clear that "After the PHE, Medicare will require all COVID-19 and related testing that is performed by a laboratory to be ordered by a physician or other practitioner."[85] Further, in order to ensure proper government spending occurred for these tests, the OIG announced in December 2021 its plans to audit tests, "looking more closely at which lab tests had declines in volume in 2020….[as well as] monitor annual payments for lab tests, including COVID-19 tests."[86]

Conclusion

Considering the various competitive, reimbursement, technological, and regulatory trends discussed in this three-part series, clinical labs may face some challenges in the coming years. As noted in the first installment, the growth in the Baby Boomer population, a significant portion of whom have one or more chronic conditions, may create significant demand that greatly benefit clinical labs. However, a clinical lab's ability to meet this demand may be tempered by the shortage of pathologists and other laboratory professionals. Therefore, as discussed in this second installment, clinical labs that are positioned to adopt rapidly-advancing technology may be able to utilize technology to automate some manual work in order to thwart any workforce shortage. Further, in some industries, a gap between supply and demand may lead to increased prices, but with the U.S. healthcare system's third-party payor system, in which the government has an outsized influence, the typical supply-demand dynamic does not affect prices. In fact, Medicare reimbursement is expected to stay stagnant (if not decrease) in the next couple of years. This will require clinical labs to be clinically efficient – while remaining compliant with regulations and keeping clear of government enforcement initiatives – in order to survive.

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Valuation of Healthcare Start-Ups

[Excerpted from the article published in March/April 2023 issue of The Value Examiner.]

Start-up companies have seen an unprecedented rise in the healthcare industry over the past decade. Driven by high service demand, service inefficiencies, opportunities for innovation, and add-on investment potential, these companies seek to disrupt the healthcare delivery system, as well as make money in a sector that has historically provided consistently lucrative returns. This article will (1) define start-ups generally and discuss the unique characteristics of the U.S. healthcare industry, and how those characteristics result in differences between healthcare start-ups and start-ups in other industries, and (2) review the valuation approaches, methods, and techniques that may be used in valuing healthcare start-ups, including a consideration of risk factors.

Introduction to Start-ups

Start-ups can be characterized as being in the preliminary stages of business operations; focusing on a single product or service; requiring significant financial investment (from the founders or outside investors, for a piece of the company); experiencing rapid growth; and having the ultimate goal of an initial public offering (IPO)—that is, going public.[1]

Start-ups in the healthcare industry have become quite popular, demonstrated in part by the record amount of private equity (PE) money invested in healthcare in 2021—$151 billion and 515 deals[2]—and where that money was invested. The top sectors for PE investment (and thus start-ups) were telehealth, digital health, and health information technology. The trends driving investment include

- Movement toward virtual management of health conditions;
- Technological support of the healthcare workforce shortage; and
- Interest in solving the mental health crisis.

Start-ups are also focusing on new paths of meeting the needs of patients and providers, including the following:

- Remote patient monitoring
- Pairing patients with providers
- Virtual care platforms
- Women's health
- Optimizing diagnosis and treatment[3]

Healthcare start-ups' focal points are largely driven by the unique characteristics of the U.S. healthcare industry. First, the healthcare reimbursement environment is unlike any other industry in the U.S. economy. The industry operates under a third-party payer system, wherein providers are often not paid for medical services by the patients themselves, but by employers, insurance companies, and government agencies. As the largest payer of healthcare in the U.S., the federal government has a significant impact on the expectation of future return on investment through

1. Stringent provider reimbursement regulation;
2. Regulation of the very existence of provider entities;
3. Restrictions on how providers can be organized and operated; and
4. Limitations on the products and services providers may offer and
5. Limitations on the types of technology and supplies that providers may use.[4]

Consequently, the federal government acts as the "price setter," with government payment rates serving as benchmarks for all reimbursement schemes. Further, while in other industries the price of products and services rise and fall to reflect changes in supply and demand, this is not the case in healthcare. The healthcare services market has historically exhibited a supply/demand profile contrary to that of the general economy, characterized as having supply-driven demand with inelastic pricing attributes. In other words, demand is unaffected by changes in consumer income or healthcare pricing.

Second, the healthcare industry has a number of barriers to entry, including state certificate of need (CON) laws and licensure requirements. CON laws are among the most significant market entrance barriers affecting the U.S. healthcare delivery system. A state CON program is one in which a government determines where, when, and how capital expenditures will be made for public healthcare facilities, services, and major equipment.[5] CON requirements are based on the highly contested theory that in an unregulated market, healthcare providers will provide the latest costly technology and equipment, regardless of duplication or need. Currently, 35 states and Washington, D.C., retain some sort of CON program.[6] In addition, state laws typically control the licensure, certification, and accreditation of healthcare facilities and providers, which allow states to regulate entry into the medical field and restrict the professional scope of practice for the delivery of healthcare services.

Third, the healthcare industry is arguably the most regulated sector in the U.S. economy. Healthcare organizations face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. This complex, overlapping regulatory scheme spans a myriad of issues, including (but not limited to) tax; fraud and abuse; antitrust; privacy; safety; corporate/organization; and licensure, certification, and accreditation.

For these reasons, the healthcare industry has historically been populated by traditional healthcare entities, such as hospitals and health systems, clinicians, and payers. However, over the past several years, in an effort to solve some of the greater issues plaguing the healthcare industry, non-healthcare entities have begun to get involved, including PE and venture capital firms; retail companies, such as Amazon and Wal-Mart; and start-ups. These nontraditional players tend to have different purposes and goals than traditional players. For example, traditional healthcare entities typically seek to grow their market share, meet their mission (if they are tax-exempt entities), and supplement their continuum of care. Nontraditional entities, on the other hand, are looking for new market

opportunities and tend to be drawn to the stability of the healthcare market. Because the healthcare industry is still largely fragmented, there are numerous turnaround and growth opportunities.

Healthcare start-ups differ from start-ups in other industries in a number of ways. For the reasons set forth above, entering the healthcare space requires industry expertise. Further, due to the complex, overlapping healthcare regulatory scheme, these entities must embody certain business structures, making it complex to scale up across state lines (due to state licensure and corporate practice of medicine laws, for example). Similarly, a number of federal and state laws dictate the handling and treatment of patient data, which is highly restricted. If accepting government reimbursement (as most providers do), establishing a revenue stream can be difficult, because government payers reimburse at a lower rate than private, commercial insurers.

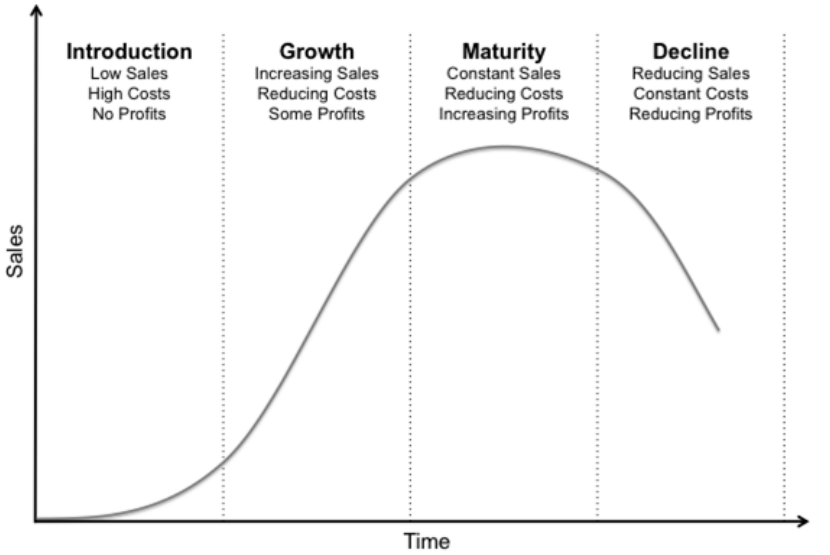
Valuation of Healthcare Start-up Companies

Healthcare start-ups may require a valuation for any number of reasons. Perhaps most often, parties to a prospective transaction involving a start-up may seek a valuation to establish a purchase/sale price. Parties seeking capital investment (equity or debt) may obtain a valuation to bolstering their prospectus, put investors' minds at ease, or comply with funder (e.g., bank) requirements. As illustrated in Figure 1, start-ups often go through a number of rounds of funding:

Figure 1: Start-up Funding Rounds

Coinciding with the four main rounds of funding, start-ups all go through the same four business life cycle stages, as set forth in Figure 2:

Figure 2: Business Life Cycle



Pre-Money versus Post-Money

When valuing a start-up business, it is important to denote whether the valuation opinion is pre-money or post-money. Pre-money valuation refers to the value of a company before (i.e., excluding) external funding. It is best described as how much a start-up might be worth before it begins to receive any investments. In contrast, post-money valuation refers to how much the company is worth after it receives funding.

Assume an investor is looking to invest in a healthcare start-up. The founder and the investor agree that the company is worth $1 million and that the investor will put in $200,000. The ownership percentages will depend on whether this is a $1 million pre-money or post-money valuation. If the $1 million valuation is pre-money, the company is valued at $1 million before the investment and at $1.2 million after the investment. If the $1 million valuation takes into consideration the $200,000 investment, it is referred to as post-money.

	Pre-Money Valuation		**Post-Money Valuation**	
	Value	**Percentage**	**Value**	**Percentage**
Founder	$1,000,000	83.3%	$750,000	78.9%
Investor	$200,000	16.7%	$200,000	21.1%
Total	$1,200,000	100.0%	$950,000	100.0%

Start-up Company Valuation Methods

Several valuation methods may be used for start-up engagements, including the following:

- Berkus method
- Scorecard valuation method
- Risk factor summation method
- Venture capital method
- Cost approach
- Market approach comparable transaction method
- Discounted cash flow method
- First Chicago method

Each will be discussed below in turn.

Berkus method. The Berkus method was created by venture capitalist Dave Berkus specifically to estimate the value of pre-revenue start-ups. The aim is to avoid unreliable valuations based on unrealistic forecasted revenues. Under this method (as set forth in Table 1), the valuator assigns equal dollar amounts to five key success factors that are important to the success of early-stage start-ups.

Table 1: Berkus Methodology

If Exists:	Add to Company Value up to:
Sounds Idea (basic value)	$500,000
Prototype (reducing technology risk)	$500,000
Quality Management Team (reducing execution risk)	$500,000
Strategic relationships (reducing market risk)	$500,000
Product Rollout or Sales (reducing production risk)	$500,000
Maximum Startup Value	$2,500,000

While many users of the Berkus method cap each category at a maximum of $500,000 (for a maximum pre-money valuation of $2.5 million), the methodology may be modified to adjust the theoretical maximum. This modification can add flexibility, in terms of both area (including geographical region) and amount (average valuation for a given start-up). For instance, the average valuation for a given start-up is $5 million, so all five areas would get up to 20 percent of $5 million. This would result in $1 million each instead of $500,000.

There are a number of advantages to using the Berkus method. For example, it is relatively quick and does not rely on forecasts (which are likely to be largely unreliable with a pre-revenue company). The method also has a number of drawbacks. First, like many of the methods described in this article, it is dependent on choosing an appropriate benchmark start-up valuation to set the maximum value. The method's simplicity is both a strength and a weakness. Because each of the five areas are weighed equally in terms of importance, skill

is required to determine how much to credit each area. Second, the method ignores some areas that the more detailed methods consider.

Scorecard valuation method. The scorecard valuation method, which is similar to the Berkus method, is another option that may be employed for pre-revenue businesses, but with added criteria. This method compares the subject start-up to typical angel-funded start-ups and adjusts the average valuation of these companies to establish a pre-money valuation of the subject.

First, find the average pre-money valuation of comparable companies. There are several sources available to identify these companies and valuations, such as Crunchbase, PitchBook, and Mergr (more of these sources are listed below).

Next, consider how the start-up compares based on the following qualities:

- Strength of the management team: 0–30 percent
- Size of the opportunity: 0–25 percent
- Product or service: 0—5 percent
- Competitive environment: 0–10 percent
- Marketing, sales channels, and partnerships: 0–10 percent
- Need for additional funding or investment: 0–5 percent
- Other: 0–5 percent

Then, assign each of these qualities a comparison percentage. These percentages identify each quality as equal (100 percent), below average (less than 100 percent), or above average (greater than 100 percent) in comparison to the benchmark companies.

An example of this method is set forth in Table 2.

Table 2: Scorecard Valuation Method

Comparison Factor	Weight %	Comparison %	Factor = (WxC)
Strength of Entrepreneur and Team	30%	110%	0.3300
Size of the Opportunity	25%	125%	0.3125
Product/Technology	15%	150%	0.2250
Competitive Environment	10%	70%	0.0700
Marketing/Sales/Partnerships	10%	100%	0.1000
Need for Additional Investment	5%	100%	0.0500
Other Factors (great location)	5%	125%	0.0625
Sum	100%		1.1500
Benchmark Startup Company Valuation			$3,000,000
Subject Startup Valuation			$3,450,000

In the example, the value of the subject start-up was determined to be 15 percent (or 1.15 times) greater than that of the industry benchmark start-up.

The scorecard valuation method can be advantageous because it covers more areas than the Berkus method and does not weigh all areas the same, since each industry may have different value drivers. On the other hand, it ignores some areas that the more detailed methods (discussed below) consider. As with the employment of any valuation methodology, the scorecard valuation method requires experience and skill to quantify each area and is dependent on having a solid understanding of the average (and range) of pre-money valuation of pre-revenue companies in the region/market.

Risk factor summation method. This method is more complex than both the Berkus and scorecard valuation methods. It typically involves performing an initial valuation based on one of the other valuation methods or selecting a proxy base value of a comparable start-up that is deemed appropriate. That initial valuation result is then increased or decreased by multiples of $250,000, based on the following risks affecting the subject start-up:

- Management risk
- Stage of the business
- Political risk
- Supply chain or manufacturing risk
- Sales and marketing risk
- Capital raising risk
- Competition risk
- Technology risk
- Litigation risk
- International risk
- Reputation risk
- Exit value risk

Factors that are determined to be low-risk are graded double (+2), which means $500,000 is added to the initial valuation result. Factors that are determined to be high-risk are reduced double (-2), and $500,000 is subtracted from the initial valuation result. An example of this method is set forth in Table 3.

Table 3: Risk Factor Summation Method

Risk Factor	Rating	Pre-Money Valuation Adjustment
Risk of Management	-1	-$250,000
Stage of the Business	-1	-$250,000
Supply Chain/Manufacturing Risk	0	0
Political Risk	+2	+$500,000
Sales and Marketing Risk	+1	+$250,000
Capital Raising Risk	0	0
Completion Risk	+2	+$500,000
Risk of Technology	-1	-$250,000
Risk of Litigation	0	0
International Risk	0	0
Risk of Reputation	+1	+$250,000
Exit Value Risk	0	0
Risk Score Adjustment	+2	+$750,000
Initial Pre-Money Valuation		$2,000,000
Subject Startup Valuation Result		**$2,750,000**

In the example, the initial value of the subject start-up was increased by $750,000 based on the risk factors considered.

The risk factor summation method is as simple as the Berkus and scorecard valuation methods and considers additional factors that those methods overlook. Additionally, if the start-up belongs to a popular industry, notably healthcare, they tend to result in higher valuations than those not belonging to it; conversely, start-ups belonging to a less popular industry tend to be penalized (serving as both an advantage and disadvantage, depending on the specific start-up). Despite these advantages, the risk factor summation method is largely pessimistic and assumes that all the risk factors weigh equally—that is, the "glass is half empty."

Venture capital method. As its name suggests, this method is often used by venture capital firms to value pre-revenue start-ups where it is easier to estimate a potential exit value once certain milestones are reached. It reflects the process of similar investors, who typically look for exit opportunities within three, five, or even seven years. The venture capital method involves estimating the expected exit price for the investment and then discounting that exit price back to post-money present value by accounting for the time and risk of investment.

The advantage of the venture capital method is that it is useful for calculating required or expected valuations for pre-revenue businesses and is computationally simple and well understood by the investment community. However, the method does not look at aspects of the business (e.g., team, product, traction, risks) in determining a valuation; it only considers the start-up's required rate of return. Additionally, the method requires the valuator to select representative start-ups to estimate future potential terminal values. As a result, it can be difficult to establish exit values and the discount rates are guesswork to some extent.

Cost approach. This approach, familiar to business valuation professionals, simply looks at the cost to replicate, or recreate, the start-up elsewhere. The value emanates from the sum of the fair market value of the company's physical and intangible assets, the latter of which is often quantified by the costs incurred to create those assets. Common costs related to intangible assets incurred by start-up healthcare businesses include:

- Research and development costs
- Product prototype costs
- Patent costs
- Other costs

The cost approach is commonly used when the subject business does not have any assets other than intellectual property (IP) and there is no other data available. Therefore, the advantages of this technique are that it is intuitive and straightforward to calculate. However, it can be problematic because it does not inherently capture the full value of a business, particularly if the business is generating revenue.

Comparable transaction method (market approach). This method estimates value by comparing the value of similar start-up businesses in transactions on the open market. A significant challenge in using methods based on the market approach is the difficulty in obtaining reliable transaction data from a sufficient number of reliably reported transactions involving start-ups. In addition, even when such data does exist, the reported valuation metrics for comparison may not be applicable (for example, if the subject start-up is pre-revenue). Several other factors for consideration of comparability include

- The relative size of the start-up;
- The industry in which the subject operates;
- The stage of investment; and
- The length of time the start-up has been in existence.

There are several sources that valuators may access to find market transactions:

- Crunchbase Pro
- CapitalIQ
- PitchBook
- Levin
- DoneDeals
- Mergr

The comparable transaction method can be beneficial because it is based on the market value of similar start-ups and does not rely on founder projections. Also, the method is commonly used and understood. It can provide a quick approximation of value if the valuator is familiar with the valuation multiple (e.g., revenue multiple) for a certain group of start-ups. However, this method assumes that the subject start-up business will have a similar outcome to other start-ups. Further, knowing which metric to use when identifying and selecting the market comparable transactions can be critical; it may be difficult to find transactions with targets in the same niche or size or with the same volume of market transactions. Lastly, the method ignores the experience of the management team or product, which as indicated in the discussion of some of the other methods, may provide a significant impact on value.

Discounted cash flow method. Another well-known business valuation method, the income-approach-based discounted cash flow (DCF) method, approximates the subject start-up's value as the present value of anticipated future economic benefits, measured in net free cash flow, that will accrue to the owner(s). The anticipated cash flows are typically discounted to present value at a higher rate of return in consideration that investment in start-ups are a higher-risk proposition than investing in businesses already operating and earning consistent revenue. The DCF method, like all income-approach-based methods, returns a value of all of a start-up's assets (both tangible and intangible). The method assumes that the assets are sold in an assemblage of assets and as part of a going-concern, income-producing business.

The principal benefit of the DCF method is that it provides an intrinsic value of a business based on estimated future cash flow and can be very detailed to

capture all future expansion plans. The challenge with this method, however, is that it depends on the analyst's or financial advisor's ability to predict how the company will perform in market conditions over the forecast period and to provide assumptions about a start-up's long-term growth, since the majority of a start-up's value comes from the terminal period (i.e., five to 15-plus years out). As a result, the DCF method is most appropriate for more mature businesses with predictable growth.

First Chicago method. The First Chicago method is a combination of the comparable transaction method (market approach) and the DCF method (income approach) that also takes into account different forecast scenarios for the subject start-up. This method, which is complicated and time-consuming, is often used by PE investors and venture capitalist to value early-stage companies. Application of the First Chicago method involves constructing valuation estimation for multiple scenarios (which may include the best case, the worst case, and one or more in between) and assigning a probability to each forecasted scenario.

The method requires data, such as the earnings, cash flows, exit-horizon, revenue, and financial forecast for each case scenario, as well as a detailed analysis of the market trends of the industry to arrive at a sound estimate for each scenario. Typically, the base-case scenario is the most likely outcome expected by the valuator, while the worst-case scenario is a total loss.

The main advantages of the First Chicago method are that it is very detailed and thorough and that it is based on concrete estimates of future exit values and cash flows. This method also provides a range of potential outcomes and accounts for unlikely but high-impact scenarios. On the other hand, this method is very complex and time-consuming and requires a lot of knowledge about the business and future estimates in order to produce accurate results; consequently, it is not useful for pre-revenue start-ups.

Benchmarking

Benchmarking is an important part of any valuation assignment. Benchmarks serve as guidance for investors and companies themselves and may be used for many purposes, including a check and balance against forecasts and comparison of a start-up's actual performance to its competition. Most of the valuation approaches, methods, and techniques discussed in this article require some form of benchmarking.

Industry benchmark metrics used for start-ups include the following:

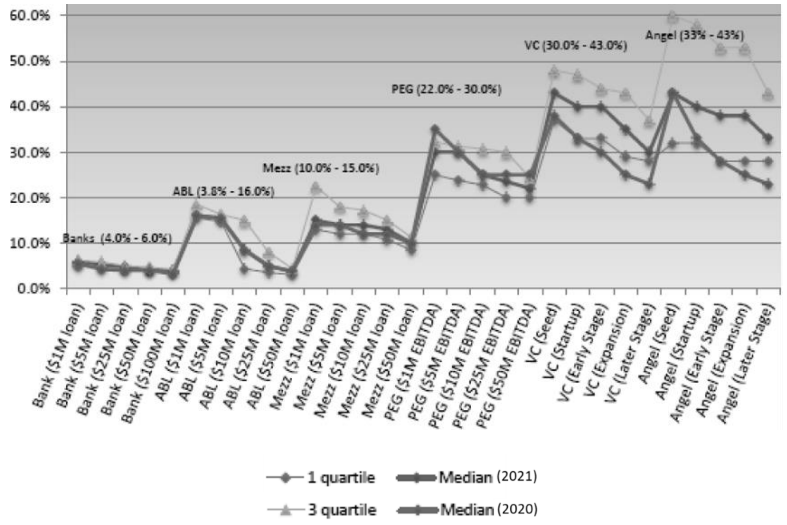
- Financial metrics, such as gross margin, net profit margin, and customer acquisition cost
- Operational metrics, such as churn rate, conversion rates, and returns and cancellations (ecommerce)

Industry benchmarks can be used to make forecasts in those methods that require it. Following are some tips to best leverage benchmarks to make better forecasts:

- Define the metric(s) to be examined
- Pinpoint the applicable industry
- Beware of, and appropriately deal with, outliers
- Use industry averages to build projections

Benchmarks may also be used as a check for the subject start-up's discount rate/investment rate in comparison to returns sought by the capital markets. A valuable resource for benchmarking required rates of return, given various levels of risk, is the Pepperdine Private Capital Markets report, an annual survey produced by Pepperdine Graziadio Business School. As shown in Figure 3, the report provides cost-of-capital data for private businesses from various sources (PE, banks, venture capital, angels, etc.).

Figure 3: Private Capital Market Required Rates of Return[7]



Sources of Funding for Start-ups

As identified by the Pepperdine Study, there are several sources of funding for start-ups, each with their own risk tolerance and funding mechanism:

- Asset-based lending. The primary difference between traditional bank lending and asset-based lending is that a traditional lender looks first to the business's earnings or cash flow then to collateral when underwriting a loan, whereas an asset-based lender looks to collateral first.
- Mezzanine financing. This is a hybrid of debt and equity that ranks below senior debt but above common stock in a capital structure. Due to the risk profile of mezzanine financing, lenders require higher returns than senior lenders and a lower return than equity investors. Lenders achieve this through a combination of interest payments and equity participation.

- Private equity (PE). This involves a group of investors that makes a direct investment in a company. PE investors typically focus on mature companies that are past the growth stage; however, they may provide funds to a business in distress. PE investment has taken a larger role in healthcare in recent years with the intention of acquiring a business (majority interest to complete buyout), improving its operations, and selling it for a profit in three to seven years. A PE investor's goal is always to make the company worth more than it was in order to generate a return on investment.
- Venture capital. This is a form of PE; the main difference is that while PE investors prefer stable companies, venture capital investors usually invest in start-ups and businesses in the introduction phase and are willing to take a minority stake in the business. Venture capital is usually given to small companies with incredible growth potential. This type of investment is not easily obtained and tends to be riskier, but venture capital investors get involved because of the potential for very high returns. If you are familiar with the television show *Shark Tank*, the "sharks" may be considered venture capitalists. While PE investors look to improve a business and then flip/exit the business for a profit, venture capital investors are interested in the long-term growth of the company.
- Angel investors. These are wealthy private investors focused on financing small business ventures in exchange for equity. Unlike a venture capital firm, which uses an investment fund, angels use their own net worth, which typically comes with a higher required rate of return.

Regulatory Considerations

As noted above, there are several legal considerations involved in start-ups. Chief among these is the protection of intellectual property (IP). IP is defined as mental creations—such as inventions, symbols, artistic and literary works, and images used in commerce—for which start-ups seek protection. While securing IP rights takes money, time, and other resources, it is vitally important to protect IP because the driving force behind a start-up is almost always a novel idea. An in-depth discussion of IP legal protections is beyond the scope of this article. However, Table 4 provides a summary of the different types of IP protection.

Table 4: Types of IP Protection[8]

IP Protection	Definition
Patent	Gives the owner of an invention exclusive property rights for that invention for 20 years, during which others cannot claim IP on the invention. The U.S. patent system currently works on a first-to-file basis: In other words, it does not matter if your start-up thought of the invention first: What matters is who files the patent first.[9]
Trademark	A word, design, or symbol that identifies a product or service as coming from a certain source. Start-ups can save money by trademarking their name and logo together instead of protecting each element separately.
Copyright	An exclusive right to use and copy a creative work in a fixed form, such as a book, article, software program, or song.
Trade secret	Processes, devices, or techniques used by a company and not known to the public. Examples can include a recipe, a list of customers, or a search algorithm used by a certain search engine. There is no legal filing required to claim an item as a trade secret.

Conclusion

Performing valuations of start-up businesses presents many challenges. Given the nature of businesses, there is some probability that a subject business will be worth a lot, but a much greater probability that it will be worth a very small amount. As valuators and appraisers, our training and experience has taught us, and professional standards require us, to look to multiple methods to estimate the value of a business, and start-ups are no exception. It is important to balance the advantages and disadvantages of each of the available methods.

Another challenge in valuing start-ups is that the information and due diligence documents provided by a start-up or client often are subjective or presented through a rose-colored lens. Therefore, the level of industry research required is typically greater with start-up engagements. The more one is able to identify appropriate benchmarks to compare and apply to the subject start-up, the less subjective the valuation opinion becomes.

Finally, it may also be helpful to explain to your clients what they need to do to make the start-up business more valuable. It can serve as both a value-added element to the valuation engagement and an opportunity to provide additional context to help the client understand the valuation conclusion.

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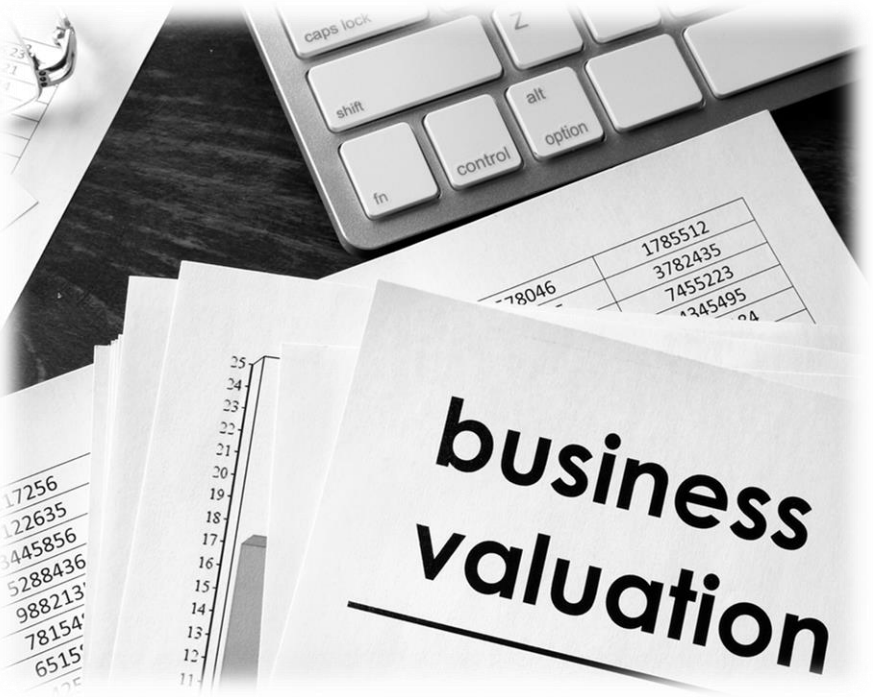

Valuation of Healthcare Data

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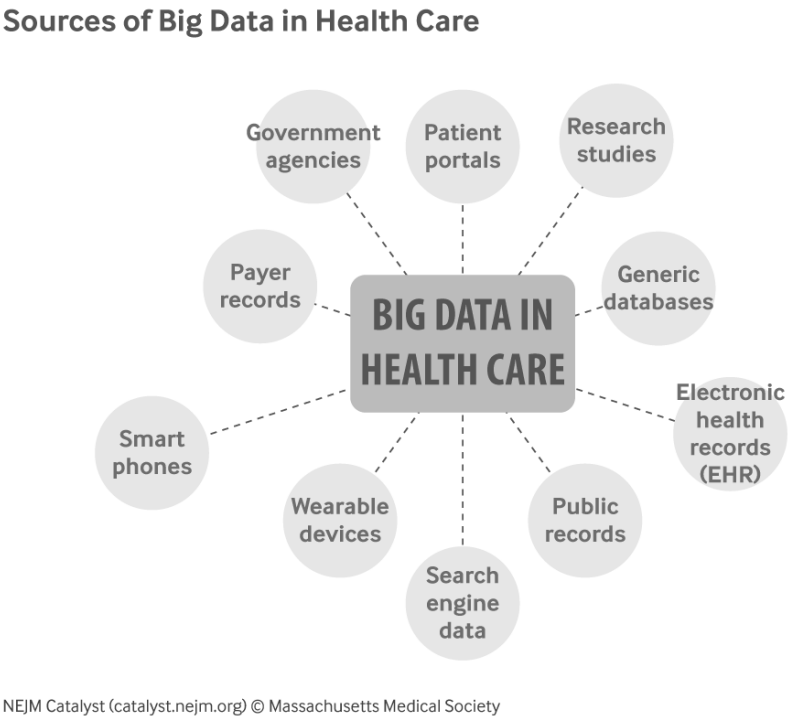
As the healthcare industry continues its efforts to permanently shift payment for services from a volume-based to a value-based system (which rewards providers based on the health of their patient population), providers have turned to technology to help them deliver care that results in better outcomes at a lower cost. The goal of such technology (e.g., wearables, predictive analytics, population health management) is to provide patients with tools to be more accountable for their own health and to help providers monitor patients (especially those with chronic conditions) and reach them before they become truly sick. Treating patients in the early stages of a worsening condition can lower emergency department utilization and hospital admissions rates. The use of this technology also captures a tremendous amount of data from patients, healthcare providers, and payors—termed "big data"—across a variety of sources. Big data is characterized by its high volume, its movement at high velocity across the healthcare digital universe, and its high variability in structure and nature.[1]



Healthcare organizations are now exploring ways not only to use data in their possession, but also to acquire data from others to complement or supplement their data and to monetize that aggregated data. However, the relative newness of healthcare big data (and transactions involving that data), in addition to the various laws and regulations that restrict the dissemination of patient information, makes it difficult to value. Nevertheless, the valuation of healthcare data will likely grow in the future as healthcare organizations explore how the aggregation and use of this data can augment current patient care.

Purchasers and Uses of Healthcare Data

Providers, software firms, and other companies are increasingly seeking to acquire clinical patient data from healthcare organizations. Transactions involving healthcare data are increasing in both number and complexity. Transaction arrangements may include:

- Outright acquisition
- Partial acquisition
- Options to acquire
- Equity sharing
- Licensing of information
- Joint venture or codevelopment arrangements
- Contingent consideration (milestone payments, royalties, contingent value rights)

As discussed further below, so long as providers de-identify data, they are allowed to sell it. However, healthcare organizations that purchase or sell such data should ensure it is priced at fair market value to mitigate any regulatory risk—that is, to show that the organization is proactively guarding against allegations of overpayment or kickbacks—particularly if the parties are in a position to refer patients to one another. Given the dearth of on-target industry normative benchmark data to consult for pricing guidance in selling or buying data, healthcare organizations often consult with valuation professionals to help determine what the market might pay. As a result, the need for fair market value opinions related to healthcare data will likely continue to increase.

Table 1 provides several examples of companies that acquire clinical data and the ways they use that data.

Table 1: Uses of Clinical Data

Clinical Data Acquirers	Uses of Acquired Data
Pharmaceutical companies	• Empower salesforce to market drugs more effectively • Understand the competition and breakdown of market share • Understand patient behaviors Large pharma companies pay $10–40 million per year for data, consulting, and services from firms such as IQVIA (https://www.iqvia.com)
Financial traders	• Use medical data to inform their trading decisions—for instance, information about which drugs are or are not popular can influence which stocks will rise and fall
Researchers	• Study outcomes of different treatments
Employers	• Study patient and spend data to determine how to reduce costs; benchmark their costs against other employers
Healthcare providers	• Compare cost and quality with competition to improve care internally
Payers	• Uncover billing fraud
Attorneys	• Contact patients for class action lawsuits
Advertising platforms	• Sell data to Google or Facebook to allow more precise ad targeting
Data brokers	• Resell data to the above • Resell for controversial or illegal uses (e.g., blackmail)

Source: Elizabeth Whitworth, "Selling Your Healthcare Data: Who Buys It & Why," Shortform, July 2, 2021, https://www.shortform.com/blog/healthcare-data.

There are several ways to price this data. For example, access to records may be provided and compensated via a licensing/access fee; one price may be set for data/information about a specific condition/ailment across a set number of individuals; or data may be sold on a per-medical-record basis.

Valuation Considerations

Valuators of healthcare data may employ one or more of the generally accepted valuation approaches: the income approach, the market approach, and the asset (or "cost") approach. The applicability of each approach is based on economics, markets, and the value drivers specific to the subject data. Value drivers include:

- Data type: clinical/claims, administrative, trials data
- Legal rights to use: exclusivity, licensing rights versus ownership rights, other limitations
- Quality of data: complete raw claims data; aggregated, structured, and filtered for a specific use; format of the data for manipulation, breadth, and depth of the fields included
- Usefulness: patient sample size, patient identification information included or de-identified

Income Approach

When employing the income approach for the valuation of data (or any other asset), the valuator analyzes the future benefits that a buyer is expected to receive after its acquisition. A key aspect of the income approach, therefore, is that it is forward-looking. It involves forecasts and projections relative to the economics of the acquired asset.

The fair market value standard must consider the benefits to be accrued by a universe of hypothetical willing buyers, not just a specific buyer or class of buyers. As discussed previously, there are many types of buyers and uses of data. Thus, one must take into account the ability to generate economic benefits based on the data's highest and best use, or by selling it to another market participant that would put the data to its highest and best use. Determining the "highest and best use" that use of the asset is physically possible, legally permissible, and financially feasible. Therefore, the income approach may involve developing more than one financial model—similar to forecasts performed for the valuation of start-up companies—to reflect the uncertainty and risk involved in the monetization of healthcare data.

Market Approach

Under the market approach, the valuator uses prices paid for comparable data as reference points to estimate the value of patient data.

Intangible asset databases, such as RoyaltySource and KTMine, may provide comparables for the sale of data or, as a proxy, data licensing agreements. Additionally, public filings—including Securities and Exchange Commission (SEC) transaction filings disclosed by public companies, company valuations, proprietary databases, and even the dark web—can provide indications of the types of data being sold, and at what price. While the market for clinical data is very strong, it has a wide range of value indications, depending primarily on the completeness of the data record.

Using the market approach to determine the fair market value of clinical data may involve the following considerations:

- Healthcare data brokers charge between $0.05 and $50 per medical record, depending on the information contained in the record. These brokers may also charge upwards of $75,000 or $100,000 per year for subscription/licensing access to data that includes information on individuals' health conditions.
- Prices paid for clinical data records range from $0.05 to over $125 per medical record, and an entire electronic health record (EHR) database can sell for up to $500,000.[2]
- Limits imposed by the Health Information Technology for Economic and Clinical Health (HITECH) Act on the fees covered entities can charge for providing EHR can constitute a market comparable transaction. Under the HITECH Act, a fee "shall not be greater than the entity's labor costs" in responding to a patient's request for data.[3] The regulations make clear that the costs are limited to labor, the cost of supplies, and postage. The Department of Health & Human Services (HHS) permits practices to charge $6.50 as a flat rate or calculate the average or actual cost of providing a patient with their EHR, whichever is most appropriate for the circumstances.[4] However, there may be limited rights associated with these transactions that may reduce their comparability to the subject data.
- One of the tenets of fair market value is that the transaction itself is legal. This prohibits consideration of comparables that include the illegal dissemination of data.

The market approach, when used to value healthcare data, poses similar challenges as it does for the valuation of business and services – finding reliable comparable transactions with sufficient and relevant facts to assess the homogeneous badges of comparability to the subject data.

Cost Approach

The cost approach estimates value as the cost of reproducing or replacing the subject data. Often, the data subject to a transaction cannot be monetized—that is, it cannot create revenue or reduce costs—for a willing buyer. However, the data may still have economic value. In these cases, the cost approach may reflect the data's highest and best use.

Using the cost approach involves identifying the costs incurred by the seller to develop and aggregate the subject data (costs that may be avoided by a willing buyer), adjusting for inflation, and adding a reasonable return on those inflation-adjusted costs. The cost approach is typically considered a "bottom-up" technique, as it often returns the minimum fee (floor) amount a "willing buyer" may reasonably be expected to pay.

A challenge in using the cost approach is identifying and separating the costs to create the subject data from other costs incurred during patient care or other

business operations. Often, industry normative benchmark cost data may be used to assess the reasonableness of identified costs or as the primary source for quantification of the costs to create the subject data.

Other Considerations

Healthcare data specific to patient health is regulated by federal law, specifically the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the HITECH Act. Among other things, the HIPAA Privacy Rule seeks to safeguard individual protected health information (PHI) from unauthorized disclosure by covered entities (e.g., providers, pharmacies, hospitals, nursing homes), without restricting the flow of healthcare information necessary to coordinate care.[5] Additionally, the HIPAA Security Rule governs the treatment of electronic PHI (e-PHI), requiring HIPAA-covered entities to ensure the confidentiality of the data, safeguard against security threats to the data, and "protect against anticipated impermissible uses or disclosures."[6] The HITECH Act expands on HIPAA regulations in part by applying the law to additional entities (i.e., business associates).

As noted above, these healthcare privacy laws effectively require that healthcare data be "de-identified" by wiping the data clean of any identifying information, such as patient names, locations, and contact information. While some business associates have agreements in place with providers to access raw patient data (and pay for that access), to comply with HIPAA and the HITECH Act, business associates would have to de-identify that data prior to selling it to any outside entities. Notably, selling de-identified patient data does not require the company to notify patients or obtain consent.

Conclusion

The aggregation and analysis of healthcare data may result in large-scale benefits, including personalization of healthcare treatments and improvements to overall care. However, there are also potential risks, such as bad actors using data to make fraudulent medical claims or potentially re-identifying the data.[7] Whether the benefits will outweigh the risks remains to be seen, but it likely will not slow down the aggregation of big data in healthcare.

As a result, this growing marketplace of buyers seeking healthcare data, coupled with the numerous applications of the data, presents an opportunity for healthcare valuation professionals. Valuations may be needed to establish the sales price, make strategic determinations, or ensure regulatory compliance. Similar to valuations of healthcare businesses and services, valuations of healthcare data may involve multiple approaches and methods. Regardless of approaches or methods, however, the valuator must consider the type of data, the purpose of the transaction, the specific facts and circumstances, the information available, and the highest and best use of the subject data.

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II. REIMBURSEMENT TOPICS

Will Americans Finally See Drug Prices Decrease?

[Excerpted from the article published in October 2022.]

According to the White House, "Americans pay two to three times as much as people in other countries for prescription drugs, and one in four Americans who take prescription drugs struggle to afford their medications. Nearly 3 in 10 American adults who take prescription drugs say that they have skipped doses, cut pills in half, or not filled prescriptions due to cost."[1] In an effort to combat this growing crisis, both the federal government and private companies have taken a number of steps over the past year aiming to lower drug prices. This Health Capital Topics article will review those actions and the potential unintended consequences of these actions.

The federal government's attention on lowering drug costs was refocused as a result of President Joe Biden's January 9, 2021 executive order that "directed various actions…[to] reduce prices for prescription drugs…"[2] On August 16, 2022, in a large step forward toward the president's goal, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other items, the omnibus law contained a number of provisions aimed at lowering prescription drug costs. First, the law allows the federal government to negotiate on behalf of Medicare beneficiaries to reduce costs for certain high-cost prescription drugs.[3] For those drugs, the U.S. Department of Health & Human Services (HHS) will negotiate for a "maximum fair price."[4] In an effort to maintain drug price levels going forward, the IRA also discourages pharmaceutical companies from arbitrarily inflating prices on certain drugs.[5] Between 2019 and 2021, 50% of Medicare-covered drugs saw price increases higher than the rate of inflation.[6] Beginning 2023, if manufacturers' prices on those drugs rise quicker than the rate of inflation, those manufacturers will be required to pay rebates to beneficiaries, which amount will be the difference between the inflation rate and the rate of increase in the drug price.[7] Second, the IRA will lessen the prescription drug costs directly incurred by patients by establishing maximum caps on various beneficiary spending. Medicare beneficiaries' out-of-pocket costs for insulin will be capped at $35 per month and all cost sharing for vaccines covered under Part D will be eliminated.[8] Additionally, starting in 2025, beneficiaries' out-of-pocket costs under Part D will be capped at $2,000 per year.[9] Then, beginning in 2024, beneficiaries will not be required to pay a coinsurance above the catastrophic threshold (which was $7,050 in 2022); previously beneficiaries had to pay a 5% coinsurance on drugs once hitting the catastrophic threshold.[10]

Buoyed by the IRA's passage, President Biden released another executive order on October 14, 2022, specifically directing the Department of Health & Human Services (HHS) to "consider whether to select for testing by the [Center for Medicare & Medicaid Innovation (CMMI)] new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries…including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that

promotes high-quality care."[11] HHS has 90 days to identify those models and report back on the agency's plan and timeline for testing those models.

There is concern that the actions taken by the federal government, which only apply to the Medicare program, will not lower drug prices across the board, as pharmaceutical companies could just shift losses onto commercial payors – this would affect approximately half of all Americans.[12] Therefore, a holistic solution to high drug prices will require involvement by private companies, which efforts are well underway.

On January 19, 2022, Dallas Mavericks owner and billionaire investor Mark Cuban announced the launch of The Mark Cuban Cost Plus Drug Company, a registered pharmaceutical wholesaler that sells generic drugs through an online pharmacy at much cheaper prices than traditional drug distributors. All of the pharmacy's drugs are priced at the manufacturers' price plus a 15% markup and a $3.00 pharmacist fee, a steep discount from traditional drug distributors.[13] These discounts are enabled by the company negotiating prices directly with manufacturers, rather than through a middleman.[14] Although the pharmacy does not accept health insurance, it claims that consumers will still pay less than if they were to pay with their insurance.[15] Over the past 10 months, it has served 1.2 million customers and now sells over 1,000 generic drugs (a significant increase from the 100 drugs it started selling in January 2022).[16] The company hopes that the "radical transparency" in its pricing model will force other pharmacies to do the same, pushing down prices. To further disrupt the drug industry, The Mark Cuban Cost Plus Drug Company is building a pharmaceutical facility in Dallas so that they can produce their own drugs, allowing them to further decrease prices and/or expand the number of drugs it sells; the building is expected to be completed next month.[17]

While The Mark Cuban Cost Plus Drug Company may be the most well-known company to take on the pharmaceutical industry, it is certainly not the only one. In July 2022, DiRX, an online pharmacy platform, launched a subscription model, where consumers pay a $300 annual flat fee and receive unlimited access to over 1,000 generic drugs.[18] One month later, CivicaScript, a hospital-owned nonprofit subsidiary,[19] began manufacturing and selling abiraterone, a prostate cancer drug, at approximately $3,000 less than the average price under Medicare Part D. This drug was specifically chosen due to its "high list price and significant patient need."[20] While this is the first drug released by CivicaScript, it will not be the last.

While this is a laudable start to combating the longstanding issue of high drug prices, there is still much to be done. For example, all of the programs discussed above are specific to generic drugs, which are a small part of the overall pharmaceutical market; brand-name drugs comprised approximately 84% of U.S. drug spending in 2021.[21] Further, taking away business from the "middlemen" – pharmacy benefit managers (PBMs) – may result in PBMs simply increasing their prices for brand-name drugs, further pushing up the costs of those newer medications.[22]

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MPFS Final Rule Cuts Physician Payments

[Excerpted from the article published in November 2022.]

On November 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released its finalized Medicare Physician Fee Schedule (MPFS) for calendar year (CY) 2023. While the finalized fee schedule cuts payments to physicians, there are a number of other (more positive) provisions in the final rule.

Payment Rate Updates for MPFS

For 2023, the conversion factor will decline by $1.55, to $33.06 (a 4.48% reduction from 2022).[1] This is nearly the same as the proposed conversion factor of $33.08.[2] CMS stated the conversion factor accounts for the expiration of the *Protecting Medicare and American Farmers From Sequester Cuts Act*'s 3% increase in physician fee schedule payments for 2022, as well as the budget neutrality adjustment for changes in relative value units (RVUs).[3]

Significant Changes to the Medicare Shared Savings Program (MSSP)

In an effort to both combat stagnant growth in the program over the past few years and correct previous "inequitable representation of minority patient groups and higher-spending populations," CMS finalized several changes to the MSSP, which currently covers in excess of 11 million Medicare beneficiaries and over 500,000 healthcare providers.[4]

In order to provide smaller providers with no previous accountable care organization (ACO) experience more time to acclimate to two-sided risk, CMS extended the amount of time during which these providers may participate in one-sided (no risk) shared savings models, up to seven years.[5]

In furtherance of its focus on health equity,[6] CMS will provide to certain low-revenue ACOs advance shared savings payments, in the form of a $250,000 one-time payment and quarterly payments for two years thereafter based on "enrollee neediness."[7] These funds may only be used to improve provider infrastructure, increase staffing, or care for underserved enrollees. These funds would then be repaid to CMS through the ACO's shared savings (if it earns any – there will be no claw back unless the ACO leaves the five-year agreement early). This will be one of the first times traditional Medicare payments would be permitted for such uses.[8]

CMS also finalized changes to the MSSP's benchmarks to promote long-term participation.[9] Previously, the benchmarks were adjusted annually based on the previous year's metrics, making it progressively harder to hit the ACO's goals required to receive shared savings. Toward that end, the agency added a prospective (rather than an historical) external factor and included a prior savings adjustment in historical benchmarks.[10] CMS also reduced the cap on negative regional adjustments, from 5% to 1.5% of national per capita expenditures, for Parts A and B services.[11]

Together, "[t]hese policies represent some of the most significant reforms since the program was established in 2011" and are anticipated to result in $650

million more in shared savings payments to ACOs and a $15.5 billion decrease in benefits spending (as a result of savings from efficiency).[12]

Other Provisions

CMS finalized several policies related to telehealth, including extending numerous temporarily available telehealth services during the public health emergency (PHE), through at least 2023.[13] The agency incorporated some of the regulations contained in the *Consolidated Appropriations Act of 2021* into its own regulatory guidance and instruction to make for an easier transition at the conclusion of the PHE. The following policies, which are currently in place, will be allowed until 151 days after the end of the PHE:

(1) Allowing telehealth services to be furnished in any geographic area and in any originating site setting (including the beneficiary's home);

(2) Allowing certain services to be furnished via audio-only telecommunications systems; and

(3) Allowing physical therapists, occupational therapists, speech-language pathologists, and audiologists to furnish telehealth services.[14]

CMS also finalized the relaxation of supervision requirements for behavioral health services in an effort to increase patient access. The agency added an exception to its *direct supervision* requirement, so that a physician or nonphysician practitioner only has to provide *general supervision* of behavioral health services provided by "auxiliary personnel" such as licensed professional counselors or family and marriage therapists.[15]

CMS finalized improved access to screening for colon and rectal cancers, the second leading cause of cancer deaths in 2020.[16] Going forward, Medicare will cover colorectal cancer screening for individuals age 45 and older (previously, coverage did not start until age 50). Medicare will also start covering, as a preventative service (which allows cost sharing to be waived), "follow-on" screening colonoscopies, to prevent beneficiaries from paying out-of-pocket for multiple tests.[17] As the agency pointed out, this provision "directly supports President Biden's Cancer Moonshot Goal to cut the death rate from cancer by at least 50%."[18]

Although "Medicare payment for dental services is generally precluded by statute," CMS also added certain dental services to its coverage, particularly when the service "is integral to treating a beneficiary's medical condition."[19]

Comments from Stakeholders

Industry trade associations strongly condemned the cuts to physician services contained in the MPFS final rule. The Medical Group Management Association (MGMA) implored Congress to act to avoid cuts to physician payments, citing its own survey that 90% of medical practices believe that the reduction in Medicare payments would reduce patient access to care.[20] Even before the final rule was released, the American Medical Association (AMA) stated that "[m]oving forward with this cut now is wrongheaded and inconceivable. …

Our patients are counting on Congress to agree to a solution, and the clock is ticking."[21] The trade association is strongly advocating for Congress to stop the payment cut, "implement an inflationary update for physicians…and waive the four percent PAYGO sequester."[22]

However, some associations did praise other finalized provisions. The National Association of ACOs President and CEO Clif Gaus stated that "[t]oday's finalized changes to Medicare's largest ACO program bring a win to patients and will absolutely help providers deliver accountable care to more patients."[23]

Conclusion

According to CMS Administrator Chiquita Brooks-LaSure, "The [MPFS] final rule ensures that the people we serve will experience coordinated care and that they have access to prevention and treatment services for substance use, mental health services, crisis intervention, and pain care."[24] However, providers believe that cuts to physician payments will in fact have the opposite effect – reduced patient access to care.

While provider trade associations are lobbying the federal government to override the MPFS final rule cuts, whether or not Congress will act has not yet been determined. Congress only has until the end of the calendar year before the cuts will become effective. There does appear to be bipartisan support for addressing these physician payment cuts, as evidenced in a November 2, 2022 letter signed by 46 senators.[25] Whether this rhetoric will translate into action remains to be seen.

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Congress Overrides Some – But Not All – Medicare Physician Payment Cuts

[Excerpted from the article published in December 2022.]

On December 20, 2022, the U.S. Congress announced its deal to fund the federal government through 2023, averting an imminent government shutdown. The 4,155-page, $1.7 trillion spending bill spans a vast array of funding initiatives and other bipartisan measures, including a number of noteworthy healthcare provisions. Perhaps most significantly, Congress intervened in the impending cuts to the Medicare Physician Fee Schedule (MPFS), overriding some, but not all, of the payment reductions. This Health Capital Topics article will discuss the congressional measures to ameliorate the payment cuts to physicians in 2023, as well as the other healthcare provisions included in the omnibus spending bill.

MPFS Payment Cuts Reduced

For 2023, the Centers for Medicare & Medicaid Services (CMS) reduced the MPFS conversion factor by 4.48% (to $33.06),[1] a second straight year of conversion factor decreases.[2] This decrease emanates from MACRA's statutory update of 0%, the end of the temporary 3% payment rate bump for 2022 pursuant to the *Protecting Medicare and American Farmers from Sequester Cuts Act*, and budget neutrality adjustments.[3] CMS stated the conversion factor decrease is due to the expiration of the *Protecting Medicare and American Farmers From Sequester Cuts Act*'s 3% increase in physician fee schedule payments for 2022, as well as the budget neutrality adjustment for changes in relative value units (RVUs).[4]

Physicians facing the threat of a 4.48% cut in Medicare funding have pleaded with Congress to cancel the cuts outright, and lawmakers ultimately met them in the middle. Section 4112 of the bill, *Extension of Support for Physicians and Other Professionals in Adjusting to Medicare Payment Changes*, dictates that physicians will see a 2% payment cut in 2023, and a 1.25% cut in 2024.[5]

Other Healthcare Provisions

As a result of the COVID-19 public health emergency (PHE), state Medicaid programs were prohibited from removing individuals from Medicaid enrollment, even if they were no longer eligible. This resulted in a record-high number of Medicaid enrollees.[6] States had agreed (by accepting additional federal funding) to hold off reviewing their Medicaid rolls, and removing ineligible enrollees, until the end of the PHE.[7] However, the spending bill accelerates that timeline, disassociating the Medicaid enrollment pause from the PHE (so that states may take these actions any time after April 1, 2023).[8] The process would not be instantaneous, so all ineligible enrollees will not be kicked off of Medicaid at once; instead, ineligible enrollees would be bumped off over a one-year period.[9]

The spending bill also extends current Medicare telehealth flexibilities, which were put in place as part of the 2020 CARES Act, for an additional two years,

to December 31, 2024.[10] Previously, the flexibilities would have expired 151 days after the end of the PHE.[11] Some of those flexibilities include a relaxation of the requirement that patients and treating physicians be located in the sane state, which types of providers who can provide telehealth, and prohibitions on audio-only telehealth services.[12]

Stakeholder Responses

Physicians and their professional trade associations have been lobbying furiously over the past few months to educate lawmakers on what is at stake should Medicare physician payments be cut amid "rising costs, staff shortages and record inflation."[13] To provide "a unique perspective into the real-world consequences such dramatic physician payment cuts would have on physician practices' ability to treat patients," MGMA surveyed its members, which "offer[ed] an alarming look into the projected impact."[14] Of the 517 medical group respondents, 92% reported that in 2022 (before the cuts even occur), Medicare reimbursement has not adequately covered the cost of care provided.[15] According to the survey, providers are considering a number of options to offset the payment reductions:

- "58% are considering limiting the number of new Medicare patients;
- 66% are considering reducing charity care;
- 58% are considering reducing the number of clinical staff; and
- 29% are considering closing satellite locations."[16]

While the spending bill does not alleviate all of providers' concerns, the reduced cuts are an improvement over the 2023 MPFS final rule and serves as a compromise. Jack Resneck, Jr., MD, President of the American Medical Association (AMA), expressed disappointment and disapproval with Congress, as they only partially allayed concerns of physicians. He also raised the prospect that some practices may cease any enrollment of new Medicare patients due to this legislation.[17] Anders Gilberg, Senior Vice President of Government Affairs at the Medical Group Management Association (MGMA), expressed concern over the physician cuts as well, calling the spending bill a failure in its treatment of payment cuts, and asserting that medical practices are not immune to economic impacts.[18]

Lawmakers have a strict deadline of December 23, 2022, to ensure the 2023 Omnibus Appropriations Bill is cleared.[19] Without this package, consisting of twelve annual appropriation bills, federal funding will run out, and key federal agencies and programs would be forced to cease operations.

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CMS Issues 2024 Physician Fee Schedule Proposed Rule

[Excerpted from the article published in July 2023.]

On July 13, 2023, the Centers for Medicare & Medicaid Services (CMS) released its proposed Medicare Physician Fee Schedule (MPFS) for calendar year (CY) 2024. In addition to the agency's suggested cut to physician payments, the proposed rule announced changes in policies for the advancement of health equity, as well as the expansion of access to critical behavioral health and oral health services.[1] According to CMS, "if finalized, the proposals in this rule ensure the people we serve experience coordinated care focused on treating the whole person, considering each person's unique story and individualized needs," including physical, oral, and behavioral health, as well as the social determinants of health.[2]

For CY 2024, CMS proposes to *decrease* the MPFS conversion factor by $1.14, to $32.75 (a 3.34% reduction from the 2023 conversion factor of $33.89).[3] Conversion factors are applied to relative value units (RVUs), i.e., the resources required to furnish a service, to become payment rates. This decrease reflects: the expiration of the 0.00% conversion factor update under the Medicare Access and CHIP Reauthorization Act (MACRA); a -2.17% adjustment for budget neutrality; a 1.25% statutory increase in payment for CY 2024; and the end of the one-year 2.5% statutory increase for CY 2023.[4]

In addition to payment rate changes, CMS proposes delaying definitional changes to evaluation and management (E/M) visits. E/M codes capture time the healthcare provider spent in a hospital or other facility setting (not in the office) "evaluating or managing a patient's health;"[5] E/M services are often performed by both a physician and an advanced practice clinician (APC), such as a nurse practitioner or a physician assistant. Who can bill for the time spent evaluating and managing a patient is important because only one provider can bill for the service, and Medicare reimburses physicians a higher rate for E/M services than APCs. CMS requires that the provider who performs a "substantive portion" of a shared (or split) E/M visit bill for their time (at their rate).[6] Previously, "substantive portion" was defined as: (1) "one of the three key E/M components," i.e., history, exam, or medical decision making, or (2) whomever spent more than half of the total time of the visit with the patient.[7] Under the new policy introduced in the CY 2023 MPFS final rule, the term "substantive portion" is simply defined as more than half of the total time of the visit with the patient.[8] If the APC is the practitioner who performs more than half of the E/M visit, Medicare would only pay 85% of the physician payment rate for the entirety of the E/M visit.[9] For now, however, CMS proposes to continue using the current definition of "substantive portion" through December 31, 2024.[10]

Further, the agency seeks to extend flexibilities for certain assessments furnished via audio-only communication, through the end of CY 2024.[11] If finalized, opioid treatment programs (OTPs) would be allowed to bill Medicare when video is not available, using technology permitted by the Drug

Enforcement Administration (DEA) and the Substance Abuse and Mental Health Administration (SAMHSA).[12] This extension would equalize telehealth flexibilities across providers of care and negate potential service disruptions due to the end of the COVID-19 public health emergency (PHE).[13]

In the wake of the end of the COVID-19 PHE, which ended a number of regulatory flexibilities and waivers, CMS proposes several additions to covered telehealth services under the MPFS, as well as an extension of several telehealth provisions from the Consolidated Appropriations Act (CAA) of 2023.[14] Proposed changes include the add-on of health and well-being coaching services on a temporary basis, as well as a refined process to review requests to add services to the Medicare Telehealth Services List.[15] Telehealth provisions extended through December 31, 2024, will include:

- The temporary expansion of the scope of sites where telehealth is furnished from, to include any location in the U.S. where a beneficiary may reside;
- A change in definition of telehealth providers to include qualified audiologists, speech-language pathologists, occupational therapists, and physical therapists;
- Continued payment for telehealth services provided by federally qualified health centers (FQHCs) and rural health centers (RHCs);
- Delaying requirements for beneficiaries to meet with practitioners six months before initiating mental health telehealth services;
- Allowing physicians in teaching environments to use video and audio communications when a resident is furnishing Medicare telehealth services; and
- Continued payment and coverage of telehealth services that are included on the Medicare Telehealth Services List.[16]

The proposed rule also includes changes to behavioral health, health-related social needs, and accountable care. CMS makes a number of suggestions related to behavioral health services, hoping to advance beneficiary accessibility.[17] The proposed rule includes a new benefit category wherein family therapists, marriage therapists, and mental health counselors would be able to bill Medicare.[18] Additionally, CMS proposes changes in payment and coding to account for resources utilized in the delivery of care involving a multidisciplinary clinical team and other staff members.[19] Further, Community Health Integration, Principal Illness Navigation, and Social Determinants of Health Risk Assessments would all receive separate payments to account for clinicians utilizing community health workers and peer support specialists in delivering patient care.[20] CMS also proposes changes in methodology for assignment that would promote access to accountable care for beneficiaries that rely on nurse practitioners, clinical nurse specialists, and physician assistants for their primary care needs.[21] Another proposal would change methodology for financial benchmarking, and encourage ACOs that serve complex

populations to participate in the Medicare Shared Savings Program (MSSP).[22] The aforementioned proposals are expected to increase MSSP participation by approximately 10% to 20%.[23]

A number of healthcare stakeholders have expressed concerns about the proposed changes to the MPFS. The American Medical Association (AMA) called for a congressional response to the proposed rule, stating that: "[t]he proposed Medicare physician payment schedule released today is a critical reminder that patients and physicians desperately need Congress to develop a permanent solution that addresses the financial instability and threatens access to care."[24] The AMA also asserted that Medicare payments failed to respond to the growing costs of physician practices, as well as growing inflation and the pandemic.[25] Similarly, the Medical Group Management Association (MGMA) is concerned about the likely impact of the proposed reduction to the conversion factor, maintaining that this reduction causes significant concern for medical groups, as the gap between Medicare reimbursement rates and the expenses of physician practices is increasing.[26] Similar to the AMA, MGMA also called on Congress to "reexamine existing law to provide an annual physician payment update commensurate with inflation and do away with Medicare's 'robbing Peter to pay Paul' budget neutrality requirements to provide much-needed financial stability for medical practices."[27] In contrast, the National Association of Accountable Care Organizations (NAACOs) commended CMS for "showing its commitment to value-based care and growing participation in accountable care organizations in this proposed rule."[28]

While proposed payment changes in the CY 2024 MPFS were not well-accepted by stakeholders given the current healthcare environment, many applauded CMS for the other, non-payment-related, proposed changes. CMS will receive comments on the proposed changes until September 11, 2023, and the final rule will be released sometime thereafter.[29]

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CMS Issues OPPS Final Rule

[Excerpted from the article published in November 2022.]

On November 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released its finalized Outpatient Prospective Payment System (OPPS) for calendar year (CY) 2023. The finalized payment update increases payments to outpatient facilities and finalizes the conditions of participation for the newest hospital type, among other provisions.

Payment Rate Updates

For CY 2023, CMS will increase OPPS payment rates to hospital outpatient departments (HOPDs) and ambulatory surgery centers (ASCs) that meet specific quality reporting criteria by 3.8% – over 1% higher than its proposed increase of 2.7% – calculated from the hospital inpatient market basket percentage increase of 4.1% *minus* the productivity adjustment of 0.3%.[1] CMS also adjusted payment rates by a 0.9998 wage index budget neutrality factor, an additional 0.9691 budget neutrality factor to account for the 340B program changes (see below), and pass-through spending adjustments.[2] This results in a conversion factor for HOPDs of $85.585.[3] CMS estimates that it will provide approximately $86.5 billion in total payments to approximately 3,500 HOPDs in 2023, a $6.5 billion increase from 2022.[4] This increase also results in an ASC conversion factor for 2023 of $51.315.[5] CMS estimates that it will make approximately $5.3 billion in total payments to 6,000 ASCs in 2023, a $230 million increase from 2022 Medicare payments.[6]

New Rural Emergency Hospital Designation

In response to the closures of (or elimination of inpatient services at) 180 rural hospitals and critical access hospitals (CAHs) since 2005, and with one-fourth of the remaining rural hospitals vulnerable to closure, the Consolidated Appropriations Act of 2021 established a new Medicare provider type – Rural Emergency Hospitals (REHs).[7] The OPPS final rule establishes the conditions of participation for REHs. Beginning January 1, 2023, facilities that: are a rural hospital or CAH; have fewer than 50 beds; and do not provide acute care inpatient services (except for skilled nursing facility services in a distinct unit), can convert to an REH.[8] In return, REHs will receive an additional 5% on top of the OPPS payment rate for each service, as well as a monthly facility payment of $272,866 for 2023 (totaling almost $3.3 million).[9]

CMS also proposed "a new [Stark Law] exception for ownership or investment interests in an REH."[10] However, CMS ultimately did not finalize this proposal based on comments that these financial relationships may present a risk of patient or program abuse. Instead, the agency simply finalized changes to certain existing exceptions to make them applicable to compensation arrangements to which an REH is a party.[11]

340B Payment Cuts

The 340B Drug Pricing Program allows hospitals and clinics that treat low-income, medically underserved patients to purchase certain "specified covered outpatient drugs" at discounted prices and then receive reimbursement under the OPPS at the same rate as all other providers.[12] This results in a margin for these participants between the amount paid for the drug and the amount received, which enables covered entities to stretch scarce federal resources as far as possible, reaching more patients and providing more comprehensive services.[13] CMS must follow a statutory formula in setting the annual reimbursement rate for 340B drugs. From 2006 to 2018, the reimbursement rate for these outpatient drugs was the drug's average sales price (ASP) *plus* 6%.[14] In the 2018 OPPS, however, CMS finalized a reduction to this reimbursement rate, specific to 340B participants only, of ASP *minus* 22.5%.[15] Hospitals and hospital associations subsequently sued CMS to challenge the cuts, asserting that CMS violated its authority in changing the rates and that the reduced drug payments would negatively affect access to care (as the 340B Drug Pricing Program is largely comprised of safety-net hospitals).[16] Ultimately, in June 2022, the U.S. Supreme Court unanimously found that CMS exceeded its authority in changing drug reimbursement rates for a subset of hospitals, but did not address how CMS should repay those hospitals that received only a portion of the 340B reimbursement to which they were entitled.[17]

In accordance with the Supreme Court ruling, CMS will go back to applying the default rate to 340B drugs for 2023 (ASP plus 6%); however, the agency has not yet determined how it will refund the money that 340B entities did not receive between 2018 and 2022 as a result of the lower rates. CMS is accepting comments on the topic and will make this decision in separate rulemaking in the first half of 2023.[18]

Other Finalized Items

Other items included in the OPPS final rule include:

(1) Removing 11 procedures (most of which are maxillofacial in nature) from the inpatient-only (IPO) list[19] and adding four procedures to the ASC Covered Procedures List (ASC-CPL) for 2023;

(2) Paying for behavioral health services rendered remotely (including audio-only care) to patients in their homes as a covered outpatient service (this makes permanent a regulatory flexibility put in place during the COVID-19 public health emergency);[20]

(3) Paying for clinic visits at excepted off-campus provider based departments under the OPPS, rather than under the physician fee schedule (which rate is approximately 40% of the OPPS payment rate), significantly increasing the payment amount for "the most frequently billed service under the OPPS;"[21] and,

(4) Utilizing 2021 claims data and 2019 cost reports data to estimate expected costs for 2023 and set ASC payment rates.

Stakeholder Responses

Stakeholders' reactions to the changes in the 2023 OPPS final rule were somewhat mixed. Stakeholders were generally pleased with the revision of the 340B payment to the default payment rate;[22] however, most were unsatisfied with the payment rate increase. Premier, a group purchasing and consulting organization, argued that the payment increase was not sufficient, stating "[t]he truth remains that a 3.8% payment update falls woefully short of reflecting the rising labor costs that hospitals have experienced since the pandemic's onset."[23] The American Hospital Association (AHA) agreed that "the increase is still insufficient given the extraordinary cost pressures hospitals face from labor, supplies, equipment, drugs and other expenses."[24] However, the AHA commended CMS on its finalization of the REH model conditions of participation.[25] The Ambulatory Surgery Center Association (ASCA) was also "relieved that CMS has increased the inflation update from what was proposed initially," but stated that "it still falls far short of addressing the escalating costs that surgery centers are experiencing in staffing, services and supplies."[26] Further, the ASCA argued, "CMS's decision to add only four new procedures to the ASC-CPL for 2023 after ASCA proposed 47 procedures that ASCs are performing safely and successfully for privately insured patients is a serious mistake and denies beneficiary access to high-value care…Forcing otherwise healthy Medicare beneficiaries to receive care in higher-cost settings for these procedures needlessly increases costs to the Medicare program and undercuts Medicare's mission of serving as a responsible steward of public funds."[27]

The OPPS goes into effect on January 1, 2023

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CMS Proposes Updates to the OPPS

[Excerpted from the article published in July 2023.]

On July 13, 2023, the Centers for Medicare & Medicaid Services (CMS) released the proposed rule for the Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Centers (ASCs) for calendar year (CY) 2024.[1] The agency proposes an increase in payments to all outpatient providers, introduces a new program, and announces their solution to repay 340B hospitals after their loss in the U.S. Supreme Court.

For CY 2024, CMS proposes to increase OPPS payment rates to hospital outpatient departments (HOPDs) that meet specific quality reporting criteria by 2.8% – calculated from the proposed hospital inpatient market basket percentage increase of 3.0% minus the proposed productivity adjustment of 0.2%.[2] This calculation results in a proposed OPPS conversion factor of $87.488.[3] ASCs that meet the required quality criteria will also receive proposed payment rate increases of 2.8%, by way of the same calculation described above for OPPS payment rates.[4] Consequently, the proposed ASC conversion factor for 2024 is $53.397.[5] For both HOPDs and ASCs, the CY 2024 proposed OPPS payment rate increase is a full percentage point less than the CY 2023 OPPS payment rate of 3.8%.[6]

In the CY 2019 OPPS/ASC final rule, CMS began applying productivity-adjusted hospital market basket updates (i.e., the updates used for HOPD payment rate updates) to ASC payment rates for a test period of five years.[7] Because of abnormal healthcare utilization in 2020 due to the COVID-19 public health emergency (PHE), CMS proposes to extend the five-year period for an additional two years, until CY 2025.[8] This will allow CMS to gather data unrelated to the COVID-19 PHE to determine if the hospital market basket update achieved one of its goals of shifting services from the hospital to the ASC setting.[9]

In 2018, the Department of Health and Human Services (HHS) reduced payments for prescription drugs to 340B-covered entity hospitals by nearly 30%.[10] In response, hospital lobbying groups, such as the American Hospital Association (AHA) sued to stop the reduction in payments, however an appellate court sided with the HHS arguing that they had the regulatory power to make the cuts in payment.[11] In June 2022, the U.S. Supreme Court unanimously found that HHS acted outside its statutory authority in changing reimbursement rates for one group of hospitals (i.e., those in the 340B Drug Pricing Program) without first surveying them on their costs, in violation of their regulations.[12]

Over one year after the Court's ruling, CMS published its proposal (which was reiterated in the OPPS/ASC proposed rule) to pay a single lump sum to those nearly 1,600 340B hospitals that received reduced payments.[13] The policy, which was active from 2018 through the third quarter of 2022, resulted in 340B hospitals losing nearly $10.5 billion in total reduced payments.[14] HHS also

proposed a plan to recoup funds from hospitals that received inflated payments for non-drug services under this policy, which would include adjusting the OPPS conversion factor by -0.5% each year beginning in CY 2025, and continuing until the full amount of the overpayment is recouped, approximately 16 years.[15] Going forward, starting in CY 2024, CMS proposes to return to paying the statutory rate for biologicals and drugs acquired through the 340B Program, which is generally the average sales price (ASP) plus an additional 6%.[16]

In 2021, CMS enacted the Price Transparency Rule and began requiring hospitals to publish information on pricing in a machine-readable format and display pricing for 300 of their services in a way that consumers can understand and digest.[17] Hospitals that fail to comply are subject to penalties between $300 and $5,500 per day.[18] For CY 2024, CMS proposes requiring that hospitals not only display pricing and charge information in a machine-readable template, but also that hospitals tie this information to their public websites.[19] CMS proposes increasing its regulatory oversight, with plans to: (1) require an authorized hospital employee to certify the accuracy of price transparency data; (2) publicize information relating to the assessment of a hospital compliance with price transparency; and (3) notify the leadership of a health system if a hospital within the system fails to comply.[20]

CMS introduced a new program in the OPPS/ASC proposed rule for CY 2024 – the Intensive Outpatient Program (IOP). The IOP is an organized outpatient psychiatric service program for individuals who have a substance use disorder or acute mental illness. [21] The goal of this program is to promote access to behavioral healthcare and address gaps in behavioral healthcare coverage.[22] The proposed rule includes IOP payment rates (proposed to be a per diem rate for a group of services), coding and billing, requirements for physician certifications, and the scope of benefits.[23] If finalized, IOP services may be furnished at Rural Health Clinics (RHCs), Community Mental Health Centers (CMHCs), Federally Qualified Health Centers (FQHCs), and hospital outpatient departments (HOPDs).[24]

Stakeholders' reactions to CMS's OPPS/ASC proposals were somewhat mixed. The American Hospital Association (AHA) stated that it was "concerned that CMS is proposing an outpatient hospital payment update of only 2.8% in spite of persistent financial headwinds facing the hospital field," arguing that "most hospitals across the country continue to operate on negative or very thin margins that make providing care and investing in their workforce very challenging day to day."[25] The Ambulatory Surgery Center Association (ASCA) noted its continuing displeasure at the lack of procedures being added to the Medicare Inpatient Only (IPO) List and ASC covered procedures list, asserting that it was "mystifying that CMS allows off-campus hospital outpatient departments to perform total shoulder joint surgeries yet prohibits similarly regulated surgery centers—served by identically trained surgeons, nurses and other staff—from performing them on even the otherwise healthiest beneficiaries."[26]

As regards the 340B Program specifically, stakeholders praised the proposal to provide lump sum payments to 340B hospitals, but expressed concerns as well. America's Essential Hospitals (AEH) was disappointed that "the remedy payments would include no interest and be budget neutral."[27] Additionally, the AEH criticized "the administration's plan to cut non-drug payments to hospitals to achieve budget neutrality" and how CMS "unnecessarily blunts the impact of the remedy by ensuring years of future underpayments."[28] Similarly, the AHA expressed its satisfaction with the proposed remedial payments to 340B hospitals; however, the AHA was "disappointed that HHS has chosen to recoup funds from other hospitals that cannot afford additional Medicare payment cuts, including rural sole community, cancer and children's hospitals that were initially exempted from HHS' illegal policy."[29]

CMS will receive comments and information on the OPPS/ASC proposed rule until September 13, 2023.[30] Comments for the proposals related to the remedial payments for 340B hospitals will be accepted until September 5, 2023.[31]

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Congress Mulling Medicare Site-Neutral Payment Policy

[Excerpted from the article published in May 2023.]

Congress is actively considering several bills related to site-neutral payment that has hospitals across the U.S. significantly concerned.[1] The proposed legislation would lower the price that Medicare pays hospitals for common outpatient services, such as x-rays and general checkups, and match what it pays outpatient facilities such as physician offices.[2] Facilities that are owned by hospitals (known as hospital outpatient departments, or HOPDs) earn more than twice what an independent outpatient facility earns for providing the same services.[3] This Health Capital Topics article will review the changes that are being considered by Congress, as well as the responses from stakeholders.

Medicare pays a substantially higher amount for services provided in an HOPD than it does when the same service is provided in a physician's office or another setting outside of the hospital, such as an ambulatory surgical center (ASC).[4] For example, Medicare's allowed payment amounts for a colonoscopy was 67% higher in an HOPD, and 62% higher in an HOPD for an MRI.[5] To sidestep the lower payment rates, some physician offices were purchased and relabeled as an off-campus component for the HOPD, resulting in higher payments.[6] For many services, there is very little evidence to demonstrate that the quality of care is higher in a hospital setting.[7] Medicare's payment disparity also affects the rates of payment under private health insurance plans, since these plans typically use Medicare's system as a basis for the payment of physicians and hospitals.[8]

The federal government has been discussing site-neutral payments for nearly a decade, and the newer policies will build off previously drafted legislation that never passed.[9] An April 26, 2023 congressional hearing focusing on the promotion of competition and transparency in healthcare referenced 17 bill drafts, several of which relate directly to site-neutral payments.[10] Two of the bill drafts build on provisions in the Bipartisan Budget Act of 2015, eliminating current exceptions by 2025, with a third bill draft building on previous regulations that had required all clinic visits to receive the same lower payment rate, including at grandfathered facilities.[11] A fourth bill draft would require, beginning in 2026, separate national provider identifiers (NPIs) for each HOPD at which a provider works.[12]

Adopting site-neutral payment policies would result in estimated savings of over $471 billion to the Medicare program and Medicare beneficiaries over the next decade.[13] Medicare's savings would be approximately $202 billion for the first year, while enrollees would save approximately $67 billion on cost sharing and an additional $67 billion on Part D premiums.[14] Further, private health insurance plan premiums would be reduced by 0.75% in aggregate (due to the link between private insurer payment rates and Medicare payment rates).[15] The reduction in private insurance premiums would increase federal tax revenues by $29 billion, meaning that adopting this site-neutral payment policy would result in total federal government savings of $231 billion in the first year

alone.[16] Moreover, private plan enrollees would save $18 billion on cost sharing from the payment of lower rates, resulting in total out-of-pocket savings of $152 billion for enrollees in both private and Medicare plans.[17]

Despite the proposed policy's potential savings for both Medicare and private health insurance plans, hospital advocacy groups and stakeholders are voicing clear opposition to such a payment adjustment. The American Hospital Association (AHA) stated that it "has repeatedly opposed additional site-neutral payment cuts to hospital outpatient departments, which would harm beneficiaries, especially those in rural and vulnerable communities."[18] The AHA also argues that site-neutral payments would "would result in a cut to hospitals of $11.6 billion in the first year and $180.6 billion over 10 years."[19] The Federation of American Hospitals (FAH) sent a letter to the House Energy and Commerce Committee's Health Subcommittee, asserting that:

> "Site-neutral payments do not consider one simple fact: hospitals and physician offices are not the same. Hospitals provide critical services to entire communities, including 24/7 access to emergency care and disaster relief. They need to maintain the ability to treat high acuity patients who require more intense care, and therefore require a different payment structure."[20]

Experts expect that hospitals and lobbying groups will go to great lengths to stop any new legislation from moving forward.[21] Eliminating the higher payments to hospital-owned facilities could even result in hospitals reducing the services provided or access to care for patients.[22] However, the impact of such a proposed policy is yet to be seen, as it is still just a consideration – for now.

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IPPS/LTCH PPS Proposed Rule Released

[Excerpted from the article published in April 2023.]

On April 10, 2023, the Centers for Medicare & Medicaid Services (CMS) released its proposed rules for the payment and policy updates for the Medicare inpatient prospective payment system (IPPS) and long-term care hospital prospective payment system (LTCH PPS) for fiscal year (FY) 2024.[1] In addition to a slight payment bump, CMS clarified its stance on physician-owned hospitals and proposed several advances in accordance with the administration's health equity initiative. This Health Capital Topics article will discuss the proposed rule and the implications for stakeholders.

By law, CMS is required to update IPPS and LTCH payment rates annually while accounting for changes in the prices of goods and services used by hospitals in the treatment of Medicare beneficiaries.[2] Under the two payment systems (IPPS and LTCH PPS), base payment rates are set by CMS prospectively for inpatient stays based on the severity of the illness, the services utilized, the treatment provided, the cost of labor in the locality, and the patient's diagnosis.[3] Hospitals receive a lump payment for each hospitalization, dependent on the Diagnosis-Related Group (MS-DRG) classification assigned at discharge.[4]

CMS proposes increasing the IPPS base rate by 2.8%, which is $3.3 billion in additional funding for FY 2024.[5] This percentage increase is comprised of a projected FY 2024 hospital market basket increase of 3.0%, reduced by 0.2% due to a productivity adjustment.[6] This proposed increase is considerably lower than the FY 2023 payment increase of 4.3%.[7] Even while CMS proposes increases in overall payments to hospitals, it proposes decreases to payments that offset the cost of charity care for low income patients; disproportionate share hospital (DSH) payments and Medicare uncompensated care payments are expected to decrease by a combined $115 million.[8] This slight overall payment bump comes after what many industry experts have referred to as the worst year financially for hospitals.[9] While hospital margins are stabilizing, hospital groups assert the increase will hardly address inflation.[10]

For FY 2024, the LTCH standard payment rate is expected to increase by 2.9%, with the LTCH PPS payments for patient discharges to decrease by approximately 2.5% or $59 million, due to a projected 4.7% decrease "in high-cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments."[11] For FY 2023, the LTCH PPS payments increased by 2.4%.[12] CMS is currently seeking comment on the methodology utilized to determine the LTCH PPS outlier threshold for the patient discharges that are paid the LTCH standard payment rate.[13]

CMS administrators are also proposing changes to how hospitals are scored under the Hospital Value-Based Purchasing Program, including adding 15 new categories for equity, which would result in more data collection and provide an avenue by which hospitals may address health equity gaps.[14] This proposal

is in line with the Biden Administration's larger ongoing focus on healthcare equity, as has been manifested in a number of Department of Health & Human Services (HHS) initiatives.[15] The agency is also aiming to address social determinants of health, by proposing increased reimbursement for providers that treat patients experiencing homelessness.[16] COVID-19 add-on payments are expected to be discontinued beginning in FY 2024, as long as the public health emergency ends as planned in May 2023.[17]

The proposed ruling also included a clarification on CMS's previous rule regarding physician-owned hospitals. The 2010 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.[18] In the 2021 Outpatient Prospective Payment System (OPPS) final rule, CMS dialed back that restriction, allowing physician-owned hospitals that are classified as "high Medicaid facilities," i.e., hospitals that serve more Medicaid beneficiaries than other hospitals in the area, 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.[19] However, CMS is now proposing to reinstate the program integrity requirements "on the frequency of expansion exception requests, maximum aggregate expansion of a hospital, and location of expansion facility capacity."[20] Additionally, CMS proposes only reviewing expansion exception requests from eligible hospitals, and identify factors that will be considered when this decision is made.[21] This proposed rollback comes at an interesting time – as detailed in a March 2023 Health Capital Topics article, academics and policymakers are pushing for the removal of barriers for physician-owned hospitals, which would make it easier for these facilities to be established and expand.[22]

Healthcare industry stakeholders have expressed frustration with CMS's proposals, arguing that the paltry proposed payment increase will not be enough. The American Hospital Association (AHA) stated that, "given the near decades-high inflation and increased costs for labor, equipment, drugs and supplies," the rate would be inadequate.[23] AHA also stated that the adjustments did not reflect the reality of the world where hospitals are providing care, and that without any significant updates in the final rule, the ability of hospitals to provide essential services to the community would be threatened.[24] Additionally, the Federation of American Hospitals (FAH) issued a similar statement, asserting that more support would be needed from Medicare.[25] FAH President and CEO, Chip Kahn, stated that "this IPPS proposed inflationary payment update is disappointing. It fails to recognize today's headwinds that will strain the health safety net in 2024, which will further threaten patients' access to care as hospitals are forced to reduce services or in some cases, especially rural areas, close completely."[26]

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Healthcare Spending Slowed in 2021 due to COVID-19

[Excerpted from the article published in December 2022.]

On December 14, 2022, the Centers for Medicare & Medicaid Services (CMS) released a report detailing healthcare spending in the U.S. for 2021, highlighting the decrease in government spending due to reductions in federal spending for COVID-19. Overall, healthcare spending grew 2.7% in 2021 (to $4.3 trillion), much slower than the 10.3% increase in 2020.[1] Healthcare spending as a share of the U.S. gross domestic product (GDP) declined from 19.7% in 2020 to 18.3% in 2021 (although still higher than the 17.6% share in 2019).[2] The overall GDP increased 10.7% in 2021 after having dipped in 2020 – a much faster rate than healthcare spending.[3] This Health Capital Topics article will review the notable findings included in CMS's report.

The healthcare spending deceleration in 2021 was largely attributed to the 62.7% decline in federal healthcare expenditures that were crucial to combatting COVID-19.[4] Supplemental funding programs such as the Provider Relief Fund and the Paycheck Protection Program, combined with a decrease in public health activities, resulted in a $121 billion decline.[5] While this was significantly lower than the $193.1 billion spent in 2020, the federal government still spent more in 2021 than in 2019, when federal healthcare expenditures were approximately $14 billion.[6]

Examining the expenditures across service categories, hospital expenditures grew 4.4% in 2021 (comprising 31% of overall healthcare spending), relatively slower than the rate observed in 2020 (6.2%).[7] This was a result of decreases in federal funding, including COVID-19 relief payments. Expenditures on physician and clinical services increased 5.6% (comprising 20% of healthcare spending), which was lower than the 6.6% growth in 2020. Much like hospital care, the slow growth in physician and clinical services was attributed to a decline in federal funding. In contrast, retail prescription drug expenditures increased 7.8% in 2021 (comprising 9% of healthcare spending), a faster rate than in 2020 when spending increased by only 3.7%. This increase was attributed to the higher utilization of prescription drugs in 2021 (i.e., more physician visits resulting in an increase of new prescriptions).[8]

Analyzing expenditures by sponsor, the federal government understandably continued to account for the largest share of healthcare spending (34%), followed by households (27%), private businesses (17%), state and local governments (15%), and other private revenues (7%).[9] While the federal government was the only sponsor with increases in expenditures in 2020, in 2021, all sponsors other than the federal government experienced faster spending growth. Again, this difference was driven by the decrease in federal COVID-19 relief funding. Federal government spending declined 3.5% in 2021, after a 36.8% increase in 2020.[10] Household health spending increased 6.1% in 2021 after a 1.2% growth in 2020, due to household out-of-pocket spending.[11] State and local governments experienced a spending growth in 2021, with spending increasing by 5.8% compared to the 1.9% decline in 2020,

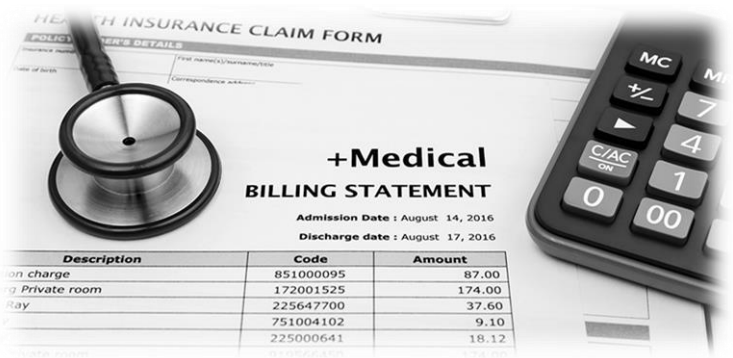
driven by the increase in state Medicaid spending.[12] Finally, spending by private businesses increased 6.5% in 2021 after experiencing a decrease of 2.9% in 2020. This was largely due to the increase in contributions to employer-sponsored private health insurance premiums.[13]

In terms of insurance coverage, the number of uninsured individuals in 2021 decreased to 28.5 million from the 2020 total of 31.2 million.[14] Enrollment increased in both Medicaid and the Affordable Care Act (ACA) Marketplace plans. These high enrollment totals are due to policies enacted over the past two years to ensure continued insurance coverage during the pandemic. However, the end of the COVID-19 public health emergency is expected to result in a reversion to previous Medicaid criteria, resulting in the loss of Medicaid coverage for 5 to 14 million Americans.[15]

There is significant uncertainty as to what these trends may mean for 2022 healthcare spending. In the first half of 2022, overall economic output declined, then grew at a slow rate in the third quarter.[16] During the summer of 2022, economy-wide inflation reached a four-decade high.[17] Data is currently incomplete to make a proper conclusion, but recent economic trends may have negatively impacted the health sector.

Looking beyond the COVID-19 pandemic, the severity of the pandemic and its impact on healthcare spending is expected to lessen healthcare expenditures.[18] Utilization trends are slowly stabilizing, and federal government funding for COVID-19 has largely ceased, with the U.S. continuing to inch toward a pre-pandemic state of normal. With the current volatility of the U.S. economy, and the unknown impact of 2022's inflation, there are many variables subject to change, which may have substantial impact on overall GDP and healthcare spending.

Healthcare finance and economics experts assert that healthcare expenditure trends highlight a key concern – price inflation. As a Johns Hopkins University associate professor noted, "Even without the coronavirus outbreak, the growth trajectory for health care spending isn't going to be bent in the foreseeable future. With the coronavirus outbreak, the trajectory will be boosted instantaneously and keep ballooning as we invest more in national health security."[19]



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MedPAC Recommends Increasing Hospital & Physician Payments for 2024

[Excerpted from the article published in March 2023.]

On March 15, 2023, the Medicare Payment Advisory Commission (MedPAC) published its annual Report to Congress regarding the status of the Medicare program.[1] Among other areas, the report detailed policy recommendations for the Medicare fee-for-service (FFS) payment systems, the Medicare Advantage (MA) program, and the Medicare prescription drug program (Medicare Part D). This Health Capital Topics article will review the recommendations made by MedPAC and responses from industry stakeholders.

MedPAC is an independent congressional agency that advises the U.S. Congress on issues affecting the Medicare program, such as "payments to private health plans participating in Medicare and providers in Medicare's traditional fee-for-service program, [as well as] access to care, quality of care, and other issues affecting Medicare."[2] Additionally, MedPAC is required by law to annually assess the adequacy of Medicare payments for various healthcare delivery sectors and make payment update recommendations.[3] In making that assessment, the commission analyzes factors such as patient access to care, quality of care, hospital access to capital, Medicare payments, and hospital costs.[4]

In Chapter 3 of its Report to Congress, MedPAC reported that in 2021, the all-payor margins for hospitals participating in the Inpatient Prospective Payment System (IPPS) reached a record high of 8.7%, indicating a stronger access to capital.[5] However, hospitals' average Medicare margins were -6.2% with federal relief funds, and -8.3% without federal relief.[6] MedPAC also noted that costs increased for hospitals in 2022, and will likely continue in 2023, resulting in lower Medicare margins of approximately -10%.[7] As regards quality of care measures, hospital readmission rates for Medicare FFS beneficiaries improved, but risk-adjusted hospital mortality rates remained higher than in 2019 and patient experience scores declined.[8] In consideration of the above, MedPAC suggested that Congress update the Medicare IPPS base payment rates for fiscal year (FY) 2024.[9] MedPAC additionally stated that the statutorily-required annual base payment rate increase should be increased by an additional 1% for FY 2024. Because MedPAC does not believe this 1% increase will be financially sustainable for safety-net hospitals (which typically have a poorer payor mix), the commission addressed these hospitals separately.[10] In addition to the outlined recommendations, MedPAC recommended payments should be redistributed through a new Medicare Safety-Net Index (MSNI), which would calculate a score for each hospital based on the hospital's proportion of Medicare beneficiaries, low-income Medicare beneficiaries, and uncompensated care.[11] MedPAC explains that the MSNI would be structured as a percentage add-on payment to current IPPS payments, so those safety-net facilities with a higher proportion of low-income patients would receive

enhanced payments.[12] To fund the anticipated cost of MSNI add-on payments, MedPAC suggests that Congress "add $2 billion to the MSNI pool."[13]

In Chapter 4 of its Report to Congress, MedPAC further recommended that for FY 2024, Congress update the Medicare Physician Fee Schedule (MPFS) "by 50 percent of the projected increase in the Medicare Economic Index [MEI]."[14] The MEI was developed by the Centers for Medicare & Medicaid Services (CMS) to measure annual changes in physicians' operating costs and earnings levels, and is a significant factor in determining the annual payment update for Medicare fee schedules.[15] In making this recommendation, MedPAC cited concerns that current payment levels may make it difficult for clinicians to absorb increasing costs due to inflation.[16] Because half of the projected MEI is designated to practice expenses, MedPAC suggested increasing the payment rates by 50% of the MEI, or 1.45%, to account for those increased practice costs.[17] By doing so, MedPAC expects that the recommended increased payments will be able to sufficiently keep up with practice costs.[18]

As relates to Medicare Part C, also known as MA (where Medicare coverage is offered by private companies), MedPAC called for a "major overhaul of MA policies," citing concerns that there is not enough financial pressure on MA plans to ensure they continue to reduce costs and improve quality of care.[19] While MedPAC reaffirmed their support for MA, they expressed concern that Medicare overpays MA plans.[20] Under the current payment policies, the report established that continuing to overpay MA plans would worsen the fiscal sustainability of Medicare overall, especially as the proportion of Medicare beneficiaries who enroll in MA plans grows.[21] The MA program enrolled 49% of Medicare beneficiaries in 2022, with Medicare paying MA an estimated $403 billion.[22] While MA plans have offered "a historically high level of benefits" to enrollees for the seventh straight year, with average rebates reaching $2,350 per enrollee in 2023 (double the rebate amounts in 2018), taxpayers are not realizing any savings from MA plan efficiencies.[23]

Reporting on the status of Medicare Part D, Medicare's prescription drug program, MedPAC reported that in 2021, total Part D spending was $110.8 billion; of total, Part D enrollees paid $14.9 billion in premiums for basic benefits, $7.5 billion in premiums for enhanced benefits, and $17.9 billion in cost sharing, accounting for 55% of the total program spending.[24] Despite this extensive spending, the value of the benefits that enrollees have received through the program has "plummeted" in recent years.[25] Consequently, MedPAC renewed its previous recommendations significantly change Part D's benefit design "to limit enrollee out-of-pocket spending; realign plan and manufacturer incentives to help restore the role of risk-based, capitated payments; and eliminate features of the current program that distort market incentives."[26]

Stakeholders quickly responded to MedPAC's report, with the general consensus that MedPAC's suggested payment updates would not be sufficient. The American Medical Association (AMA) agreed with MedPAC's acknowledgment of the rising costs to practice medicine, which it claimed to

be a good first step.[27] AMA President, Jack Resneck, Jr. M.D., stated that the AMA feels "strongly that an update tied to just 50% of MEI will cause physician payment to chronically fall even further behind increases in the cost of providing care. Congress should adopt a 2024 Medicare payment update that recognizes the full inflationary growth in healthcare costs."[28] The Medical Group Management Association (MGMA) agreed that this update would not be enough.[29] The Senior Vice President of Government Affairs of MGMA, Anders Gilberg, said that "[i]n the best of times, such a nominal increase would not cover annual medical practice cost increases. In the current inflationary environment, it is grossly insufficient. Medical practices have been suffering from significant staffing shortages and cost increases across the board. An update of any amount less than the full MEI will not adequately remedy the negative impact of the broader economy on practices' financial stability."[30] The AMA, along with 134 other organizations, memorialized these sentiments in a letter that was sent to Congress urging legislators to tie future MPFS payment updates to the full MEI rate, rather than just half.[31] Congress's response to the letter – and to MedPAC's recommendations – will most likely be included in CMS's proposed payment updates for these payment systems, which are typically released in the late spring/summer.

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CMS Announces New Primary Care Model

[Excerpted from the article published in June 2023.]

On June 8, 2023, the Centers for Medicare and Medicaid Services (CMS) announced the establishment of Making Care Primary (MCP) Model, a voluntary primary care model that will be tested in Colorado, Massachusetts, Minnesota, New Mexico, North Carolina, New York, New Jersey, and Washington.[1] Set to launch on July 1, 2024, the 10 ½ year model will seek to improve the coordination and management of care, enable primary care clinicians to form relationships with healthcare specialists, and form community-based connections to address the health needs of patients, as well as health-related social needs such as nutrition and housing.[2] This Health Capital Topics article will discuss the new MCP Model and its implications for the healthcare industry.

The MCP Model aims to improve the care Medicare and Medicaid beneficiaries receive by the delivery of advanced primary care services, which are foundational to high-performing health systems.[3] The model was built upon previous primary care models such as the Maryland Primary Care Program (MDPCP), the Primary Care First (PCF) model, and the Comprehensive Primary Care (CPC/CPC+) Model.[4] The MCP Model will give primary care clinicians a pathway to adopt population-based payments while driving equitable access to care and building infrastructure to improve specialty integration and behavioral health.[5] Not only will the model strengthen coordination among specialists and clinicians, but it will include behavioral clinicians and social service providers, in an effort to lower emergency room utilization, prevent chronic disease, and achieve overall better health outcomes.[6]

Enhanced reimbursement through the MCP Model will be risk-adjusted to suit the needs of the community and patient populations.[7] While provider reimbursement will start out as traditional fee-for-service (FFS), this model is designed to prepare providers for newer payment arrangements and slowly move them away from the traditional models.[8] Model participants will be placed in one of three tracks, based on their experience with value-based care:[9]

(1) **Track 1:** Intended for those who will require support to incorporate value-based care into their organization. Participants will focus on establishing the foundational infrastructure for advance primary care services, e.g., "risk-stratifying their population, reviewing data, building out workflows, identifying staff for chronic disease management, and conducting health-related social needs screening and referral." While CMS will continue to pay FFS payments to participants in this track, the agency will also provide additional financial support to help with the establishment of this foundation. Participants will also be able to earn financial incentives for improving outcomes.[10]

(2) **Track 2:** Participants are expected to partner with medical specialists and social service organizations to institute care management programs and screen patients for behavioral health conditions. In this track, primary care reimbursement will be a 50/50 mix of FFS and prospective, population-based payments, while participants will also receive financial support from CMS (similar to Track 1) and can continue to earn incentive payments in exchange for improving outcomes.[11]

(3) **Track 3:** Participants are expected to expand upon the above tracks by "using quality improvement frameworks to optimize and improve workflows, address silos to improve care integration, develop social services and specialty care partnerships, and deepen connections to community resources." Primary care payments in this track will be 100% prospective, with continued additional financial support (although at a lower level) and the ability to earn higher incentive payments for improved outcomes.[12]

The goal of this model is to transform the delivery of healthcare, especially in primary care, through three major parts: (1) community integrations, which will address social needs that are related to health; (2) care management, where participants will offer support services; and (3) care integration, where primary care providers will align with specialists.[13] Not only will the model support Medicare and Medicaid providers in transitioning to value-based care, but it will aim to help Indian Health Service (IHS) and federally qualified health centers (FQHCs) providers, as well as rural providers and small physician practices.[14] CMS will also work with Medicaid in the participating states to transform and align public programs with the MCP Model.[15]

For an organization to be eligible to participate in the MCP Model, they must:

- Be enrolled in Medicare;
- Provide care to at least 125 Medicare beneficiaries;
- Have a majority of their primary care locations or sites located in an MCP state; and
- Be a legal entity formed under the applicable laws, authorized to conduct business within the state it operates.[16]

Organizations will be unable to participate in both the Medicare Shared Savings Program (MSSP) and the MCP at the same time after the first six months of the MCP Model.[17] Concierge practices, rural health clinics, current PCF practices, grandfathered Tribal FQHCs, and current ACO REACH providers will all be ineligible for the MCP Model.[18]

Provider groups are largely applauding CMS's next iteration in the shift to value-based care.[19] Susan Dentzer, the President and Chief Executive Officer of America's Physicians Group (APG), stated that "holding primary care physicians accountable for costs and quality is central to achieving the promise of value-based health care. It's therefore important to continue to provide accessible 'on ramps' for small practices to enable them to make what could

otherwise be a difficult transition for them."[20] She also added that longer-term models such as the MCP will offer more stability to those who participate, and may ensure greater overall participation.[21]

The test period established in this model is responsive to recommendations by the American Medical Association (AMA), which called for more stability and transparency to encourage provider participation.[22] The AMA's president stated that "the AMA strongly believes value-based care models are essential to the long-term wellbeing of the Medicare program and its ability to meet the needs of a diverse and aging population."[23]

CMS did receive pushback from the National Association of Accountable Care Organizations (NAACOS), which stated that this latest model will exclude providers who have already been in accountable care organizations (ACOs), and will force organizations to decide between participating in the MCP Model or in an ACO.[24] The President and CEO of NAACOS, Clif Gaus, said that "while aspects of the new model are positive, practices should not be forced to choose between Making Care Primary and participating in an ACO.[25] Within ACOs, primary care practices are the quarterback of care teams, but they must work with providers across the care continuum to achieve quality outcomes and cost savings."[26]

CMS plans to begin the application period for this model later in the summer of 2023, with more technical details on the model to come soon.[27]

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Projected National Health Expenditures to Surpass $7 Trillion

[Excerpted from the article published in June 2023.]

On June 14, 2023, the Centers for Medicare and Medicaid Services (CMS) released health insurance enrollment and national health expenditure (NHE) projections for 2022 through 2031.[1] The NHE, which is published annually, is the official U.S. estimate of insurance enrollment and health spending.[2] CMS projects that from 2022 to 2031, the NHE's annual growth rate of 5.4% will surpass the U.S. gross domestic product (GDP) annual growth rate of 4.6%.[3] As a result, health spending as a share of the U.S. GDP is set to jump from 18.3% in 2021 to 19.6% in 2031.[4] This Health Capital Topics article will review the notable findings from CMS's projection report.

Recent legislation is expected to influence future trends in healthcare spending and insurance enrollment.[5] Medicaid enrollment is set to decline in the next two years, with the greatest enrollment losses due to states resuming their annual Medicaid redeterminations.[6] During the COVID-19 public health emergency (PHE), states were prohibited from removing anyone from their Medicaid rolls, even if that individual was no longer Medicaid-eligible.[7] The expiration of the PHE ended that prohibition and is expected to cause a significant reduction in Medicaid enrollment, with numbers falling to 81.1 million by 2025 after peaking at 90.4 million in 2022.[8] In contrast, enrollment in private health insurance is expected to increase through 2025, due to the expanded eligibility for ACA Marketplace plan subsidies promulgated by the American Rescue Plan Act of 2021.[9]

In addition to enrollment trends, recent legislation has also influenced projected spending. The end of the PHE resulted in the expiration of add-on provider payments for COVID-19 related hospital admissions.[10] Additionally, the Inflation Reduction Act (IRA) of 2022 required the U.S. Department of Health and Human Services (HHS) to negotiate pricing for some high-cost drugs.[11] The IRA will further impact spending trends by reducing out-of-pocket costs for Medicare Part D beneficiaries limiting drug pricing increases, and reducing the cost of certain high-priced pharmaceuticals through negotiation.[12] These various legislative initiatives, spurred by the pandemic, will have varying effects on healthcare spending, with some policy changes expected to reduce spending, while others are anticipated to increase it.[13]

For Medicare and Medicaid, the average annual expenditure growth rates from 2022 through 2031 are projected to be 7.5% and 5.0%, respectively, while private health insurance spending is projected to grow 5.4%.[14] Due to the cap on out-of-pocket spending for Medicare Part D beneficiaries, payment responsibility will shift to Medicare, resulting in increased spending.[15] Medicare spending is expected to grow 8.9% in 2025; however, with out-of-pocket spending capped for Medicare beneficiaries, projected spending for Medicare is due to slow by 2030 and 2031, to a rate of 6.8%, as a result of slow enrollment, and IRA provisions related to inflation rebates and negotiations over drug pricing.[16] The spending growth from private health insurers in 2023,

with projected growth in healthcare pricing and utilization, is projected to lead to a 7.7% increase in spending.[17] With enhanced Marketplace plan subsidies set to expire in 2026, and enrollment expected to drop as a result, private health insurance spending is expected to decline by 10%.[18] In 2022, enhanced Marketplace plan subsidies increased enrollment by 2.5 million, improving affordability.[19] Once those subsidies expire, the additional enrollees who had signed up due to lower premiums may not be able to afford it anymore, which could lead to a decline in private health insurance spending.[20]

Hospital spending is expected to grow rapidly from 2022 through 2031, at an annual average rate of 5.8%.[21] The spending growth from the hospital sector is expected to overtake spending in both the physician and clinical services sector (5.3%) and the prescription drug sector (4.6%).[22] Growth in utilization rates for hospitals and pricing are expected to accelerate in 2023; however, spending trends will normalize between 2025 and 2031 due the cessation of pandemic funding.[23] From 2025 through 2031, spending growth for physician and clinical services is projected to be 5.7%, with Medicare spending for these services exceeding that of the private health insurance spending due largely to an uptick in Medicare enrollment.[24] Retail prescription drug expenditure growth during 2023 (3.6%) and 2024 (3.7%) will reflect impacts from decreasing out-of-pocket spending, a decline in Medicaid spending on prescription drugs due to declining enrollment (as discussed above), and higher Medicare spending due to the IRA's cap on enrollee out-of-pocket spending.[25] Prescription drug spending is expected to slow to an average rate of 4.8% from 2025 through 2031.[26] Trends for this sector are expected to be driven by the introduction of new pharmaceuticals and an aging population, as well as legislative action.[27]

While the nation's spending on healthcare slowed down during the pandemic due to disruptions in the delivery of care, growth will reach $7.2 trillion by 2031.[28] The unwinding of pandemic-era provisions are expected to have a significant impact on CMS's projections, with the number of insured expected to drop significantly.[29] Health spending is set to grow rapidly in the next decade, and by the year 2031, for every $5 spent in the U.S. economy, $1 will account for health spending.[30]

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III. REGULATORY TOPICS

AHA Advocates for New Hospital Designation

[Excerpted from the article published in October 2022.]

The American Hospital Association (AHA) is advocating for the creation of a new hospital designation for certain urban safety net hospitals. In a report released in mid-October 2022, as well as in an accompanying fact sheet and letter sent to congressional leaders, the AHA defines these so-called Metropolitan Anchor Hospitals (MAHs), outlines their importance to the communities they serve, and explains why MAHs deserve supplemental financial support from the government.

At a high level, the AHA describes MAHs as "safety net hospitals…that serve large numbers of urban, low-income and historically marginalized individuals."[1] Specifically, MAHs are defined as hospitals:

(1) "Located in an urban area;
(2) With a Medicaid Inpatient Utilization Rate (MIUR) greater than the statewide average, and
(3) With either:
    (a) A disproportionate patient percentage (DPP) greater than 70%, or;
    (b) A DPP greater than 34.5% combined with a ratio of uncompensated care costs (UCC)-to-beds of $35,000 or more."[2]

AHA identified 465 hospitals across 162 metropolitan statistical areas that fall within this definition, i.e., one in eight urban hospitals.[3]

Compared to other hospitals, MAHs:

(1) "are typically larger, accounting for 33% of market-wide beds and an estimated 34% of market-wide inpatient revenue";
(2) "[a]re major teaching hospitals";
(3) "[a]re more likely to provide essential services…[and p]rovide a greater number of these essential services, such as burn care, neonatal intensive care, inpatient psychiatric care, substance use disorder services, HIV care";
(4) "provide a disproportionately high amount of care to historically marginalized populations, accounting for about 48% of market-wide Medicaid inpatient days and 49% of market-wide uncompensated care costs";
(5) have an "average Medicaid Inpatient Utilization Rate (MIUR) of…nearly 37%, compared to 17% in other hospitals"; and
(6) "[a]re larger employers in their catchment areas."[4]

Because MAHs provide vital services in their communities, AHA is urging congressional leaders to create a "special statutory designation for MAHs."[5] Such a designation would pave the way for enhanced federal funding for those hospitals, which AHA argues is necessary because MAHs operate under low margins, due to treating more Medicaid patients and having above-average uncompensated care costs. These issues were highlighted by the COVID-19 pandemic, which stressed all hospitals, but was particularly devastating to those hospitals that serve in a safety net role (due not just to their already-low margins, but also to the sizable increase in the Medicaid population).[6] Those financial challenges are not yet over – a September 2022 report by healthcare consulting firm Kaufman Hall found that hospitals are on track for their worst financial year in decades.[7]

On October 24, 2022, AHA sent a letter to congressional leaders requesting that as leaders determine the legislative branch's end-of-year agenda, they consider additional priorities important to the trade association's member hospitals and health systems, including addressing workforce shortages and providing targeted relief to hospitals.[8] Further, the AHA letter specifically requested Congress to create an MAH designation.

If AHA's initiative is pursued by the federal government, it will be the second new hospital designation established in 2022. The Consolidated Appropriations Act of 2021 established the Rural Emergency Hospital (REH) designation.[9] Beginning January 1, 2023, facilities that are a rural hospital or a critical access hospital (CAH); have fewer than 50 beds; and do not provide acute care inpatient services (except for skilled nursing facility services in a distinct unit), can convert to an REH and receive an additional 5% on top of the Outpatient Prospective Payment System (OPPS) payment rate for each service, as well as a monthly facility payment.[10] The MAH initiative is a shift in focus for AHA, which has been advocating heavily for rural hospitals over the past few years. Since 2005, 183 rural hospitals and CAHs have either closed or eliminated inpatient services, and one-fourth of the remaining rural hospitals are vulnerable to closure.[11] With hospitals across the U.S. undergoing a third straight year of unprecedented challenges, driven by the COVID-19 pandemic, labor shortages and supply-chain disruptions, and the highest inflation rates in four decades – and soon to be further tested by a possible "tripledemic"[12] – finding creative ways for hospitals to receive enhanced funding may be necessary to save the U.S. healthcare delivery system from collapse.

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CMS Proposes Modernizing Prior Authorizations

[Excerpted from the article published in December 2022.]

On December 6, 2022, the Centers for Medicare & Medicaid Services (CMS) proposed a modernization of the prior authorization process for health insurance. The proposed rule seeks to require certain insurers to implement electronic prior authorization, shorten decision timeframes, and make the process more transparent and efficient.[1] The rule includes "five key provisions and five Requests for Information," aiming to "improve patient and provider access to health information and streamline processes related to prior authorization for medical items and services."[2] This Health Capital Topics article will review those provisions and requests for information, as well as stakeholder responses to the proposals.

Prior authorization requires providers to obtain approval from a patient's health insurance plan for certain procedures and drugs before the procedure is performed or the drug is prescribed. While insurers assert that prior authorization serves an important function in containing costs, providers counter that the number of services and drugs, as well as the administrative hurdles involved, that require prior authorization have increased, causing excessive hardships for providers.[3]

This 2022 proposed rule is the latest agency guidance in a number of other regulatory rulemakings over the past couple years. In May 2020, CMS issued its Interoperability and Patient Access final rule, which mandated the establishment of various technologies and the sharing of data to facilitate interoperable and promote patient access to health information.[4] Building upon this May 2020 final rule, CMS published in December 2020 a proposed rule that was nearly identical to the one proposed in December 2022.[5] CMS finalized the proposals but withdrew it soon thereafter "after concerns about costs and a short deadline."[6] With the December 2022 proposed rule, CMS formally withdrew the December 2020 proposed rule, but incorporated the public feedback it received from that previous proposed rule.[7] Importantly, the December 2022 proposed rule expands upon its 2020 predecessor by including Medicare Advantage plans.[8]

CMS introduced a number of major proposals to modernize the prior authorization process relating to:

(1) Patient Access Application Programming Interface (API);

(2) Provider Access API;

(3) Payer-to-Payer Data Exchange on FHIR®;

(4) Improving Prior Authorization Processes; and

(5) Electronic Prior Authorization Measure for Merit-based Incentive Payment System (MIPS) Eligible Clinicians and Hospitals and Critical Access Hospitals (CAHs).[9]

First, the insurers targeted by the proposed rule – Medicaid, Medicare Advantage (MA), and health insurance exchange carriers – would be required to include additional information in their Patient Access API by January 1, 2026.[10] APIs are "mechanisms that enable two software components to communicate with each other using a set of definitions and protocols."[11] An example of an API is "[t]he weather app on your phone [which] 'talks' to [the weather bureau's software] system via APIs and shows you daily weather updates on your phone."[12] Insurers were already required to implement a Patient Access API pursuant to CMS's 2020 final rule (discussed above);[13] this proposed rule simply requires payors to add information related to previous prior authorization decisions and begin reporting certain metrics each year regarding patient use of the API. [14]

Second, insurers would be required to build and maintain a Provider Access API (an API similar to that already implemented for patients) so that providers in the same network can share patient data. This API should include patient claims and encounter data and be up and running by January 1, 2026. CMS asserts that the implementation of this API will "better facilitate coordination of care, and support movement toward value-based payment models."[15]

Third, CMS proposes requiring insurers build and maintain a Fast Healthcare Interoperability Resources® (FHIR®) API. The FHIR® is a data standard that defines how healthcare information can be exchanged; this allows electronic health record (EHR) systems and other systems to be interoperable, i.e., through FHIR®, so that payors or providers can exchange information even if different systems are utilized.[16] Importantly, setting up an FHIR® API will allow for electronic prior authorization. If finalized, this means that if a patient switches insurers, and gives their permission, the previous insurer must share the patient's data with the new insurer through the FHIR® API. Further, if a patient has two insurances, those payors must share the patient's data with each other at least quarterly. CMS reasons that requiring this data sharing will "ensure a patient's data can follow them throughout their health care journey."[17]

Fourth, calling the current prior authorization process "a major source of provider burnout," and recognizing that it "can become a health risk for patients if inefficiencies in the process cause care to be delayed," CMS proposes a number of updates to make the process "more efficient and transparent."[18] For example, providers will be required to build and maintain a Prior Authorization Requirements, Documentation and Decision (PARDD) API, utilizing FHIR® (discussed above) to streamline the process.[19] Additionally CMS proposes cutting in half the amount of time that insurers have to respond to prior authorization requests, depending on their urgency. For urgent requests, insurers would be required to respond within 72 hours, while standard requests must be resolved within 7 days.[20] Insurers would also have to publicly report certain data related to their prior authorization decisions, and provide reasoning for any denials.[21]

Fifth, CMS proposes adding a new metric for Merit-based Incentive Payment System (MIPS) eligible providers to report. In order to achieve the metric,

which will be under the Promoting Interoperability performance category of MIPS, eligible providers will have to report the number of prior authorizations requested from a PARDD API. [22]

While CMS previously proposed, in its 2020 final rule, to require "the use of certain Implementation Guides (IGs) for the implementation of the APIs," the agency ultimately decided not to move forward with requiring these IGs. However, CMS strongly recommends their use and will continue to observe their development for possible future rulemaking.[23]

In totality, CMS estimates that these policies, if finalized, would save healthcare providers over $15 billion over a 10-year period.[24] In addition to those five key proposals, CMS also introduced a number of requests for information (RFI). Specifically, the RFI that CMS seeks include:

(1) "Accelerating the Adoption of Standards Related to Social Risk Factor [e.g., housing instability, food security] Data" – specifically, CMS is interested in how it can "better standardize and liberate these data";

(2) "Electronic Exchange of Behavioral Health Information" – specifically, CMS "seek[s] comment on how CMS might leverage APIs, or other solutions, to facilitate electronic data exchange with behavioral health providers who have lagged behind other provider types in EHR adoption";

(3) "Improving the Electronic Exchange of Information in Medicare Fee-for-Service (FFS)" – specifically, CMS "seek[s] comment on how Medicare FFS might best support improvements to the exchange of medical documentation between and among providers/suppliers and patients, as well as how [CMS] might best inform and support the movement and consistency of health data to providers for their use to inform care and treat patients";

(4) "Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)" – TEFCA has the goal of establishing "a universal floor for interoperability" throughout the U.S.[25] CMS is interested in "how enabling exchange under TEFCA can support these proposals…[and CMS's] approach to incentivizing or encouraging payers to enable exchange under TEFCA."

(5) "Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health" – CMS seeks public input "on evidence-based policies [the agency] could pursue that leverage health IT, data sharing, and interoperability to improve maternal health outcomes."[26]

In announcing the proposed rule, CMS Administrator Chiquita Brooks-LaSure stated "[t]he prior authorization and interoperability proposals…would streamline the prior authorization process and promote health care data sharing to improve the care experience across providers, patients, and caregivers – helping us to address avoidable delays in patient care and achieve better health outcomes for all."[27]

Industry stakeholders seemed to agree with CMS, lauding the proposed rule. The American Hospital Association (AHA) commended CMS on the rule, particularly in the inclusion of Medicare Advantage plans.[28] The Medical Group Management Association (MGMA) stated that "[a]n alarming number of medical groups report completing prior authorization requests via paper forms, over the phone, or through varying proprietary online payer portals…The onerous methods of completing these requests, coupled with the increasing volume is unsustainable."[29] Consequently, "[t]his is a positive step forward for both medical groups and the patients they treat. We look forward to working with CMS to refine and finalize this rule."[30] Insurer trade associations have also spoken positively on the rule. An MA advocacy group said that the proposed rule "complements our goals of protecting prior authorization's essential function in coordinating safe, effective, high-value care."[31] AHIP, an insurer trade group, offered their support for the proposed rule, but warned that "a gap remains in our nation's privacy framework" that needs to be addressed and bridged.[32]

Stakeholders may now comment on the proposed rule, through March 13, 2023.

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Advisory Opinion Allows Nurse Practitioner Support in Hospitals

[Excerpted from the article published in January 2023.]

On December 19, 2022, the *Department of Health and Human Services* (HHS) *Office of Inspector General* (OIG) published *Advisory Opinion* (AO) No. 22-20, analyzing the utilization of nurse practitioners (NPs) in lieu of attending physicians within medical units. The OIG concluded that the arrangement utilizing NPs in certain medical units, subject to several safeguards, presented a low risk for fraud or abuse.[1]

The OIG typically releases several AOs each year regarding their opinions on certain business arrangements – either existing or proposed – on which a party (such as a healthcare organization) has requested an opinion. An AO is the OIG's position on whether a certain business arrangement is in conflict with the federal Anti-Kickback Statute (AKS), one of the laws the OIG is charged with enforcing.

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.[2] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[3] Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited. Consequently, the law has a number of exceptions, termed *safe harbors*,[4] which set out regulatory criteria that, if met, shield an arrangement from liability, and are meant to protect transactions unlikely to result in fraud or abuse.[5] However, failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[6]

Under the arrangement proposed to the OIG, the Requestor of the AO, an acute care hospital comprised of two campuses that provides both inpatient and outpatient hospital-based services, would provide NPs to assist in rendering certain care to patients of Participating Physicians, which patients are admitted or in observation status in two designated medical units.[7] The NPs would perform a wide range of tasks, some of which tasks the Participating Physicians would otherwise have to perform, including:

- Initiating plans of care through existing protocols;
- Implementing any applicable care protocols instituted by the hospital (e.g., stroke or community-acquired pneumonia protocols);
- Making rounds on assigned units, during which the NPs would address concerns of patients and their families, as well as those of nurses and other clinicians (e.g., physical therapists and speech therapists);
- Responding to laboratory or imaging studies, including arranging follow-up testing and attending to abnormal studies as needed;

- Addressing rapid changes in patient condition, including adjusting care plans and ordering imaging, laboratory tests, or other diagnostic tools or interventions in real time;
- Educating and supporting patients and families;
- Coaching, educating, and otherwise supporting nurses in the unit, including providing certified continuing education;
- Overseeing and supporting unit-based quality improvement projects; and
- Discharge planning, which at times may include obtaining insurance authorizations for post-acute care (such as for home health, skilled nursing, or acute inpatient rehabilitation) and scheduling follow-up testing and appointments.[8]

The aforementioned medical units subject to this agreement are general care units, i.e., not surgery or specialty care units (e.g., critical care, cardiology), and the Participating Physicians are predominantly primary care physicians.[9] From the experience of the hospital Requestor, having NPs readily available in these medical units improves patient care by allowing quick and efficient patient evaluations so that diagnoses can be received and treatment can be rendered as soon as practicable.

As communicated to the OIG, the Requestor's proposed arrangement includes various safeguards, meant to protect against any fraud and abuse, including that:

- The NPs perform their duties in communication and collaboration with the Participating Physician treating the patient;
- The Participating Physician (or other qualified physician if the Participating Physician is unavailable) must still round daily, and Participating Physicians must maintain the same accountability as physicians who do not participate in this agreement;
- Participating Physicians are prohibited from billing for the services provided by NPs;
- Consistent with Medicare guidelines, Participating Physicians must conduct their own patient assessments and generate their own documentation in order to bill for services;
- The Requestor will pay for all services rendered by the NPs, and will not separately bill any payor, including Federal healthcare programs, for the NPs' services;
- Each year, the Requestor will send a letter to all physicians with privileges at the hospital who regularly admit patients to the two designated medical units, including physicians employed by affiliates of the Requestor and physicians employed by independent physician groups, informing them of the proposed arrangement;
- The Requestor will not take into account a physician's volume or value of expected or past referrals, nor will it target any particular referring

physicians, when offering and providing NP services under this agreement;

- Payments will not be made to Participating Physicians, and there will be no ancillary agreements with Participating Physicians that would otherwise induce reward referrals to the Requestor; and
- Any compensation the Requestor pays to Participating Physicians outside of the proposed arrangement does not reflect or take into account any NP services performed.[10]

The OIG concludes its analysis by opining that this arrangement does implicate the AKS, specifically because the Requestor is providing remuneration in the form of in-kind NP services to Participating Physicians, which could induce such physicians to make referrals to the Requestor for items and services reimbursable by Federal healthcare programs. However, the OIG identifies three main reasons why this arrangement poses a minimal risk of fraud and abuse:

(1) The arrangement is restricted to two non-surgical, non-specialty units at one of the Requestor's hospital campuses;

(2) The arrangement contains safeguards that lower the risk of fraud and abuse under the AKS (e.g., duties performed by nurse practitioners are done so in communication and collaboration with Participating Physicians); and

(3) The design of this arrangement appears unlikely to increase costs to federal healthcare programs and may ensure an appropriate level of care for patients within the aforementioned units.11

As noted by legal experts, this AO deviates from OIG's typical approach to limiting arrangements involving potential remuneration from a hospital to its referring physicians.[12] This deviation may be attributed to OIG's emphasis on healthcare providers offering quality care to Medicare and Medicaid beneficiaries.[13] In this case, the proposed arrangement's focus is on promoting quality and timely patient care, which is consistent with the OIG's push for value-based care.[14]

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Public Health Emergency Will End in May 2023

[Excerpted from the article published in February 2023.]

On January 30, 2023, President Joseph Biden announced that the *public health emergency* (PHE) and national emergency declaration related to the COVID-19 pandemic will finally end on May 11, 2023, after being in place for over three years.[1] This Health Capital Topics article will discuss the changes that will take place after both declarations cease, and the implications for stakeholders.

The PHE was declared by the Secretary of *Health and Human Services* (HHS) on January 31, 2020, and was extended every 90 days thereafter.[2] The PHE granted the federal government temporary powers to help alleviate the effects of the pandemic, particularly in the healthcare sector.[3] Subsequent to the PHE, then-President Donald Trump issued a COVID-19 national emergency declaration, a separate declaration from the PHE, on March 13, 2020.[4] The ultimate end date of both of these declarations was purposefully selected by The White House, with a specific goal of giving at least a 60-day advance notice of the PHE's end to healthcare providers, rather than abruptly ending this declaration, which could have created chaos and uncertainty throughout the healthcare system.[5]

With the end of the PHE and national emergency declaration, all of the regulatory waivers and flexibilities that were granted (CMS has "a 47-page list of blanket waivers that have been in effect during the emergency"[6]) are set to expire, and most flexibilities granted by the declarations will end.[7] The declarations provided the federal government additional power to waive and modify regulatory requirements in a variety of areas, including private health insurance, Medicare, and Medicaid.[8] Some of the major policies due to go away on May 11, 2023, at the end of the national emergency declaration and PHE, are listed below:

- During the COVID-19 pandemic, states were not allowed to remove Medicaid enrollees from their rosters, even if the enrollee was no longer Medicaid-eligible. Beginning May 12, 2023, states will be able to proceed with Medicaid redetermination. HHS expects this redetermination will result in 15 million Americans losing Medicaid benefits.
- Portions of the Anti-Kickback Statute and Stark Law were waived during the PHE to ensure care accessibility for Medicare and Medicaid beneficiaries. The waivers allowed hospitals to, among other things, compensate physicians above fair market value, e.g., provide hazard pay, and deliver other, additional benefits.
- The Centers for Medicare and Medicaid Services (CMS) waived requirements for hospital discharge planning during the PHE, and allowed hospitals significant administrative flexibility such as

extended timelines for completing medical records and increasing the use of verbal orders.

- Hospitals were allowed to render patient care in locations beyond the hospital facility (i.e., at alternate care sites), as long as approval was gained from the state in which the hospital was located.
- Beneficiaries were not required to be admitted to the hospital for at least three days before Medicare would cover subsequent skilled nursing home stays.
- The Drug Enforcement Agency (DEA) allowed providers the flexibility to prescribe controlled substances through telehealth, which boosted care in rural areas.[9] However, the DEA is working to make some of these flexibilities permanent. On February 27, 2023, the agency published a proposed rule that, if finalized, would establish two new limited exceptions for the telemedicine prescribing of controlled substances without a prior in-person exam.[10]

In addition to the waivers and flexibilities ending with the PHE, other policies were extended for a certain period of time beyond the PHE through acts of Congress or by the Biden Administration, including those listed below:

- The *New COVID-19 Treatments Add-on Payment* (NCTAP), the add-on Medicare payment for new treatments surrounding COVID-19, is expected to lapse at the end of the 2023 fiscal year.
- During the PHE, Medicare beneficiaries were able to receive telehealth services anywhere, not just in rural settings. Telehealth visits were able to be provided through smartphones in lieu of audio and visual capable equipment, and beneficiaries were able to remain in their houses for telehealth visits, without needing to step foot in a healthcare facility. The Consolidated Appropriations Act of 2023 extended these flexibilities through December 31, 2024. [11]

The Biden Administration's announcement that the PHE declaration will end on May 11, 2023, prompted responses from healthcare stakeholders such as the *American Hospital Association* (AHA) and the Medical Group Management Association (MGMA). Stacey Hughes, the AHA Executive Vice President for Government Relations and Public Policy, stated that the decision to end the declaration represented progress made, but that the progress should not end with the PHE.[12] She also stated that the AHA will work with the Biden Administration to build on lessons learned during COVID-19, and the organization strongly urges that many of the flexibilities granted during the PHE be made permanent.[13] MGMA asserted their appreciation that the administration provided at least 90 days' notice prior to the conclusion of the PHE.[14] Additionally, MGMA sent a letter to the Senate and House of Representatives committees on telehealth, urging a permanent expansion of the telehealth services that was enacted during the PHE.[15] Suggestions from MGMA included allowing permanent coverage of audio-only telehealth

services and eliminating in-person requirements for mental telehealth services.[16]

Regardless of whether certain COVID-19 era waivers and flexibilities are made permanent, providers will be hard pressed to move away from what has become common practice over the past three years. A Premier Inc. survey of its "hospitals and non-acute providers reveals 69 percent of respondents are currently leveraging" these waivers and flexibilities.[17] While 80% of respondents have a plan in place to unwind their reliance on the waivers, more than half of those relying on waivers say they may need 120 days or more to fully revert to pre-COVID-19 operations.[18] Therefore, whether the U.S. healthcare delivery system actually can go back to pre-COVID, "business as usual" operations remains to be seen.

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The COVID-19 Public Health Emergency Officially Ends

[Excerpted from the article published in May 2023.]

After being in place for over three years – and after 1.1 million deaths and 6 million hospitalizations in the U.S. – the COVID-19 public health emergency (PHE) finally ended on May 11, 2023.[1] The PHE, which was originally declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, granted the federal government temporary powers to help alleviate the effects of the pandemic, particularly in the healthcare sector.[2] During the PHE, the federal government also took action to cushion the effect of the pandemic on providers, supporting public health efforts and stimulating the economy with investments of $4.4 trillion through multiple legislative packages and the enactment of over 200 regulatory waivers.[3] The measures taken were able to support the vaccination and testing efforts, while expanding coverage and access to care, giving a lifeline to providers that were facing unprecedented challenges.[4]

The PHE was extended every 90 days after its initial declaration, until President Joseph Biden announced on January 30, 2023 that the PHE would no longer be extended.[5] The end of the PHE has triggered the expiration of most pandemic-related flexibilities and programs, including those implemented by the Centers for Medicare and Medicaid Services (CMS), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA), among other agencies.[6] However, these and other agencies have extended some of their regulatory flexibilities past the end of the PHE. For example, on May 10, 2023, the DEA announced their extension of certain exceptions, such as:

- An exception to the requirement that an authorized individual must sign an invoice at the time of the delivery of controlled substances to a program for narcotics treatment;
- An exception that allowed DEA-registered hospitals/clinics to use (non-registered) satellite hospital/clinic locations under certain conditions. A related exception allowed distributors to ship controlled substances directly to these satellite hospitals/clinics, even though they were non-registered locations;
- An exception that allowed an individual manufacturer's inventory to exceed 65% of estimated net disposals;
- An exception that allowed a DEA-registered practitioner to distribute controlled substances beyond 5% of the total number of dosage units of controlled substances distributed and dispensed during the year without having to register as a distributor;
- An exception allowing deliveries to "safe zones" next to the purchaser's registered location, as long as the delivery was still made in person; and
- An exception that allowed DEA-registered practitioners 15 days to provide a follow-up hard copy prescription to the pharmacy after

issuing an emergency oral prescription, which prescription could be a photograph/scan of the written prescription and/or could be provided via fax.[7]

While many COVID-19 PHE flexibilities and policies have already been extended or made permanent for a certain amount of time, others expired as of May 11, 2023.[8] On May 9, 2023, HHS released a fact sheet detailing the agency's post-PHE changes, including (but not limited to) the following:

- Certain waivers for Medicare and Medicaid, and other broad flexibilities for healthcare providers that are no longer necessary, ended. Many of these waivers and flexibilities were essential to expanding facility capacity and allowing the healthcare system to weather the strain created by COVID-19;
- COVID-19 coverage testing changed, with over-the-counter (OTC) COVID tests no longer covered by Medicare, and Medicaid coverage set to end on September 30, 2024. However, the government is maintaining stockpiles of tests, and channels for distribution, so that tests remain accessible at no cost in certain locations.
- HHS no longer has the authority to require COVID-19 data surveillance from laboratories, negatively affecting test results (and COVID-19 positivity rates). Data reporting for hospitals will continue as required through April 30, 2024, but reporting is reduced from the current daily reporting to weekly reporting.
- While the FDA will maintain their authority to detect and address other medical product shortages, it is seeking authorization from Congress to extend the requirement for device manufacturers to notify FDA of interruptions/discontinuances of critical devices outside of a PHE, which will strengthen the ability of FDA to help prevent or mitigate device shortages in the future.[9]

Other PHE-related policies that have ended include the 20% payment bump that hospitals received for the treatment of COVID-19 patients and waivers that allowed non-physician providers expanded scope of practice, with certified registered nurse anesthetists (CRNAs) no longer able to work without the supervision of a physician.[10] Additionally, HHS will resume on August 9, 2023 the enforcement of telehealth providers that violate Health Insurance Portability and Accountability Act (HIPAA) by utilizing non-compliant platforms such as Skype or FaceTime to conduct patient visits.[11]

The PHE flexibilities and waivers most popular with both providers and patients during the pandemic were those related to telehealth. In response to calls to keep expanded telehealth coverage, CMS released additional guidelines addressing agency-specific waivers and flexibilities related to the technology. For example, until December 31, 2024, Medicare beneficiaries can access telehealth services anywhere (in most cases), rather than only in rural areas. Beneficiaries can access telehealth from their homes, and certain visits can be conducted through just audio (if someone is unable to use both video and

audio). Additionally, physicians and practitioners can continue to bill Medicare for telehealth services under the Medicare physician fee schedule for telehealth services through December 31, 2024.[12]

Perhaps one of the most significant changes post-PHE is the end of the Medicaid continuous enrollment requirement. In 2020, states agreed to an increased federal matching rate for Medicaid payments in exchange for not removing anyone from their Medicaid rolls for the duration of the COVID-19 PHE, even if that individual was no longer Medicaid-eligible.[13] Now that this has ended, states will have to determine eligibility again, a task that is expected to take anywhere from a few months to a year.[14] The Urban Institute estimates that 18 million Americans could lose Medicaid coverage, with 4 million becoming completely uninsured.[15]

The anticipated end of the PHE had prompted responses from healthcare industry stakeholders such as the American Hospital Association (AHA) and the Medical Group Management Association (MGMA). Stacey Hughes, the AHA Executive Vice President for Government Relations and Public Policy, stated that the decision to end the declaration represented progress made, but that the progress should not end with the PHE.[16] She also stated that the AHA will work with the Biden Administration to build on lessons learned during COVID-19, and the organization strongly urges that many of the flexibilities granted during the PHE be made permanent.[17] Additionally, MGMA has urged Congress to pass a permanent expansion of the telehealth services that were expanded during the PHE.[18] MGMA's suggestions included allowing permanent coverage of audio-only telehealth services and eliminating in-person requirements for mental telehealth services.[19]

Although the COVID-19 PHE has expired, the White House's COVID-19 Response Coordinator, Dr. Ashish Jha, warned that the pandemic itself is not over, and stated that he sees the end of the PHE "as a transition out of this emergency phase into a very different phase."[20] Dr. Jha also mentioned that while pandemic preparedness has come a long way, the U.S. is nowhere near where it needs to be for the next pandemic.[21] It is clear that there is more work to be done, including building better platforms for vaccines, bringing more rapid tests to the market, and tackling the greater healthcare issues and disparities the pandemic highlighted.[22]

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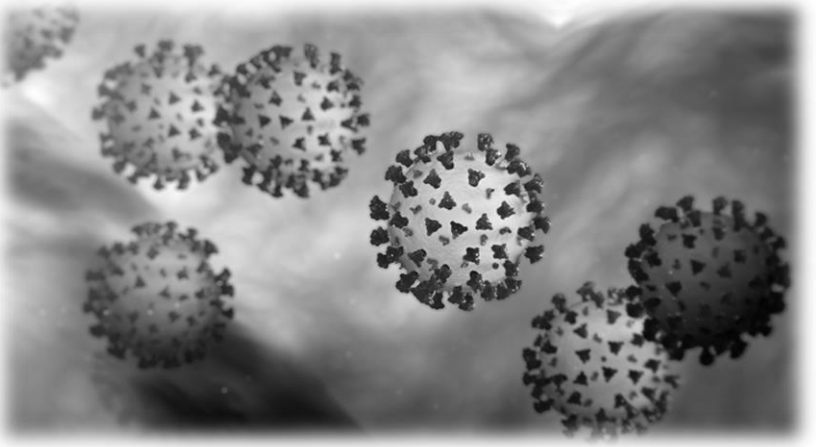

Supreme Court Agrees to Hear FCA Case

[Excerpted from the article published in February 2023.]

On January 13, 2023, the U.S. Supreme Court agreed to resolve a circuit split related to the *False Claims Act* (FCA) in granting certiorari in two lawsuits. The decision is expected to be the most significant development for the FCA in recent history, as it will finally resolve the necessary state of mind needed to violate the FCA.[1] This Health Capital Topics article will discuss the FCA, the two cases being decided by the Supreme Court, and potential implications for stakeholders.

In 1863, the FCA (a federal statute) was enacted in response to fraud committed by a defense contractor during the Civil War.[2] The FCA established that any person who knowingly submitted false claims to the government was liable for double the government's damages, plus a penalty; since its enactment, the law has been amended several times. Now, violators are liable for treble damages, along with a penalty linked to inflation.[3] Not only does the FCA give the U.S. government the ability to pursue fraud, it also enables private citizens to file suit on behalf of the federal government through what is known as a "*qui tam*" or "*whistleblower*" suit.[4]

For one to be held liable under the FCA, the perpetrator must act with "scienter," i.e., "knowingly," which is defined as acting with actual knowledge, deliberate ignorance, or in reckless disregard to the truth or falsity of the information.[5] Notably, "specific intent to defraud" is not required.[6] Defendants in such cases will often argue that their interpretation of complex statutes and regulations was reasonable, and not rising to the level of scienter.[7]

In deciding on the necessary state of mind required for liability under the FCA, the Supreme Court will review the lower court decisions of two cases: *Schutte v. SuperValu* and *Proctor v. Safeway*.[8] In *Schutte v. SuperValu*, two private citizen plaintiffs allege that SuperValu, a grocery store chain with 2,500 locations, knowingly submitted false payment claims to federal healthcare programs, and incorrectly reported drug prices.[9] SuperValu had implemented a price matching program for customers, but they did not report the price match amounts as their customary pricing, violating Medicaid regulations. A lower court ruled that the plaintiffs failed to prove the element of "scienter," i.e., they failed to demonstrate that SuperValu had an objectively unreasonable interpretation of the reporting requirement.[10]

In *Proctor v. Safeway,* the *qui tam* plaintiff alleged that Safeway, a grocery chain with over 900 locations, reported retail prices to government healthcare programs for certain drugs when customers actually paid less through price-matching and discounts.[11] In *Safeway*, lower courts ruled against the plaintiff, finding they had failed to prove the element of "scienter," and affirmed that Safeway had not acted in disregard to regulations and the grocery chain's interpretation of the law was objectively reasonable.[12]

Stakeholders will be closely watching the Supreme Court's analysis and ultimate decision as to whether a defendant's belief or understanding about the lawfulness of its conduct is relevant in determining whether the defendant knowingly violated the FCA. Previous legal rulings have established that defendants can avoid liability under the FCA as long as the defendant could prove an "objectively reasonable" interpretation of the law they are accused of violating.[13] The Department of Justice (DOJ) has expressed concern that if the Supreme Court finds that the *Safeway* and *SuperValu* defendants interpreted the law with objective reasonability, defendants in future litigation could potentially escape FCA liability.[14] On the other hand, if the Supreme Court rejects the standard set by the lower courts (that plaintiffs had failed to prove that the defendants had an objectively unreasonable interpretation of the law) and the "objective reasonability" shield is removed, it will become harder for defendants to argue that they did not possess the requisite knowledge (regardless of whether or not their actions were objectively reasonable), and clearing the path for the Department of Justice to reach FCA judgments and settlements, ultimately increasing recovery amounts. [15] In fiscal year 2022 alone, $2.2 billion was recovered through false claims and fraud ($1.7 billion of which was related to healthcare matters).[16]

Oral arguments for the two cases are scheduled for April 18, 2023.[17] Regardless of the outcome, stakeholders can expect that such a ruling from the Supreme Court will significantly impact future FCA cases[18] and could even prompt amendments to the FCA, potentially changing the way federal agencies and government contractors may issue any guidance.[19]

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Supreme Court Justices Hear False Claims Act Cases

[Excerpted from the article published in April 2023.]

On April 18, 2023, the U.S. Supreme Court heard oral arguments in two False Claims Act (FCA) cases, which cases center on the necessary state of mind needed to violate the FCA.[1] This Health Capital Topics article will review the oral arguments in the combined cases and how the justices seem posed to rule based on their questions and comments during the session.

The FCA is a Civil War-era federal statute that prohibits any person from "knowingly" submitting false claims to the government. Violators are liable for triple the government's damages (treble damages), plus a penalty linked to inflation.[2] Not only does the FCA give the U.S. government the ability to pursue fraud, it also enables private citizens to file suit on behalf of the federal government through what is known as a *qui tam* or "whistleblower" suit.[3]

For one to be held liable under the FCA, the perpetrator must act with "scienter," i.e., "knowingly," which is defined as acting with actual knowledge, deliberate ignorance, or in reckless disregard to the truth or falsity of the information.[4] Notably, "specific intent to defraud" is not required.[5] Defendants in such cases will often argue that their interpretation of complex statutes and regulations was reasonable, and not rising to the level of scienter.[6]

The Supreme Court's review centers on two decisions out of the 7th Circuit – *Schutte v. SuperValu* and *Proctor v. Safeway*.[7] In *Schutte v. SuperValu*, two private citizen plaintiffs allege that SuperValu, a grocery store chain with 2,500 locations, knowingly submitted false payment claims to federal healthcare programs, and incorrectly reported drug prices.[8] SuperValu had implemented a price matching program for customers, but did not report the price match amounts as their customary pricing, violating Medicaid regulations. In *Proctor v. Safeway*, the *qui tam* plaintiff alleged that Safeway, a grocery chain with over 900 locations, reported retail prices to government healthcare programs for certain drugs when customers actually paid less through price-matching and discounts.[9] In both cases, different judges within the 7th Circuit found for the defendants, holding that the defendants' subjective belief is never relevant to the determination of scienter. In fact, "[u]nder the 7th Circuit's view, even a post hoc objectively reasonable interpretation that was never considered by the defendant would seemingly immunize them from FCA liability."[10]

On January 13, 2023, the Supreme Court agreed to hear the cases and determine "[w]hether and when a defendant's contemporaneous subjective understanding or beliefs about the lawfulness of its conduct are relevant to whether it 'knowingly' violated the False Claims Act,"[11] or as Justice Elena Kagan framed it: "whether the intent of someone to make a false statement is actionable even if later they come up with a different…objectively reasonable argument."[12]

During the April 18, 2023 oral arguments, the Supreme Court appeared likely to reverse the lower court.[13] Justices Kagan, Sonia Sotomayor, and Ketanji Brown Jackson indicated their intent to affirm that evidence of subjective intent

was relevant to the inquiry of scienter, with Justice Neil Gorsuch agreeing.[14] Justices Clarence Thomas, Brett Kavanaugh, and Samuel Alito suggested that the issue may not be as straightforward as "a statement requiring an interpretation of law cannot be 'false,' let alone knowingly false, if the law is subject to more than one reasonable interpretation."[15] While the justices largely expressed skepticism regarding lower courts' ruling that subjective intent is irrelevant, some of the justices outright suggested a potential decision that subjective intent could be relevant in certain cases.[16]

Despite the fairly clear message sent by the justices during argument as to their interpretation of the objectively reasonable standard in these two particular cases, it remains to be seen whether the Court's opinion expands beyond this case and delves into the various nuances within the FCA scienter standard, such as when there are multiple objectively reasonable interpretations. For example, Justice Kavanaugh posited a hypothetical that was the focus for a substantial portion of the oral argument: "At the time, you have three different interpretations possible, and one's clearly safe, one's a little more aggressive, and the third's really aggressive, but you still think it's reasonable, and you go with that third one, and it's later – [the courts] don't agree later on, so it's 'false.'"[17] While the justices seemed to generally agree that the cases at issue fell under the third interpretation in Justice Kavanaugh's hypothetical, there was some discussion as to whether the court should go further and decide the legality of first two interpretations, and if so, what the rules would be for those two hypothetical interpretations.[18]

The plaintiffs welcomed the additional clarification, and asserted that the Court should do more than send the case back to the lower court to reconsider the defendants' conduct in light of their subjective belief.[19] The defendants were similarly interested in an expanded ruling, so as to provide clarity to the business community.[20]

The U.S. Supreme Court's ultimate decision (and the scope of that decision) will likely have a significant impact on future FCA claims. If the Court were to affirm the lower court holdings that objective reasonability negates scienter, the standard would remain as a powerful defense.[21] If the Court decides that the subjective intent of a defendant should be a factor to consider, it would be more difficult to dismiss on the grounds of scienter.[22]

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2022 DOJ False Claims Act Recoveries Surpassed $2.2 Billion

[Excerpted from the article published in February 2023.]

On February 7, 2023, the U.S. Department of Justice (DOJ) announced their recovery of $2.2 billion in settlements and judgments from civil cases involving the False Claims Act (FCA) for fiscal year (FY) 2022.[1] The overall recoveries in FY 2022 were far less than the DOJ's FY 2021 recoveries of $5.6 billion.[2] Of the $2.2 billion recovered in FY 2022, over $1.7 billion was recouped from the healthcare industry alone (much less than the over $5 billion recovered from the industry in FY 2021), and included recoveries from drug and medical manufacturers, home health and managed care providers, hospitals, pharmacies, hospice organizations, and physicians.[3] Healthcare industry settlements far outstripped recoveries from defense, energy, construction, and other industries.[4] The recoveries for FY 2022 reflect the DOJ's focus on new enforcement priorities, including violations of cybersecurity requirements in government funded grants and contracts, and fraud in pandemic relief programs.[5]

The DOJ pursued a number of cases related to providers allegedly billing federal healthcare programs for unnecessary medical services.[6] Such services waste taxpayer money and can potentially expose patients to harmful treatments or procedures.[7] Claims for unnecessary medical services were filed against the following organizations:

- **The American Health Foundation (AHF), AHF's management corporation, and three nursing home affiliates** were pursued for providing skilled nursing care that was substandard from 2016 through 2018. The government alleged that the nursing homes involved in the suit failed to meet standards of care in multiple ways, including failure to follow appropriate infection control protocol and not having adequate staffing.
- **Providence Health & Services Washington,** a healthcare system operating in several states in the Western U.S., paid $22.7 million to resolve federal allegations that they billed federal healthcare programs for neurosurgeries that were unnecessary.
- **Eargo Inc.,** a hearing aid device seller and dispenser, paid $34.4 million to resolve FCA and common law allegations that they submitted claims containing hearing-loss diagnosis codes that were not supported to a federal healthcare program for device reimbursement.
- **Carrefour Associates LLC** and related companies paid $5.5 million to resolve allegations that they had knowingly submitted claims to Medicare for hospice services for patients that were not terminally ill.
- **Signature Home Health Services of Florida LLC** paid $2.1 million to resolve allegations that they had provided services to beneficiaries of Medicare who were not homebound, not in need of skilled care, and

who did not have enough face-to-face encounters to warrant home health services.

- **Hayat Pharmacy** paid $2.05 million to resolve allegations that they submitted false claims to Medicaid and Medicare for prescription drugs that were switched to higher costing medications without any valid need.
- **Physician Partners of America LLC** paid $24.5 million to resolve allegations that they had billed federal healthcare programs for unnecessary genetic, psychological, and urine drug screenings. The DOJ alleged that physicians ordered multiple tests without a valid reason and claimed to not partake in illicit activity when receiving Paycheck Protection Program (PPP) funding.
- **MD Spine Solutions LLC** paid $16 million to resolve allegations that they similarly submitted false claims for unnecessary urine drug tests, and **Radeas LLC** paid $11.6 million to resolve allegations that they submitted false claims billing Medicare for urine drug testing that was medically unnecessary, while running multiple tests on the same urine sample.[8]

Several lawsuits were resolved in 2022 related to unlawful kickbacks. For example, the DOJ filed suit against a chiropractor, alleging that the defendant had offered physicians the opportunity to invest in the chiropractor's labs in exchange for referring their patients there for the treatment of their peripheral arterial disease.[9] **Biogen Inc.** paid $843.8 million to address allegations that the company paid and offered kickbacks in multiple forms to physicians that had attended company-sponsored programs relating to Biogen's multiple sclerosis drugs.[10] **Phillips RS North America LLC (formerly Respironics, Inc.),** paid $24.8 million to resolve allegations that they provided kickbacks to medical equipment suppliers to induce the selection of **Respironics'** equipment.[11] **Flower Mound Hospitals Partners LLC** paid $18.2 million to resolve allegations that they had knowingly submitted claims to federal healthcare programs that resulted from violations of the Anti-Kickback and the Stark Law.[12] According to the government, the physician-owned hospital repurchased shares from physician-owners over the age of 63, and resold the shares to physicians that were younger, and the number of shared offered were dependent on volume of patients the physician was referring to the hospital.[13] **Kaleo Inc.** paid $12.7 million over false claims related to their drug used to reverse opioid overdoses; illegally remunerating physicians and their office staff; and directing physicians to send prescriptions for their drug to preferred pharmacies, where the pharmacy would file false and misleading prior authorizations to insurers.[14]

The DOJ recovered significant sums from a number of entities related to Medicaid fraud, including:

- **Mallinckrodt ARD LLC (previously Questor Pharmaceuticals Inc.)** paid $260 million to resolve allegations relating to a drug their

company manufactured, which was approved to treat acute exacerbations of multiple sclerosis and infantile spasms. The government alleged that the company underpaid rebates to the Medicaid program by designating the drug as "new," in contrast to a previous product that cost significantly more. Separately, the government also alleged that Mallinckrodt used a foundation to subsidize the drug's copays so their drug could be marketed as "free" while prices increased significantly.

- **Gold Coast Health Plan (a health system comprised of three of its providers)** paid $70.7 million to resolve claims that they had knowingly submitted false claims to the Medicaid program in California. The government alleged that payments were not for expenses that were approved in the contract between the state and the plan, did not reflect fair market value, and were unlawful gifts of public funding (in violation of California's state constitution).[15]

In addition to pursuing cases related to Medicaid fraud, the DOJ intervened in cases related to Medicare Advantage (also known as Medicare Part C) plans. Because Medicare Advantage pays providers a set amount per enrolled patient, which amount is then adjusted by a number of risk factors that affect expected healthcare expenditures (i.e., a plan with more higher-risk patients would receive more reimbursement), the government has a strong interest in ensuring that providers do not manipulate the risk adjustment process. One case was filed against **Cigna**, and other cases continued to be litigated against **UnitedHealth Group**, **Independent Health Corporation**, **Elevance Health**, and the **Kaiser Permanente group**.[16]

During the COVID-19 pandemic, Congress authorized emergency funding to provide financial assistance directly to state, local, and Tribal governments, as well as to businesses and individuals. The DOJ has pursued cases involving improper payment from the PPP, which provided forgivable loans to small businesses for payroll, rent, and other operational costs. In FY 2022, the department resolved 35 FCA matters related to improper loans from the PPP, recovering $6.8 million and avoiding nearly $1.5 million in losses.[17] The DOJ also pursued cases against lenders that improperly dispersed PPP funds and against others that misused pandemic-related funding and resources.

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. Of the $2.2 billion recovery, $1.9 billion resulted from lawsuits that were filed under the qui tam provisions of the FCA.[18] The number of lawsuits filed under the qui tam provisions[19] has grown significantly since 1986, with 652 qui tams filed in FY 2022, an increase from the 598 qui tams filed in FY 2021.[20] Nevertheless, the DOJ's continued active interest and involvement in fraud and abuse cases in 2022 suggests that FCA enforcement will remain high going forward.

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Supreme Court Rules on False Claims Act Case

[Excerpted from the article published in June 2023.]

On June 1, 2023, the U.S. Supreme Court published their decision in two *False Claims Act* (FCA) lawsuits. The decision is one of the most significant developments for the FCA in recent history, as it resolves the necessary state of mind needed to violate the FCA.[1] This Health Capital Topics article will discuss the FCA cases and the Supreme Court's decision.

The FCA (a federal statute) was enacted in 1863 in response to fraud committed by a defense contractor during the Civil War.[2] The FCA established that any person who knowingly submitted false claims to the government was liable for double the government's damages, plus a penalty; since its enactment, the law has been amended several times. Now, violators are liable for treble damages, along with a penalty linked to inflation.[3] Not only does the FCA give the U.S. government the ability to pursue fraud, it also enables private citizens to file suit on behalf of the federal government through what is known as a "qui tam" or "whistleblower" suit.[4]

For one to be held liable under the FCA, the perpetrator must act with "scienter," i.e., "knowingly," which is defined as acting with actual knowledge, deliberate ignorance, or in reckless disregard to the truth or falsity of the information.[5] Notably, "specific intent to defraud" is not required.[6] Defendants in such cases will often argue that their interpretation of complex statutes and regulations was reasonable, and not rising to the level of scienter.[7]

In determining the necessary state of mind required for liability under the FCA, the Supreme Court reviewed the lower court decisions of two cases: *Schutte v. SuperValu* and *Proctor v. Safeway*.[8] In both cases, the retail pharmacy defendants were required to bill Medicare and Medicaid for their "usual and customary" drug prices to the general public.[9] In *Schutte v. SuperValu*, two private citizen plaintiffs allege that SuperValu, a grocery store chain with 2,500 locations, knowingly submitted false payment claims to federal healthcare programs by reporting higher drug prices than it typically charged customers.[10] SuperValu had implemented a price matching program for customers, but they did not report the price match amounts as their customary pricing (despite the popularity of the program, resulting in these lower process comprising the majority of sales for many drugs at the time, i.e., establishing a "usual and customary" price for those drugs), violating Medicaid regulations. The lower courts found that the plaintiffs failed to prove the element of "scienter," i.e., they failed to demonstrate that SuperValu had an objectively unreasonable interpretation of the reporting requirement.[11]

In *Proctor v. Safeway*, the qui tam plaintiff alleged that Safeway, a grocery chain with over 900 locations, similarly reported retail (non-discounted) prices to government healthcare programs for certain drugs when customers actually paid less through price-matching and discounts.[12] The lower courts ruled against the plaintiff, finding they had failed to prove the element of "scienter,"

and affirmed that Safeway had not acted in disregard to regulations and the grocery chain's interpretation of the law was objectively reasonable.[13]

The Court sought to answer the following legal question: "If respondents' claims were false and they actually thought that their claims were false—because they believed that their reported prices were not actually their "usual and customary" prices—then would they have "knowingly" submitted a false claim within the FCA's meaning?"[14] In their highly anticipated ruling, the Supreme Court unanimously vacated the standards set by the lower courts, which had previously enabled defendants to avoid liability under the FCA as long as their interpretation after the fact was objectively reasonable, regardless of whether the defendant actually believed that interpretation.[15] In rejecting this view, the Court made it clear that the focus should be on what the defendant thought *at the time* of submission for a false claim.[16] The 9-0 opinion, authored by Justice Clarence Thomas, laid out three types of scienter that can result in FCA liability:

(1) "Actual knowledge," which "refers to whether a person is 'aware of' information";

(2) "Deliberate ignorance," which "encompasses defendants who are aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statement's truth or falsity"; and

(3) "Reckless disregard," which "similarly captures defendants who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway."[17]

The Court agreed that "the phrase 'usual and customary' on its phase appears somewhat open to interpretation, but reasoned that "such facial ambiguity alone is not sufficient to preclude a finding that respondents knew their claims were false."[18]

Further, the justices stated that:

> "Under the FCA, petitioners may establish scienter by showing that respondents (1) actually knew that their reported prices were not their "usual and customary" prices when they reported those prices, (2) were aware of a substantial risk that their higher, retail prices were not their "usual and customary" prices and intentionally avoided learning whether their reports were accurate, or (3) were aware of such a substantial and unjustifiable risk but submitted the claims anyway. If petitioners can make that showing, then it does not matter whether some other, objectively reasonable interpretation of "usual and customary" would point to respondents' higher prices. For scienter, it is enough if respondents believed that their claims were not accurate."[19]

The Supreme Court's decision will likely limit the ability of FCA defendants to pursue motions to dismiss based on the argument of objective reasonability.[20] Without appropriate documentation to show compliance with the FCA at the

time of the false claim submission, defendants may struggle to prevail.[21] However, on the other hand, a defendant may be able to prevail if they can produce documentation demonstrating good-faith subjective intent.[22] This reliance on documentation to substantiate the focus on the defendant's intent at the time of the submission of a false claim may present challenges for relators and the government in identifying documents and witnesses that can attest to the defendant's subjective intent at the time of the claim submission, particularly given the long timeframe of FCA cases – relators and the government have three years from the date of the alleged false claim to bring suit, the most FCA cases are sealed for years before being made public.[23]

Going forward, legal counsel recommends that stakeholders document their decision-making processes regarding compliance with FCA, so that such documentation will be readily available to demonstrate good-faith subjective intent.[24]

The Supreme Court vacated the lower court's judgments and remanded the cases to the Seventh Circuit, for proceedings and rulings consistent with the Court's decision.[25]

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CMS Announces Updates to ACO REACH Model

[Excerpted from the article published in August 2023.]

On August 14, 2023, the Centers for Medicare and Medicaid Services (CMS) announced updates to their Accountable Care Organization Realizing Equity, Access, and Community Health (ACO REACH) model.[1] In response to feedback from stakeholders, starting in performance year (PY) 2024, the agency expects to increase the predictability for the model and further advance health equity.[2] Only in its first PY, ACO REACH is a revision and replacement of the Global and Professional Direct Contracting (GPDC) model and the Geographic Direct Contracting (Geo Model) model, a subset of the GPDC model.[3] This Health Capital Topics article will discuss the updates to the ACO REACH model and its implications for existing accountable care organizations (ACOs).

As discussed more fully in a previous Topics article,[4] the GPDC model was widely considered a laissez-faire approach to the ACO concept, creating an "un-fair" environment for new entrants and incentivizing corporate profitability over quality of care.[5] CMS has a set of guidelines to follow when it develops a new ACO model. For example, a potential model must:

(1) Allow Medicare beneficiaries to retain all rights that are afforded to them, including freedom of choice of all Medicare-enrolled providers and suppliers;

(2) Work to promote greater equity in the delivery of high-quality services; and

(3) Extend their reach into underserved communities to improve access to services and quality outcomes.[6]

Because the GPDC model did not sufficiently meet these criteria, CMS attempted to fix these problems through the new ACO REACH model.[7] According to CMS, the ACO REACH model meets these three criteria and addresses other areas of concern that existed in the GPDC model by supporting value-based initiatives and changing the governance structures of ACOs; specifically, it requires a minimum of 75% of the ACO's governing body to be held by participating providers, up from the 25% minimum under the GPDC model.[8] Further, the ACO REACH model is more in line with CMS's ten-year strategic plan, as it better supports care innovation and focuses more on the social determinants of health.[9] For example, ACO REACH model does more than the GPDC model to advance health equity, increase access, and drive affordable accountable care.[10] Specifically, the ACO REACH model directly improves upon the GPDC model by promoting:

(1) A greater focus on health equity and closing disparities in care;

(2) An emphasis on provider-led organizations and strengthening beneficiary voices to guide the work of model participants;

(3) Stronger beneficiary protections through ensuring robust compliance with model requirements;

(4) Increased screening of model applicants and increased monitoring of model participants;
(5) Greater transparency and data sharing on care quality and financial performance of model participants; and
(6) Stronger protections against inappropriate coding and risk score growth.[11]

CMS's announced updates include a number of changes to the ACO REACH model that are spread out over the next couple of PYs. CMS will reduce the minimum required number of beneficiaries for new entrant ACOs from 5,000 to 4,000 for PY2025.[12] Minimums for high needs populations will also be reduced, from 1,200 to 1,000 for PY2025 and from 1,400 to 1,250 for PY2026.[13] As an additional flexibility, a 10% "alignment buffer" will be applied across all ACOs, allowing for ACOs to drop under the beneficiary minimum count temporarily; however, an ACO cannot remain below the beneficiary threshold for more than one of the remaining years for the model.[14]

CMS is also revising the composite measure that is utilized for the Health Equity Benchmark Assessment (HEBA).[15] The HEBA is a mechanism through which CMS "adjusts beneficiary-level premiums based on a composite measure of neighborhood and individual need" in an effort to "direct the right resources to the right people."[16] The revised measure incorporates a State-Based Area Deprivation Index and a Low-Income Subsidy Status to more easily identify underserved beneficiaries who live in high-cost areas.[17] Additionally, the HEBA benchmark amounts will be adjusted in order to increase the HEBA's impact. Starting in PY 2024, benchmarks will be:

(1) $30 per beneficiary per month (PBPM) for beneficiaries who have equity scores in the top decile;
(2) $20 PBPM for beneficiaries who have equity scores in the second decile;
(3) $10 PBPM for beneficiaries who have equity scores in the third decile;
(4) $0 PBPM for beneficiaries in the following four deciles; and
(5) -$10 PBPM for the lowest three deciles.[18]

CMS's revised model will also allow for physician assistants (PAs) and nurse practitioners (NPs) participating in ACO REACH to certify and order pulmonary rehabilitation plans of care for beneficiaries who have chronic obstructive pulmonary disease (COPD).[19]

CMS asserts that these updates are "expected to improve the model test by 1) increasing predictability for model participants, 2) protecting against inappropriate risk score growth and maintaining consistency across CMS programs and Center for Medicare and Medicaid Innovation models, and 3) further advancing health equity."[20]

The National Association of ACOs (NAACOS) lauded CMS on their updates to the model.[21] Clif Gaus, President and CEO of NAACOS, stated:

> "[w]e appreciate that CMS continues to improve on the ACO REACH Model by addressing many concerns raised by NAACOS members.[22] These include financial protections from midyear changes to benchmarks, additions to the Health Equity Benchmark Adjustment to account for more patient characteristics, and updates to its risk adjustment policies.[23] We believe these changes will satisfy many concerns and stabilize future participation."[24]

Gaus added that NAACOS encourages "CMS to explore adding features of REACH into a permanent track within the Medicare Shared Savings Program."[25] The President and CEO of America's Physician Groups (APG), Susan Dentzer, shared the sentiment, applauding CMS for their updates. Dentzer stated that:

> "APG advocated for many of these changes based on the recommendations of our ACO REACH coalition members, and we appreciate the fact that the Innovation Center was so responsive to our members' perspectives and input.26 We look forward to working with CMS on additional refinements to the ACO REACH Model that will further improve the health care of Medicare patients and the model's financial and operational sustainability."[27]

ACO REACH model participants are required to identify disparities in care and implement a health equity plan.[28] The new model, which allows providers to take on more financial risk, and pushes providers to form ACOs for fee-for-service Medicare beneficiaries, currently has 132 participants.[29] The model is due to run for three more PYs, through PY 2026.[30]

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FTC & DOJ Announce Revised Merger Guidelines

[Excerpted from the article published in August 2023.]

On July 19, 2023, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) released a draft update of its Merger Guidelines, which guides the regulatory agencies in their review of both mergers and acquisitions in evaluating compliance with federal antitrust laws.[1] The new Guidelines replace, amend, and consolidate the Vertical Merger Guidelines and Horizontal Merger Guidelines, which were published in 2020 and 2010, respectively.[2] This Health Capital Topics article will discuss the new Guidelines and the proposed changes to antitrust laws that may affect the future of healthcare.

Horizontal consolidation is the acquisition or merger of two companies at the same level in the supply chain, while vertical integration is the merger or acquisition of two or more companies in the same line of production, but not at the same level.[3] Each type of merger has its own purpose, such as increased revenue, market share, or diversified product offerings accomplished through horizontal consolidation or increased efficiency and lower costs achieved through vertical integration.[4] Vertical integration in the healthcare industry translates to hospitals, health systems, or insurers offering, indirectly or directly, a broad range of patient care and support services.[5] This is seen most commonly when hospitals, health systems, and insurers buy-out or absorb physician groups. In doing so, health systems and insurers claim to increase their organizational performance and decrease costs.[6] The U.S. healthcare industry has seen a rise in vertical integration transactions since the passage of the Patient Protection and Affordable Care Act (ACA), particularly among physician groups integrating with health systems or insurers, as providers seek to fill gaps in their continuum of care.

Federal antitrust laws, such as the Clayton Act, Sherman Act, and Fair Trade Act, govern mergers and acquisitions that may restrain trade or result in unfair compensation. Specifically, these laws prohibit any attempt or conspiracy to monopolize or unreasonably harm or restrain industry trade;[7] further, companies and individuals may not engage in deceptive business practices.[8] Violating one or more of these acts can result in fines up to $1 million for individuals and up to $100 million for corporations.[9] The purpose of antitrust laws is to maintain healthy competition and avoid price-fixing, rigged bids, and monopolization.[10] The U.S. healthcare industry's recent uptick in vertical integration (particularly those deals whose size do not trigger regulatory review) has given rise to concerns over what mergers and acquisitions are allowed under current U.S. antitrust laws.[11]

The draft Guidelines expand, clarify, and build on existing frameworks. They provide an overview of 13 principles meant to aid agencies in determining if mergers are anticompetitive and unlawful under current antitrust laws. Those principles are as follows:

(1) Mergers should not increase concentration significantly in markets that are highly concentrated;
(2) Mergers should not eliminate competition that is substantial between firms;
(3) Mergers should not increase any risk of coordination;
(4) Mergers should not eliminate potential entrance to a concentrated market;
(5) Mergers should not lessen competition substantially by creating firms that control services or products that rivals may use to compete;
(6) Vertical mergers should not create structures within a market that foreclose competition;
(7) Mergers should not extend or entrench a dominant position;
(8) Mergers should not further trends toward market concentration;
(9) When a merger is part of a series of multiple acquisitions, the agencies may examine the entire series;
(10) When mergers involve a multi-sided platform, the agencies will examine competition on a platform, between platforms, or to displace a platform;
(11) When a merger involves buyers that are competing, agencies may examine whether it may lessen competition substantially for other sellers or workers;
(12) When an acquisition involves minority interests or partial ownership, agencies may examine its impact on competition; and
(13) Mergers should not lessen competition substantially or tend to create a monopoly.[12]

The new Guidelines "place an emphasis on transactions that tend to create a monopoly," codify new thresholds regarding which transactions will be considered presumptively illegal by the regulatory agencies, and advance new harm theories relating to labor market competition.[13] The Guidelines also suggest that regulatory agencies will focus on transactions within markets that are highly concentrated, and markets where the dealing party may hold a dominant position.[14] Further details include how agencies will analyze proposed transactions to conclude if post-transaction firms would be able to decrease and degrade employee benefits, wages, and working conditions.[15] New presumptions within the Guidelines also describe how proposed transactions could harm competition based on dominance in the market, relationships with suppliers, trends toward market consolidation, and market concentration.[16]

The DOJ and FTC's Guidelines on mergers have not yet gone into effect and will first be subjected to a 60-day public comment period, which will conclude on September 18, 2023.[17] The two agencies will then update and evaluate the draft before finalizing the Guidelines.[18] On July 17, 2023, numerous industry groups, including the American Hospital Association (AHA), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the

Federation of American Hospitals (FAH), sent a letter to the FTC requesting that the agency extend their comment period by an additional 60 days so that industry groups could provide detailed responses.[19] The agencies have yet to respond to this request.

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IV. COMPETITION TOPICS

Non-Traditional Players Moving into the Insurance Space

[Excerpted from the article published in October 2022.]

In the past two months, two retail giants – Walmart and Apple – have announced plans to enter the health insurance space. This direct entry into the health insurance market by non-traditional players has been encouraged in part by health insurer-retailer partnerships, which gained traction due to rising demand for Medicare Advantage (MA) in particular and the expansion of the types of benefits that MA plans may offer. This Health Capital Topics article will discuss reasons behind the insurer-retailer partnerships and how Walmart and Apple plan to disrupt the health insurance market.

MA plans, also known as Part C plans, serve as a supplement or substitute for fee-for-service (FFS) Medicare Part A and Part B coverage.[1] MA was created by Congress to provide seniors an alternative to original Medicare, with an emphasis on treating and managing the health of the whole patient. MA plans are offered to Medicare beneficiaries by Medicare-approved private companies, known as MA Organizations (MAOs), that must follow rules set by Medicare.[2] These plans can be advantageous for beneficiaries because they limit out-of-pocket costs for covered services and may cover supplemental benefits, e.g., vision, dental, and hearing insurance; fitness programs; drugs/services that promote wellness; and, transportation to appointments.[3] Enrollment in MA plans has grown much faster than overall Medicare, more than doubling between 2010 and 2020.[4] As of 2022, 28 million Americans – 48% of the eligible Medicare population – are enrolled in an MA plan.[5] Likely driven by the increasing number of Medicare enrollees, the number of MA plans has similarly increased over the past decade, from 1,982 total plans in 2012 to 3,834 plans in 2022, the greatest number of MA plans to date.[6] In 2022, the average Medicare beneficiary has access to 39 MA plans (more than double the 2017 number).[7]

As noted above, MA demand is driven both by the sheer number of potential plan members (approximately 10,000 Baby Boomers are becoming Medicare-eligible every day) and a growing preference for MA plans, which offer additional benefits.[8] Additionally, in 2018, the Centers for Medicare & Medicaid Services (CMS) granted MAOs more flexibility in the types of benefits they may offer.[9] These factors have motivated a number of innovative arrangements. Health insurer-retailer partnerships can allow insurers an additional, lower-cost care setting that differentiates them from the competition (without the real estate investment), while retailers can use the partnership to attract more patients to their clinics and pharmacies while guarding against changes in consumer preferences that have trended away from in-store purchasing.[10]

Walmart was one such retailer to enter into a partnership with an insurer. In October 2020, the retail giant announced a partnership with insurer Clover Health to offer MA plans to low-income beneficiaries in Georgia (this partnership has since ended).[11]. Walmart eventually evolved from being a

partner to being an insurance provider, announcing on September 7, 2022 that it and UnitedHealth Group would begin offering in January 2023 a jointly-branded MA plan – "UnitedHealthcare Medicare Advantage Walmart Flex" – to seniors in Georgia and Florida, near 15 current Walmart Health clinic locations.[12] Walmart Health Virtual Care will also be offered in-network for UnitedHealthcare's commercial Choice Plus PPO plan members.[13] The 10-year "wide-ranging" partnership plans to eventually expand across the country to cover hundreds of thousands of beneficiaries.[14] UnitedHealth Group's subsidiary, Optum, will help Walmart clinicians deliver comprehensive value-based care through the use of Optum's robust data and analytics obtained from its hundreds of owned/operated physician practices, outpatient clinics, and surgery centers, as well as its health plans as the largest MAO in the country.[15] The partnership may be mutually beneficial for the parties, as a deluge of seniors may start using Walmart Health for their healthcare, and UnitedHealth Group may acquire additional plan members who find value in the convenience of getting their healthcare where they shop.[16]

While the Walmart/UnitedHealth Group partnership may be one of the biggest to date in the MA space, it is not the first. In 2021, Elevance Health (formerly known as Anthem) announced its partnership with grocery chain Kroger to offer a joint MA plan in Atlanta, Louisville, Cincinnati and southern Virginia starting in 2022.[17] A number of these partnerships are likely to materialize over the next several years, for the reasons discussed above.

In addition to disruption in the MA space, commercial insurance is also experiencing an entry of non-traditional players. On October 18, 2022, it was reported that tech giant Apple will begin offering insurance in 2024.[18] While there are currently a dearth of details, industry analysts anticipate that Apple will partner with a major insurer and will leverage the health data it has been collecting over the past several years through its Apple Watch.[19] It is believed that the data Apple has related to body temperature, blood pressure, blood oxygen, and ECG readings will give it a running start in the insurance space as they may be able to utilize the data to cut costs for beneficiaries.[20] While this will be Apple's first insurance offering, the company has participated in insurer partnerships previously, working with MAO Devoted Health to provide discounted Apple Watches to beneficiaries as a fitness benefit and working with commercial insurers and life insurers to help their beneficiaries gain access to Apple watches.[21]

The entry of these nontraditional players may serve to disrupt the insurance space, requiring current plan providers to be nimble in their provision of health services in order to engage and maintain plan members and remain creative in how to provide the most benefit to plan members in a cost-effective fashion.

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FTC Proposes Banning Non-Compete Clauses

[Excerpted from the article published in January 2023.]

On January 5, 2023, the Federal Trade Commission (FTC) published a proposed rule that would ban employers from imposing non-competes on their employees. The FTC asserted that this practice is widespread and often exploitative, and such actions can suppress wages, hamper innovation, and block entrepreneurs from starting their own businesses.[1] Notably, while the proposed rule will affect all industries, not just healthcare, this proposal comes at a time when healthcare employers across the U.S. are struggling with staffing shortages.[2] This Health Capital Topics article will discuss the proposed rule, reactions from healthcare industry stakeholders, and potential implications.

Non-compete agreements are defined as "employment provisions that ban workers at one company from going to work for, or starting, a competing business within a certain period of time after leaving a job."[3] About 30 million Americans are restricted from pursuing other employment opportunities, as they are bound by non-compete clauses.[4] Further, a 2020 study found that approximately 18% of the labor force is bound by non-competes, with 38% agreeing to a non-compete in the past.[5] Regardless of the timing of non-competes, the study also found lower wages associated with areas where non-compete enforcement is easier.[6]

In healthcare, the medical profession has grown from small practices comprised of just a few physicians to mega-practices totaling a few hundred physicians, especially in urban settings. Non-competes in healthcare have traditionally been utilized as a tool to limit the harm that a physician may inflict upon departing a practice. While these large practices need to protect their investments, non-compete clauses may make it hard for a departing physician to seek employment within the same geographic area.[7] Non-compete clauses in specialty practices further complicate the ability for physicians to seek employment, as specialists only serve a subset of the population (i.e., there may be fewer outside opportunities for specialists).[8]

Multiple states have provisions that flat out ban or place a limit on an employer seeking to restrict the activity of a physician or other healthcare professional post-employment.[9] States that ban such clauses include Alabama, Arkansas, Colorado, Delaware, Massachusetts, New Hampshire, New Mexico, Rhode Island, and South Dakota.[10] Some states, such as Arkansas, allow non-competes, but have exceptions carved out for medical professionals.[11] Other states, such as Florida, impose limitations on healthcare non-competes, banning agreements for physicians specialists in a county when all those within the specialty are employed by a single entity.[12]

In response to the proposed rule, while the American Medical Association (AMA) did not take a position on the issue, noting their membership's "diverse perspectives on noncompetes," it noted that their ethics policy opposes unreasonable non-competes.[13] Additionally, the AMA stated how the "balanced

approach of [states that have already legislated against healthcare-specific non-compete clauses] must be considered against a proposed universal federal ban on all noncompete agreements."[14] In addition, the American Hospital Association (AHA) asserted that the FTC lacks the authority to outright ban non-competes and stated their intention to submit comments highlighting their observed shortcomings.[15] The final rule, pending potential edits from the FTC based on commentators' suggestions, may face legal challenges down the road.[16]

This proposed rule is the latest step in the federal government's push (over two presidential administrations) to increase competition in the healthcare industry. In December 2018, the U.S. *Department of Health and Human Services* (HHS), as well as the *Treasury* and *Labor* departments, issued a 119-page report comprising over 50 recommendations to increase quality, decrease cost, and promote competition in healthcare.[17] Some of the report's main recommendations included:

- An endorsement for broadening the scope of practice for advanced practice registered nurses (APRNs), physician assistants (PAs), optometrists, pharmacists, and other highly trained professionals, to combat the lack of competition with the limited supply of providers;
- Encouraging entry into markets through the repeal of restrictive *certificate of need* (CON) laws, which would affect states that had some form of the CON program;
- Urging Congress to consider repealing Patient Protection & Affordable Care Act (ACA) changes to the Stark Law that limited physician-owned hospitals in order to increase competition and provide consumers with more choices; and
- Shifting toward consumer-driven healthcare through the expanded utilization of *health savings accounts* (HSAs) and *health reimbursement arrangements* (HRAs).[18]

Nearly one year later, 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."[19] The final rule asserted that informing patients of the prices 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.[20]

Subsequently, in 2021, President Biden issued an executive order to promote competition in the American economy.[21] The executive order directed the FTC to combat consolidation in the healthcare industry, arguing that consolidation drives up prices for consumers and limits access to care. Beyond responding to the executive order (which directive the FTC has pursued with a vengeance, resulting in a number of scrapped hospital deals over the past year[22]), the FTC has signaled that it also has an interest in pursuing other legal theories of

antitrust enforcement aside from traditional mergers, such as those related to vertical mergers.[23]

By halting the practice of imposing non-competes, the FTC aims to increase wages by upwards of $300 billion per year and expand career opportunities for approximately 30 million Americans.[24] The FTC is currently seeking the public opinion on the proposed rule until March 10, 2023.[25]

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2022 M&A in Review: Indications for 2023

[Excerpted from the article published in January 2023.]

After a record year in 2021 transactional activity, where healthcare mergers and acquisitions (M&A) were up by 56%, the market continued to thrive in 2022.[1] Preliminary results revealed that 2022 M&A deals hit a record high of 2,409 deals, 150 transactions over what was observed in 2021.[2] Despite economic challenges (e.g., rising interest rates and borrowing costs, inflation, and labor costs), the healthcare transactional market has remained active.[3] This Health Capital Topics article will review the U.S. healthcare industry's M&A activity in 2022, and discuss what these trends may mean for 2023.

While the healthcare sector has not been immune to the fears of an economic downturn, deal volumes have remained resilient despite these headwinds.[4] Health services deal volumes increased in comparison to 2021 levels, although activity cooled in the fourth quarter of 2022. The year-over-year deal volumes have increased progressively, but only 251 deals were announced in the fourth quarter of 2022, compared to 307 deals in the fourth quarter of 2021.[5] Specifically, physician market transactions remained strong, with over 600 transactions reported.[6] Specialties such as dermatology and eye care remained a strong target for potential investors, with rising demand for practices specializing in cardiology, podiatry, and women's health.[7] In contrast, the transactional market for hospitals hit a decade low in 2022, with only 55 hospital mergers and acquisitions reaching definitive agreements; however, 2022 deal value nearly doubled from the previous record set.[8] While the number of hospital deals for 2023 are expected to rebound, they are not expected to return to the levels observed in 2017 and 2018.[9]

Although deal volumes continued to increase from 2021 levels, the value of those deals declined in 2022 from the 2021 peak.[10] Industry-wide enterprise value (EV) to earnings before interest, tax, income, depreciation, and amortization (EBITDA) multiples declined from the high levels seen toward the end of 2021.[11] As of November 15, 2022, health services EBITDA multiples were down to 14.4x, comparatively lower than in both 2021 (15.9x) and 2020 (14.9x).[12] Hospice and home health continued to be a health services sub-sector that drove transaction values in 2022, serving as one of two sub-sectors that saw deal volume and deal value increase from 2021 levels.[13] There were 114 hospice and home health deals in the twelve months that ended November 15, 2022, contributing to a 74% increase in deal value from 2021.[14] Two megadeals within this sub-sector were largely responsible for the growth – CVS's acquisition of Signify Health for $8.0 billion and United Health/Optum's acquisition of LHC Group for $6.0 billion.[15]

In total, the value of all transactions reached $250.8 billion, a considerable decline from the 2021 transaction value of $476.6 billion.[16] The largest transaction by price was the purchase of Horizon Therapeutics by Amgen Inc. for $27.8 billion, followed by the other significant deals listed below.[17] Certain sectors cooled off in 2022, with activity in Behavioral Health, Home Health,

and Hospice & Rehabilitation falling in comparison to the rates observed in 2021. Transaction values were driven by Home Health & Hospice, however in this health services subsector, the activity waned. The decline in certain sectors does not represent waning interest in the market, but more of a "cooling off."[18]

Nearly half of the deal values announced through November 15, 2022, were megadeals that remained consistent from the values seen in 2021.[19] There were seven major megadeals within this twelve month period, including the CVS/Signify and United Health/LHC Group transactions, as well as:

- A merger between two healthcare real estate investment trusts, valued at $18.0 billion;
- An acquisition of Summit Health City MD (primary, specialty, and urgent care providers) by Village MD (a Walgreens subsidiary), worth $8.9 billion;
- Quidel Corporation's (diagnostic healthcare product manufacturer) acquisition of Ortho Clinical Diagnostics (blood testing diagnostics manufacturer) for $8.0 billion;
- Mediclinic International's (private hospital group) acquisition by an investor consortium for $7.4 billion; and
- Chubb's (insurance firm) acquisition of Cigna's life, accidental, and supplemental benefits businesses, worth $5.4 billion.[20]

While the total number of transactions in 2022 remained below the pre-pandemic levels, there is clear evidence that M&A activity is beginning to regain momentum, which is expected to continue into 2023.[21] This expectation is driven by the following factors:

- The Need to Transform Healthcare: Ken Kaufman of Kaufman Hall notes that "this is a transformative period in American healthcare," where organizations will be forced to reinvent themselves from a clinical and financial standpoint;
- Moving Forward from the Pandemic: While COVID-19 still remains, the worst of the pandemic seems to be behind the U.S. This will likely restart strategic discussions among healthcare organizations regarding the intellectual and capital capabilities of the healthcare marketplace essential to remaining competitive, which were largely put on pause during the pandemic; and
- Financial Pressure: The past year has been extremely challenging for health systems and hospitals across the U.S. Organizations with strong balance sheets were able to cushion the financial pressure, but the resources used to offset operating losses will not hold out for most healthcare organizations much longer. Smaller organizations that did not have strong balance sheets may have to seek out alternatives, such as stronger partners that can help stabilize them financially.[22] Further, an increase in divestitures across the health services sector is anticipated for 2023, "based on a variety of economic, regulatory, and overall strategic repositioning."[23]

While significant uncertainty looms in the greater U.S. economic at the start of 2023, it is not anticipated to slow down healthcare industry M&A. Reset in valuations, availability of capital, and increased corporate competitiveness should provide openings for healthcare dealmakers in 2023.[24]

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Is the Return of Physician-Owned Hospitals Imminent?

[Excerpted from the article published in March 2023.]

Recent congressional actions and a white paper authored by officials from the Department of Justice (DOJ), Federal Trade Commission (FTC), and the American Medical Association (AMA) are pushing for the removal of barriers for physician-owned hospitals (POHs), potentially paving a path by which these controversial facilities can be established and expanded going forward.

Approximately 250 hospitals across the U.S. are completely or partially physician owned (comprising less than 5% of all hospitals).[1] These POHs can offer a variety of services, from general care to specialty services such as cardiovascular or orthopedic care, known as "focused factories." Over the past several decades, healthcare providers and policymakers have claimed that POHs have a negative impact on the healthcare industry, arguing that: (1) POHs "cherry-pick" the most profitable patients; (2) the quality of care provided at POHs is substandard; and, (3) conflicts of interest exist due to the financial incentive for physician owners to refer patients to their POHs.[2] Such concerns have led to policies restricting the purview of POHs in their communities, such as limiting the application of POH exceptions in the Stark Law and the Anti-Kickback Statute, and most recently, the Patient Protection and Affordable Care Act's (ACA's) prohibition on new or expanded POHs.[3]

However, the negative outlook on POHs seems to have softened in recent years, as studies have been published challenging the claims asserted above,[4] and the government has turned its focus to promoting competition in the healthcare sector. This focus has manifested through a number of strategic moves in the healthcare antitrust space over the past couple of years. As discussed in other Health Capital Topics articles:

- The Biden Administration has issued numerous executive orders to promote competition, particularly in the healthcare industry;[5]
- The FTC is currently reworking its merger guidelines, which are anticipated to result in stricter oversight;[6]
- Emboldened FTC scrutiny of hospital mergers has resulted in a number of scrapped hospital deals over the past year or more;[7]
- The FTC published a policy paper and fact sheet asserting that the use of Certificates of Public Advantage laws (COPAs) by states in regulating healthcare mergers can negatively impact healthcare costs, quality of care, and hospital staff wages;[8] and
- The FTC published a proposed rule that would ban employers from imposing non-competes on their employees.[9]

The report, a draft of which was released on February 5, 2023 and has not been peer reviewed,[10] seeks to maximize the government's increasing focus on healthcare competition by offering "a competition policy perspective that focuses on restrictions on market competition created by the recent ban on POH

growth and expansion."[11] Specifically, the authors assert that the entry of more POHs in the healthcare market would promote:

- "Care delivery innovation and the development of specialized care models – Physicians are well-positioned to innovate in care delivery, redesigning care around a specific area of medicine or process…
- Workforce recruiting and retention – Giving physicians an ownership stake, akin to employee stock ownership plan models, can improve recruiting and retention
- Combatting monopsony power in labor markets – POHs present a counterweight to rising physician corporate employment and hospital monopsony power in labor markets, leading to increased competition in markets for physician services
- Increased patient choices for medical services – An increased number of community hospitals in addition to the development of specialty hospitals would increase competition, driving down prices and raising quality through price and non-price competition
- Increased competition in hospital service markets – Increased price, quality, and innovation for hospital services serving patients and for payors constructing networks including hospital services."[12]

Citing the above, as well as "decades of research demonstrating that competition results in lower costs, improved quality, and greater innovation," the report concludes by urging Congress to repeal the ban on POHs.[13]

On February 21, 2023, Senators Bill Cassidy (R-La.) and James Lankford (R-Okla.), both of whom are physicians, introduced the *Patient Access to Higher Quality Health Care Act* (cosigned by ten additional senators), to rescind the ACA's ban on the creation and expansion of POHs.[14] A similar bill is expected to be introduced in the House of Representatives.[15] Senators Cassidy and Lankford stated that "[l]ifting this ban will increase competition among hospitals, decrease costs, and expand access to quality care for more Americans, especially those with Medicare and Medicaid."[16]

Physician-Led Healthcare for America (formerly known as Physician Hospitals of America), a trade association for physician-owned hospitals, applauded the introduction of the bill, stating that "[n]ow more than ever, we need to introduce competition into our healthcare market in order to help reverse the dramatic cost escalations and hospital bed insufficiencies being exacerbated by our health system rapidly consolidating into monopsonies."[17] Similarly, the American Medical Association (AMA) underlined the need for such a bill: "Physician-led hospitals meet community needs by focusing on the most important relationship in health care—the patient-physician relationship. Yet, the combination of current law and hospital consolidation is making these success stories rare….After witnessing hospital closures—especially in rural areas—patients must wonder what Congress is doing about it."[18] Conversely, the American Hospital Association (AHA) expressed its opposition to the bill, asserting that "Congress should maintain current law; preserve the ban on

physician self-referrals to new physician-owned hospitals; and retain restrictions on the growth of existing physician-owned hospitals."[19]

Whether these moves by Congress and DOJ and FTC officials are sufficient to result in a reversal of laws that are over a decade old remains to be seen. But if the ban on POHs is ultimately repealed, it could be a paradigm change in the U.S. healthcare delivery system.

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Corporate Moves in Healthcare Continue to Disrupt the Industry

[Excerpted from the article published in March 2023.]

Due to political impasses and systemic problems, the federal government is often powerless to make meaningful improvements to the healthcare industry. Increasingly high costs, large deductibles, healthcare workforce shortages, and delays in treatment and obtaining medication are plaguing the U.S. healthcare delivery system.[1] Instead of waiting on regulatory reform, corporate America has sought to disrupt the healthcare industry over the last few years, by streamlining the delivery of healthcare (and associated costs) and taking advantage of technological advancements. This entrepreneurial approach to problem-solving may provide meaningful competition to traditional healthcare organizations, which may result in higher quality, more affordable healthcare.[2] Some of the biggest companies in the U.S. – CVS Health, Walgreens, Amazon, Walmart, and Best Buy – are expanding their healthcare empires through acquisitions and other strategic moves.[3] This Health Capital Topics article will briefly survey some of these current private sector deals and initiatives.

CVS Health began its healthcare expansion, moving beyond the retail pharmacy space to integrated healthcare, with its 2017 acquisition of Aetna (a health insurance provider) for $70 billion.[4] On September 5, 2022, CVS Health announced its successful acquisition of Signify Health (a home health and physician technology company) – beating out a number of other bidders – for $8 billion.[5] Five months later, CVS announced the acquisition of Oak Street Health (a publicly-traded, private equity backed group of Chicago-based primary care providers) for $10.8 billion.[6] With these acquisitions, CVS aims to become a one-stop shop for consumers by combining their retail pharmacy with a clinical care delivery arm.[7]

Over the past couple of years, Walgreens Boots Alliance has made a number of acquisitions, including of: (1) Shields Health Solutions (specialty pharmacy company) on September 21, 2021, for $2.3 billion; (2) VillageMD (primary care service company) on October 14, 2021, for $5.2 billion; (3) CareCentrix (a home care company) on October 14, 2021, for $722 million; and (4) SummitHealth – CityMD (an urgent care clinic group) on November 7, 2022, for $8.9 billion.[8] These acquisitions have strengthened Walgreens' stake in the healthcare services market. With demand for COVID-19 testing and vaccines decreasing, the pharmacy retail company is aiming to diversify by increasing their presence in the healthcare services market (similar to CVS).[9] With 75% of Americans not having a primary care provider, Walgreens is also looking to become a healthcare destination for consumers.[10]

In June 2018, Amazon acquired PillPack (an online pharmacy that delivers medications to consumers) for $753 million, in an attempt to break into the pharmaceutical market.[11] On November 2020, Amazon Pharmacy was launched, providing customers in 45 states transparent drug pricing and free,

unlimited deliveries of medications.[12] Since then, the service has expanded to all 50 states, and in 2023, Amazon announced the commencement of RxPass, a new service targeting those with common, chronic conditions, which will cost patients only $5 per month.[13] Beyond the pharmaceutical sector, Amazon also acquired Health Navigator (a digital healthcare startup) on October 23, 2019, for an undisclosed amount, and One Medical (a network of primary care providers) on July 21, 2022, for $3.9 billion.[14] With the One Medical deal finalized, Amazon will acquire 836,000 members, and 221 medical offices spread across 27 markets, expanding the company's ability to provide healthcare services to patients.[15] It appears that with these moves, Amazon seeks to apply its successful direct-to-consumer retail model to the healthcare industry.

Over the past few years, Walmart has announced its acquisitions of: (1) FloCare (a health-technology business) on July 9, 2019, for an undisclosed amount; (2) CareZone (prescription management startup) on June 15, 2020, for $200 million; and (3) MeMD (telehealth provider) on May 6, 2021, for an undisclosed amount.[16] These acquisitions highlight Walmart's continued expansion in the healthcare services market. Additionally, Walmart has expanded Walmart Health, a network of health centers providing "primary and urgent care, labs, x-ray and diagnostics, behavioral health, dental, optometry and hearing services," regardless of insurance status.[17] Since launching in 2019, Walmart Health has opened more than 25 locations across the South; in early 2023, Walmart Health announced its plans to open an additional 28 centers in 2024.[18] Through this transactional activity, the retail giant is looking to increase access to healthcare and promote better health outcomes by rendering healthcare services to patients where they are – in Walmart stores – and by providing transparent and affordable pricing for healthcare services.[19]

In 2018, technology retailer Best Buy entered the healthcare market with an $800 million acquisition of GreatCall, an emergency response company for the elderly.[20] In late 2021, Best Buy acquired a home health technology platform, Current Health, for $400 million.[21] The company is pushing further into the healthcare sector, announcing partnerships with several major health systems to expand their Current Health platform.[22] In a recent agreement, Best Buy will begin offering technology support to Atrium Health, a hospital-at-home program.[23] Best Buy Geek Squad employees will deliver equipment and assist patients in equipment setup.[24] Best Buy's goal is to enable providers to deliver high quality care to patients in their own homes, and reduce the financial and emotional burden on caregivers and patients.[25]

Corporate America's recent transactional activity in the healthcare industry seems to follow the same themes – meeting patients where they are and utilizing technology and established retail locations to make healthcare as convenient as possible. These companies' recent moves in the healthcare sector may result in increased price competition, a greater variety of services, and more price transparency 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. The transactional activity undertaken by companies like CVS Health, Walgreens, Amazon, Walmart, and Best Buy, among others, serves as a striking example of corporate America's push to expand their presence in the healthcare services market.[26]

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UnitedHealth Group's Physician Acquisition Efforts Accelerate

[Excerpted from the article published in April 2023.]

On February 22, 2023, UnitedHealth Group's (UHG's) Optum division, the health insurance giant's care delivery arm, acquired Crystal Run Healthcare, a New York based physician group of almost 400 physicians, nurse practitioners, and other providers.[1] This significant move is just the latest in UHG's concerted effort over the past few years to acquire outpatient providers, surgery centers, and physician groups.[2] This Health Capital Topics article will briefly survey some of the insurer's recent acquisitions and initiatives to expand their physician services network.

UHG is the largest health insurance company in the U.S., offering benefit programs for individuals, employers, and beneficiaries with Medicare and Medicaid.[3] The company has partnerships with over 1.3 million medical providers and 6,500 healthcare facilities across the U.S.[4] Optum, a subsidiary of UHG, provides data analytics, infrastructure, a pharmacy benefit manager, OptumRX, and a bank providing loans to patients, OptumBank.[5] Additionally, Optum is now the largest employer of physicians in the U.S., with over 70,000 physicians in 2,200 locations.[6]

In 2022 alone, UHG and Optum made five major acquisitions:

Texas Medicare insurer KS Plans Administrator;

- Kelsey Seybold (a KS Plans Administrator affiliate), a group practice employing 500 physicians and allied health professionals offering treatments across 55 specialties in 24 locations throughout Houston;
- LHC Group, a Louisiana-based home health company, was acquired for $5.4 billion;
- Atrius Health, a Massachusetts-based health system employing over 645 physicians and primary care providers across 30 locations, was acquired for $236 million; and
- Refresh Mental Health, a Florida-based mental healthcare provider with more than 1,500 employees spanning 300 outpatient sites across 37 states, was acquired for an undisclosed amount.[7]

This transactional activity follows a 2021 buying spree wherein the company acquired 10,000 physician practices.[8] The care delivery arm of UHG reported total revenue of $71.2 billion in 2022 – five times the total revenue the company reported in 2015.[9] Optum's services include primary, specialty, urgent, and surgical care, with the company aiming to integrate more home health and behavioral services into their strategy for the delivery of care.[10]

UHG is able to keep more of the premiums that they collect when the medical providers a patient visits belongs to their company.[11] By steering their members toward their own providers, profits will grow.[12] While the corporate takeover of physician practices could pose a threat to healthcare costs and the autonomy

of clinicians, it could also boost access for those who are insured, and provide better work-life balance for physicians.[13] Working for a corporate-owned physician practice could potentially relieve a physician's burden of managing the administrative duties of a practice, reduce their patient loads, provide better compensation, and allow for flexible schedules or hours that are reduced.[14] Physicians may be flocking to companies like Optum due to burnout from being overworked, time pressures, a demanding pace, and the emotional intensity that comes with being a medical provider.[15]

Stakeholders have expressed concern regarding Optum's moves in the physician services sector. Chip Kahn, President and CEO of the Federation of American Hospitals, stated that "efforts by Optum to dominate physician markets is a concern generally with consolidation of the insurance market. The two go hand-in-hand and it's got to be of some concern to consumers and patients."[16] After a $7.84 billion deal was announced in March of 2021 between Optum and Change Health, a health technology company, the American Hospital Association (AHA) sent a letter to the Department of Justice (DOJ) requesting an investigation into possible antitrust concerns.[17] In the letter, the AHA stated that proposed transaction "threatens to reduce competition for the sale of health care information technology (IT) services to hospitals and other health care providers, which could negatively impact consumers and health care providers."[18] AHA also expressed concerns related to the market power held by UHG, stating that such an acquisition could likely result in patients having lower quality outcomes, and providers having to pay more.

UHG is not the only insurer seeking to employ providers. In fact, Anthem invested so heavily in care delivery and health tech that it recently changed its organization's name to Elevance Health to reflect the wide breadth of services offered by the company.[19] In addition to UHG and Anthem, insurers Humana and Aetna have been similarly active in healthcare services space, blurring the line between payor and provider.[20] These actions are indicative of a growing "payvider" trend, where organizations are streamlining their supply chain by acquiring both care delivery assets and plan assets.[21]

In response to changes enacted by the Patient Protection and Affordable Care Act (ACA), such as caps on the amount of profits providers can keep (due to medical loss ratio limits) and the significant growth in Medicare Advantage, insurers have shifted their business models.[22] These insurers have pivoted to bringing providers and health plans under their umbrella in order to give them control over not just where patients seek care, but how that care is delivered, by aligning providers' financial and care delivery incentives with that of the insurer.[23]

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Kaiser Permanente Acquires Geisinger Health

[Excerpted from the article published in May 2023.]

On April 26, 2023, the California-based healthcare giant Kaiser Permanente announced a $5 billion "mega deal" to acquire Pennsylvania health system Geisinger Health.[1] Kaiser also announced the formation of a new nonprofit health system, to be called Risant Health.[2] Geisinger Health will be the first health system under the umbrella of Risant Health, although Kaiser aims to add approximately five more systems to the entity.[3] This Health Capital Topics article will review this mega deal and discuss what this transaction may mean for hospitals and health systems.

While Geisinger has maintained a strong market share in central and northeastern Pennsylvania, it has been slow to gain any traction outside of its normal service areas.[4] In 2022, Geisinger reported $239 million in operating losses, as its expense growth increased at twice the rate of their revenue gains.[5] Kaiser – a $95 billion health system with locations in eight states and Washington, D.C. – may be able to help reduce Geisinger's operating costs post-acquisition, including in supply chain management, purchasing agreements, and other administrative expenses.[6] Geisinger, which has its own insurance operation, may also benefit from Kaiser's 12.6 million member health plan, as well as its capacity for data analytics. This acquisition will result in a healthcare "behemoth," with annual revenue in excess of $100 billion, nearly 50 hospitals, and over 25,000 physicians.[7]

When this transaction will close is to be determined, as regulatory agencies have yet to announce whether they will allow the deal to move forward.[8] In general, health systems have been pursuing mergers and acquisitions more carefully (highlighted by the number of hospital transactions decreasing each year since 2019[9]), stemming from the Federal Trade Commission (FTC) and their increased scrutiny of hospital transactions.[10] For example, in June 2022, the FTC filed a lawsuit to block a proposed transaction by HCA Healthcare to acquire five Utah hospitals in the Steward Health Care System, resulting in HCA Healthcare calling off the acquisition.[11] The FTC asserted that the HCA-Steward transaction would have reduced the number of health systems that offer acute services from three to two and increased HCA's bargaining power with insurers, resulting in higher prices for consumers in the form of increased premiums, deductibles, and out-of-pocket expenses.[12] The same week that HCA scrapped its acquisition plans, New Jersey-based RWJBarnabas Health announced its decision to abandon its acquisition of St. Peter's Healthcare System in New Brunswick, NJ.[13] The parties originally announced their plans in September 2020,[14] and the FTC unanimously voted to file suit opposing the acquisition on June 2, 2022 (the same day that it voted to file suit in the HCA/Steward case), arguing that combined, the entity would have approximately 50% market share for general acute care services in Middlesex County, which is sufficient to result in a presumption of harm under federal antitrust laws.[15] These two scrapped transactions are certainly not the only ones,

with a greater number of hospital transactions being abandoned after pushback from federal and state authorities.[16] However, the Kaiser-Geisinger deal is dissimilar from these deals in the sense that the two health systems are geographically separate; former Department of Justice healthcare antitrust attorney and health law professor Thomas Greaney believes that the deal could be pro-competitive, as currently "only four major insurers are handling national accounts."[17]

If the merger between Kaiser and Geisinger is allowed, and Geisinger is able to reduce its overhead, it could allow for more resource allocations to service expansion and care improvement needs.[18] The potential threat of such a merger may place pressure on other health systems within Pennsylvania (and even across the mid-Atlantic and Northeast), such as the University of Pittsburgh Medical Center (UPMC), to expand through mergers, acquisitions, or other affiliations, in order to remain competitive.[19] It may also create a "new category of health services organization" – geographically disparate health systems that have centralized resources and capabilities.[20]

The launch of Risant marks the beginning of a new era for value-based care, where providers are incentivized to offer lower cost, high quality care, with pay dependent on the health outcomes of patients.[21] While much of the healthcare industry continues to operate on a fee-for-service model, value-based care will allow organizations like Risant that control much of the healthcare supply chain, from the coverage of care to the delivery of it (often referred to as "payviders") to incentivize their providers to focus on preventative healthcare and population health.[22] Kaiser's strategy may spur health systems to think about expansion in more creative ways and motivate health systems and hospitals to think outside the box when considering growth.

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Pricing Increases at Independent Hospitals Post-Acquisition

[Excerpted from the article published in August 2023.]

Over the past decade, hospital acquisitions have changed the healthcare market, with transactions leading to hospital consolidation and resulting in larger health systems and fewer hospitals.[1] In the $4.3 trillion healthcare industry, over one third is spent annually on hospital care;[2] therefore, changes in the hospital subsector have significant implications for the rest of the healthcare industry. An August 2023 study conducted by the Public Policy Institute[3] of health insurer Elevance Health (formerly known as Anthem) found that when independent hospitals are acquired by health systems, employers, payors, and consumers are exposed to higher pricing without a similar increase in hospital care access or quality of care.[4] This Health Capital Topics article will review the Elevance study and the impact of acquisitions on independent hospital pricing.

Over the past two decades, the percent of hospital bed capacity that is part of a health system has increased from 58% to 81%.[5] Similarly, the percentage of markets with no independent hospitals increased from 7% to 25%.[6] These increases accelerated in the second half of the timeframe, concurrent with escalating hospital prices.[7]

The report authors utilized data from Elevance Health-affiliated health plans in twenty states and compared independent hospitals that remained independent to independent hospitals that merged with a hospital system.[8] The authors analyzed insurance claims and quality performance measures from 2012 through 2018 showed that after health systems acquired independent hospitals, prices at those hospitals rose while expenses decreased; simultaneously, some quality metrics at those hospitals decreased.

Not surprisingly, hospitals experienced a 6% decrease in operating expenses post-acquisition.[9] 60% of the decline was attributed to personnel spending reductions, with employment falling 3% due to decreases in support staff.[10] While operating expenses decreased, the average inpatient price rose 5% for commercially-insured patients, and prices increased 5-8% across the major diagnostic categories.[11] Specifically, prices in the circulatory system, digestive, respiratory, infectious disease, and labor and delivery categories experienced the highest increases.[12] The health system size did not seem to play a role in the extent of increases in pricing; however, price growth was observed in every one of the formerly-independent facilities.[13]

Perhaps the report's most concerning findings regard the declining quality of independent hospitals post-acquisition. For example, readmission rates for cardiac care increased by 12% at acquired hospitals and remained high for three years post-acquisition.[14] Additionally, readmission rates for admitted Medicare patients increased 2-3%.[15] Overall, the report did not find increases in any quality category post-acquisition. Further, the report found that access to care

at these hospitals declined post-acquisition. For example, a number of maternity wards were closed at independent rural hospitals post acquisition.[16]

While hospital acquisition activity slowed during the COVID-19 pandemic, it has rebounded over the last year.[17] The number of independently-operated hospitals are starting to decrease once more, as acute care markets have become more consolidated.[18] Independent hospitals claim that joining large health systems that have more resources will help them negotiate better contracts with commercial insurers.[19] These hospitals also assert that being acquired by larger systems will also reduce the cost of information technology (IT) and supply chain operations, while increasing access to and improving the quality of care.[20]

Elevance's report received pushback from the American Hospital Association (AHA).[21] AHA CEO Rick Pollack stated that the Elevance analysis drew "absurd conclusions about the impact of healthcare systems on access to care, cost and quality."[22] Pollack also argued that "of greatest irony is that while the national health plan behemoth, which dominates many insurer markets, is pointing fingers at the actual healthcare providers serving patients, it is pocketing record profits."[23] Dr. Richard Stefanacci, a physician at the Jefferson College of Population Health, also spoke about the benefit of acquiring independent hospitals, but mentioned how financial savings needed to be used appropriately.[24] Dr. Stefanacci stated that "there's an opportunity to capitalize on the additional resources gained through these mergers by directing them towards enhancing the value of healthcare delivery."[25]

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V. TECHNOLOGY TOPICS

Generative AI's Disruption of the Healthcare Industry

[Excerpted from the article published in July 2023.]

Introduction

Generative artificial intelligence (AI) is the utilization of algorithms to create content such as text, code, imagery, videos, and even simulations in mere seconds.[1] The goal of AI generally is to mimic the intelligence of humans to perform tasks, with generative AI (a type of AI) aiming to learn from data without the assistance of humans.[2] While today's generative AI bots are not yet prepared for widespread utilization in patient care settings, AI is garnering significant interest in the healthcare industry as providers begin to test the capabilities of AI in clinics and offices.[3] This Health Capital Topics article will review the role that generative AI is beginning to play in the U.S. healthcare system, the potential of AI in healthcare, and concerns related to the technology.

Advantages & Disadvantages

In the coming years, AI will likely be critical to the success of quality improvement, risk adjustment, and population health management, all key tenets of value-based care.[4] With the rapid growth in the amount and accessibility of clinical data, AI will likely be utilized to analyze this data to reduce inefficiencies and costs while contributing to better patient outcomes.[5] Providers are often time-constrained due to manually entering electronic health records (EHR), increasing chances of burnout.[6] Leveraging AI can streamline workflow, close gaps in care, and allow for risk adjustment and the elimination of delays in reimbursement.[7] Additionally, with a projected shortage of nurses – the gap between nurse supply and demand is expected to surpass 100,000 by 2030 – AI can serve as an additional "set of hands" by understanding patient medical records and codifying documents, improving clinician efficiency and patient outcomes, and driving higher reimbursement.[8] AI also has the potential to question the decisions of a physician that may unknowingly exacerbate the ongoing issue of bias in medicine, and potentially push towards a more equitable healthcare system.[9]

AI is a tool that is likely to transform the healthcare industry and revolutionize the way patients are treated; however, there are concerns to keep in mind regarding potential bias, security risks, and even privacy.[10] Biases have been identified within information technology (IT) applications, which results in possibly exacerbating healthcare inequities that exist within the healthcare, such as ethnicity, income, gender, or race.[11] While generative AI can provide solutions to biases in healthcare, there are other challenges that will need to be accounted for.[12] The accuracy of generative AI's outputs is reliant on the data that are utilized to train them, which could include lab results, imaging studies, and medical records.[13] Potential errors could put the health of patients at risk, which is why addressing the implications of these challenges, and how they affect patient care, will be imperative.[14]

Generative AI poses a number of risks to providers and patients. There are significant privacy concerns related to generative AI, especially considering the types of information that healthcare providers handle, including sensitive and patient identifying information.[15] For example, patient information may be sold to companies for use in targeted ads. However, these types of potential risks are similar to the risks related to social media generally.[16] Other major risks with generative AI could be security – AI will not solve the susceptibility of medical data to being hacked or stolen unless EHR companies allow their application programming interface to be utilized.[17] Organizations that maintain EHRs are known to maintain a certain level of security, ensuring that data is at minimal to no risk, and it will be in the best interest of generative AI software to utilize similar tactics.[18]

While generative AI can make the healthcare system more efficient by reducing bias, detecting errors, and reducing the amount of paperwork, it is very unlikely that they will replace physicians.[19] Generative AI is infamous for not providing appropriate (or any) context, which is necessary in real-world settings, particularly in healthcare.[20] Physicians can also provide compassion and integrated care more than any AI software or program.[21] Generative AI will certainly be able to complement and augment physician work, by reducing inefficiencies within the healthcare system, but will likely never be able to replace the physician workforce.[22] Recent reports have shown that 40% of working hours in healthcare settings could be supported by generative, language-based AI.[23] The application of AI in healthcare will depend on training in the human experience, along with perception and expertise.[24]

Regulatory

The sprint toward AI in all industries has raised concern about risks and a lack of scrutiny, and regulators have been scrambling to modify existing rules to cover issues on data privacy and copyright.[25] While regulatory agencies are in uncharted territory, few have stepped forward with any sort of strategy to address the negative impacts of AI. The Food and Drug Administration (FDA) has developed an action plan to provide reassurance on effectiveness and safety while utilizing AI in the healthcare industry.[26] The plan outlines five areas for focus: (1) develop the proposed framework, including guidance on software that learns over time; (2) develop good practices in machine learning to further improve algorithms; (3) ensure a patient-centered approach with complete transparency; (4) advance pilot performances in a real world setting; and (5) develop methods to evaluate algorithms in machine learning.[27]

In addition to regulatory agencies, the rapid implementation of AI will require healthcare organizations to monitor any risks (e.g., reputational, legal, and ethical) emanating from AI use and determine how to address those risks, particularly given the current lack of regulatory framework and oversight.[28] In June 2023, the American Medical Association (AMA) voted to adopt a proposal to protect patients against misleading or false medical information from AI tools.[29] The AMA aims to work with agencies such as the Federal Trade

Commission (FTC) and the FDA to mitigate any misinformation, and anticipates the establishment of federal and state regulations in the near future.[30]

Despite the fluidity of regulation, AI companies are starting to face government scrutiny. In July 2023, the FTC opened an investigation and sent a records request to OpenAI, the company behind ChatGPT.[31] In its investigation as to whether OpenAI engaged in practices that resulted in consumer harm, the FTC requested information regarding how OpenAI obtained data used to train their models and descriptions of ChatGPT's abilities.[32] The agency also requested descriptions of OpenAI's testing, algorithms, responses, and the company's false information policies.[33]

The level of development and the pace of clinical AI implementation may be directly influenced by the liability faced by practitioners, designers, and health systems, as more liability could discourage the use of AI in healthcare.[34] As technology develops, new legal pathways need to be established, especially as increased liability would likely repel practitioners, designers, and health systems from implementing and developing clinical AI models.[35]

Advancements & Entrants

ChatGPT, the free-to-use generative AI bot developed by OpenAI, has become the preeminent bot in the field, and has piqued interest across multiple industries with its capability to replicate relevant, coherent, and human-like responses when prompted by users.[36] These various capabilities have made it ideal for application in healthcare.[37] The generative AI bot is pre-trained on vast amounts of data and can generate content based on the data on which it has been trained.[38] Other big tech companies, including Microsoft and Google, have also created publicly accessible generative AI bots such as Bing AI, Copilot, and Bard.[39]

The rapid evolution of generative AI at large has spurred advancements in AI specifically designed to assist providers in healthcare settings.[40] Carbon Health, a primary care company, recently launched a proprietary AI-enabled EHR assistant for hands-free charting within its clinics.[41] The company is aiming to reduce provider workload, allowing each provider more time to see patients, and generally enhance the doctor-patient connection by focusing on the care of patients, rather than typing.[42] Additionally, Tempus, a precision medicine and AI company, recently launched an AI-enabled clinical assistant that helps clinicians seamlessly access patient data.[43] Utilizing Tempus, clinicians can access reports from clinical tests, filter patient incidence by diagnosis, access summarized patient information, and query clinical guidelines for updated standard of care insights.[44]

In April 2023, Epic, a healthcare software company, announced a collaboration with Microsoft to combine Microsoft's Azure OpenAI and Epic's EHR software to respond to patient messages, alleviating provider workload.[45] The initial rollout will begin at UNC Health with five to ten clinicians and eventually expand to other health systems.[46] The first iteration of this technology will draft

suggested responses to the most common patient questions and messages for physicians to review and send.[47]

Conclusion

While generative AI will continue to disrupt the healthcare industry, it aims to ultimately increase the efficacy of the healthcare system. By streamlining clerical work, performing literature searches, and even reducing error and bias within medicine, generative AI has the potential to revolutionize the way healthcare is delivered.[48] While generative AI has nearly unlimited potential, there are also risks associated with the technology, particularly in healthcare. Patient data could result in bias by the bot and even be susceptible to hacking or stealing. Generative AI has the potential to revolutionize the healthcare industry, but industry stakeholders will need to remain up-to-date on the risks and ongoing regulatory changes that affect the usage of generative AI.

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Amazon's Healthcare Act II: The Introduction of Amazon Clinic

[Excerpted from the article published in November 2022.]

On November 15, 2022, retail giant Amazon announced the introduction of Amazon Clinic, "a virtual health service that delivers convenient, affordable care for common conditions."[1]

The message-based virtual storefront will operate in 32 states and provide care for the following common health conditions:

(1) Acne
(2) Asthma Refills
(3) Birth Control
(4) Cold Sores
(5) Conjunctivitis
(6) Dandruff
(7) Eczema
(8) Erectile Dysfunction
(9) Eyelash Growth
(10) Genital Herpes
(11) Gastroesophageal Reflux Disease (GERD)
(12) Hyperlipidemia Refills
(13) Hypertension Refills
(14) Hypothyroidism Refills
(15) Men's Hair Loss
(16) Migraines
(17) Motion Sickness
(18) Rosacea
(19) Seasonal Allergies
(20) Sinusitis
(21) Smoking Cessation
(22) Urinary Tract Infections (UTIs)
(23) Yeast Infections[2]

Amazon Clinic patients will be able to select their condition from the 23 above-listed choices, then "choose from a network of leading telehealth providers [provided by Steady MD and HealthTap] based on their preferences."[3]

Patients will be able to see the waiting time and cost (since Amazon Clinic does not yet accept insurance) associated with each clinician so patients can make a fully-informed decision.[4] Patients will fill out an intake questionnaire and then will be connected to a clinician for a message-based consultation.[5] The clinician will call in any needed prescriptions, and then follow up with the patient as needed for up to two weeks thereafter.[6]

This launch is also expected to eventually be augmented by Amazon's deal with OneMedical (which transaction is currently under antitrust review[7]). In July 2022, Amazon announced its $3.9 billion acquisition of One Medical, a

"publicly traded, membership-based primary-care practice offering virtual and brick-and-mortar services to commercially insured patients" in 25 markets.[8] It is anticipated that "Amazon will bring One Medical's clinical network, subscription telehealth service, electronic health record and thousands of employer contracts in-house."[9] Exactly how One Medical will fit in with Amazon Clinic, however, has not yet been disclosed.

The launch of Amazon Clinic comes less than two months after the announcement that Amazon Care would be shut down. Amazon Clinic, the retail giant's virtual and in-person medical care service, was rolled out in 2019 as a pilot employee benefit for their own employees and quickly expanded to servicing non-Amazon employers across the U.S. (including large companies such as Hilton, TrueBlue, and Silicon Labs) by 2021.[10] The service combined virtual and in-person care, offering home health services, telehealth appointments, and prescription delivery.[11] The telehealth portion was facilitated via an 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.[12] The August 2022 announcement rolling back Amazon Care came as a shock, as Amazon had announced just six months prior that it would be expanding Amazon Care's in-person services to 20 cities by the end of the year.[13] Amazon executives explained that Amazon Care was not the "right long-term solution for [its] enterprise customers" because it was not a "complete enough offering for the large enterprise customers [Amazon had] been targeting."[14]

Further, Amazon Care is not Amazon's only failed healthcare initiative. The Haven joint venture, formed between Amazon, Berkshire Hathaway, and JPMorgan Chase, disbanded in January 2021, three years after its formation.[15] The goal of Haven was to tackle high and increasing costs for employee healthcare.[16]

As reported by one industry commentator:

> "Clinic is very much built in the Amazon mold. It's a marketplace where third parties can leverage Amazon's platform and reach to find customers, and Amazon can leverage third parties to quickly scale what [it] offers to its consumers. And it helps Amazon extend the business funnel for other Amazon operations — in this case Amazon Pharmacy..."[17]

As one tech industry pundit noted in response to Amazon's announcement ending Amazon Care, "Amazon is known for sticking to a long-term vision while experimenting with different approaches to achieve its goals."[18] True to form perhaps, Amazon has pivoted from one approach (Amazon Care) to another (Amazon Clinic), and has gone back to its roots – as a marketplace in which third parties are aggregated for use by consumers – albeit with a healthcare spin.

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VI. About
Health Capital Consultants

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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.

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Todd A. Zigrang, MBA, MHA, FACHE, CVA, ASA, ABV, is the President of Health Capital Consultants (HCC), where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has 30 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 2,500 transactions and joint ventures involving acute care hospitals and health systems; physician practices; ambulatory surgery centers; diagnostic imaging centers; accountable care organizations, managed care organizations, and other third-party payors; dialysis centers; home health agencies; long-term care facilities; and, numerous other ancillary healthcare service businesses.

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

Mr. Zigrang holds a Master of Science in Health Administration (MHA) and a Master of Business Administration (MBA) from the University of Missouri at Columbia. He is a Fellow of the American College of Healthcare Executives (FACHE) and holds the Certified Valuation Analyst (CVA) designation from NACVA. Mr. Zigrang also holds the Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers, where he has served as President of the St. Louis Chapter. He is also a member of the America Association of Provider Compensation Professionals (AAPCP), AHLA, AICPA, NACVA, NSCHBC, and, the Society of OMS Administrators (SOMSA).

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

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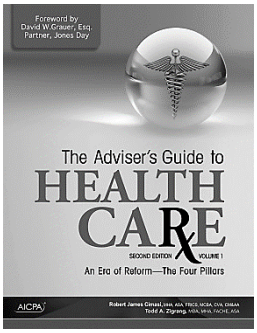

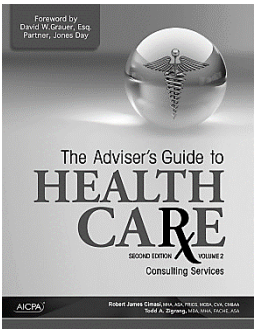

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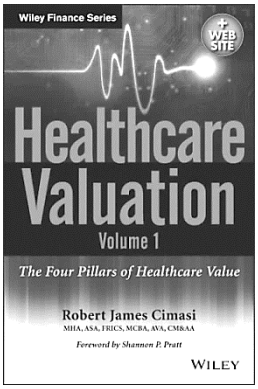

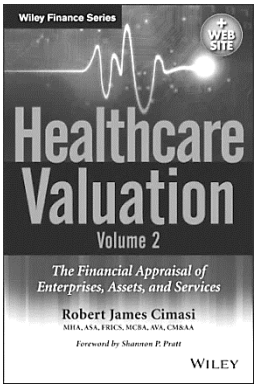

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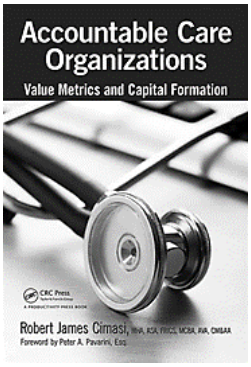

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