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DISCLAIMER

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

DEDICATION

As we celebrate our twenty-eighth year in service, the entire team at **HEALTH CAPITAL CONSULTANTS** *dedicates this 11th edition of Health Capital Topics to the many clients nationwide whom we have had the privilege to serve; to their attorneys, accountants, consultants, and vendors with whom HCC has worked to serve the needs of the projects we undertake on their behalf; and, to our professional colleagues nationwide, who both inform and inspire us toward excellence.*

PREFACE

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

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

ACKNOWLEDGEMENTS

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

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

Janvi R. Shah, MBA, MSF, 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.

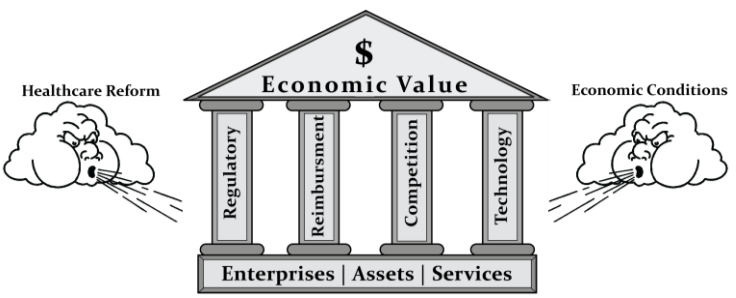
HCC's research and library staff, as well as, members of HCC's consulting and administrative support team, were of great help.

INTRODUCTION

This past year, the healthcare industry has showcased its tenacity in its continued battle against the COVID-19 pandemic, and the challenges it continues to impose. Despite ongoing challenges, the healthcare industry is starting to right-size, and we are seeing providers starting to look forward and think about what's next: eyeing novel partnerships, undertaking recruitment efforts to provide access to care, and embracing technological advancements to augment services. As providers have had to adapt, their healthcare legal counsel have similarly had to be innovative in formulating solutions for their clients in structuring transactions while remaining persistent in tracking rapidly-evolving legal developments while maintaining regulatory compliance. As a result, and because of ongoing regulatory scrutiny, healthcare valuation professionals have also gotten creative. The challenges presented over the past couple of years, such as the aberrations in physician compensation surveys stemming from the pandemic and the recent changes to the Medicare Physician Fee Schedule (MPFS), are not as straightforward as they were previously, and therefore do not lend themselves to the same valuation considerations going forward. This book is a compendium of what we have seen over the past year, and the valuation considerations that emanate from those healthcare industry developments.

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. See figure below.

The Four Pillars of the Healthcare Industry



INTRODUCTION *(Continued)*

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

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

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

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

Sincerely,

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

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I. VALUATION TOPICS

Valuation of Internal Medicine Services: Introduction

[This is the first article in a five-part series regarding Valuation of Internal Medicine This installment was published in September 2021.]

Internal medicine is the largest specialty among active physicians in the U.S., comprising 120,171 physicians of 938,980 total active physicians in the U.S. in 2019.[1] The strain on the healthcare delivery system as a result of the COVID-19 pandemic (and the resulting financial impact on independent practices[2]) and the continued increase in demand for healthcare services by the aging Baby Boomer population, may serve to spur more transactions in this space (related to internal medicine practices as well as internist employment agreements and professional services arrangements). Consequently, an understanding of the reimbursement, regulatory, competitive, and technological environments in which internal medicine providers operate, and the impact of these forces on the value of internal medicine services, is timely. This first installment in a five-part series will introduce the internal medicine specialty.

The discipline of internal medicine focuses on adult care in diagnosis, treating chronic illness, promoting health, and preventing disease.[3] Internists handle a wide range of issues across many organ systems and also are equipped to treat patients dealing with multiple acute, chronic illnesses.[4] Internal medicine physicians can either be designated as a Doctor of Medicine (MD) or Doctor of Osteopathic Medicine (DO). MDs generally practice allopathic medicine, while DOs practice osteopathic medicine.[5] While allopathic medicine is characterized by treatment through traditional, science-based means, osteopathic medicine is focused on holistic care and includes a focus on osteopathic manipulative medicine to bolster natural functions and healing.[6] In fact, the influence of structure on function is one key concept for osteopathic physicians.[7] Besides their philosophies, MDs and DOs also differentiate themselves through training and certification.

All aspiring internists, whether MDs or DOs, take the Medical College Admissions Test (MCAT), spend four years earning their medical degree, complete a residency, and obtain their license from the same state boards.[8] In 2019, there were 26,641 medical school graduates; of these, approximately 25% graduated from osteopathic medical schools.[9] This number has grown in recent years, up from nearly 15% in 2002, the first year that this differentiation between MDs and DOs was tracked.[10] The growing proportion, and sheer number, of students pursuing the DO track exhibits the increasing popularity of this degree.[11]

Following medical school, all internal medicine graduates enter three years of categorical residency training.[12] The training of internal medicine physicians focuses specifically on treatment related to adults, although physicians may decide to also study internal medicine pediatrics to include a wider age range of patients in their practice.[13] Internists are trained in both inpatient and outpatient settings, including at least one year in the hospital and many months in critical care settings.[14] Training programs also typically require training in

cardiology, hematology-oncology, and gastroenterology.[15] Graduates may then decide to work in an office or in a hospital, with about 50% of recent internal medicine graduates planning to work in the latter setting.[16]

Once the residency is successfully completed, internists are "board eligible," meaning they are able to become board certified and work in general internal medicine. At this juncture, a physician can choose to practice general internal medicine without obtaining further certification, become board certified and commence practicing medicine, or become board certified and continue on for one to three years of fellowship training in a sub-specialty of internal medicine.[17] Internists can become certified through the American Board of Internal Medicine (ABIM) or through the American Osteopathic Board of Internal Medicine (AOBIM). Both certifications include general internal medicine and subspecialties.[18] Common internal medicine subspecialties include cardiology, endocrinology, gastroenterology, hematology, oncology, infectious diseases, nephrology, pulmonary care, critical care, and rheumatology.[19] More physicians in internal medicine are entering these subspecialties. From 1951 to 1960, only 7% of internal medicine residents chose to enter a subspecialty, but between 2011 and 2015, this proportion had increased dramatically, to 88%.[20]

While not technically considered a subspecialty by either the American College of Physicians or the ACGME, a growing internal medicine career path is that of "hospitalist," i.e., an internist who focuses their practice on care in the hospital setting.[21] As of 2016, more than 50,000 hospitalists were actively practicing in the U.S., most of whom are general internal medicine physicians.[22] The term "hospitalist" was first coined in 1996, and the profession evolved out of a changing and evolving reimbursement landscape, including managed care for private insurance and diagnosis-related group (DRG) payments from Medicare.[23] These changes created a need and financial incentive for hospitals to reduce costs while improving or maintaining quality of care and patient satisfaction.[24] As the number of hospitalists began to grow, the evidence became clear that this new specialization within internal medicine could fulfill all of these factors for hospitals.[25] At the same time, the community-based primary care physicians, who had traditionally provided nonprocedural inpatient care in hospitals, began to back out of these roles, especially as care became more complex and financial incentives failed to follow.[26] Evidence for hospitalists' important roles in improving outcomes while reducing the length of stays and costs mounted, and hospitals consequently began to increasingly rely on, and offer incentives to, hospitalists to fill the role of primary care provider for their patients.[27] A large pool of trained general internists eager to move out of office-based primary care internal medicine also fostered quick growth in this sector.[28] By 2016, hospitalist was the largest internal medicine subsector, with approximately 75% of U.S. hospitals employing hospitalists.[29] Further, a 2015 survey found that nearly 50% of recent internal medicine graduates planned to work as hospitalists,[30] indicating that the role of this subsector is likely only to grow with increasing emphasis on value-based reimbursement (VBR) in recent years.[31]

No matter a physician's chosen educational pathway, internal medicine providers are an increasingly important piece of the healthcare system that can help bridge the gap between the supply and demand for healthcare services, especially for the aging Baby Boomer population and the growing number of patients with multiple, complex chronic illnesses.

Future installments in this internal medicine series will discuss: (1) the regulatory environment; (2) the reimbursement environment; (3) the competitive environment; and, (4) the technological environment, in which internal medicine providers operate.

Valuation of Internal Medicine Services: Reimbursement

[This is the second article in a five-part series regarding Valuation of Internal Medicine This installment was published in October 2021.]

Introduction

As noted in the first installment of this five-part series, internal medicine is the largest specialty among physicians and an understanding of the various environments in which these physicians operate is crucial in determining their numerous value drivers. In particular, healthcare reimbursement, the process by which private health insurers and government agencies pay for the services of healthcare providers (including internists), is perhaps one of the most important environments to understand, as it comprises a provider's expectation of future return on investment.[32] This second installment will discuss the reimbursement of internal medicine services.

The U.S. government is the largest payor of medical costs, through Medicare and Medicaid, and has a strong influence on physician reimbursement. In 2019, Medicare and Medicaid accounted for an estimated $799 billion and $614 billion in healthcare spending, respectively.[33] 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.[34]

Since 1992, Medicare has paid for physician services under Section 1848 of the Social Security Act (SSA).[35] The SSA mandates that physician fee schedule payments be calculated according to Medicare's Resource Based Relative Value Scales (RBRVS) system, which was designed with the intent of bringing medical practice payment more in line with a prospective payment system and away from a purely fee-for-service (FFS) system. The RBRVS physician payment system is updated annually by the Centers for Medicare & Medicaid Services (CMS). In assigning the relative values to procedures and in making yearly updates to these levels, the government has deliberately shifted payment levels to primary care specialties such as internal medicine in order to redress what they believe are historic inequalities perceived to cause medical students

to over specialize and thereby raise healthcare costs (as specialists and surgeons generally command higher fees and compensation). These adjustments in reimbursement levels have historically, and are forecasted to continue to have, significant impacts for the internal medicine specialty.

As mentioned above, 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 Medicare Physician Fee Schedule (MPFS) is assigned RVUs for three categories of resources: (1) physician work (wRVUs); (2) practice expense (PE RVUs); and, (3) malpractice (MP RVUs) expense.

Further, each procedure's RVUs are adjusted for local geographic differences using Geographic Practice Cost Indexes (GPCIs) for each RVU component. The GPCI accounts for the geographic differences in the costs of maintaining a practice. Every Medicare payment locality has a GPCI for the work, practice, and malpractice component,[36] which is determined by taking into consideration median hourly earnings of workers in the area, office rents, medical equipment and supplies, and other miscellaneous expenses.[37] There were 89 GPCI payment localities as of 2018.[38]

Once the procedure's RVUs have been modified for geographic variance, they are summed, and the total is then multiplied by a conversion factor (CF) to obtain the dollar amount of governmental reimbursement. The formula for calculating the Medicare physician reimbursement amount for a specific procedure and location is as follows:[39]

$$\text{Payment} = [(\text{wRVU} \times \text{work GPCI}) + (\text{PE RVU} \times \text{PE GPCI}) + (\text{MP RVU} \times \text{MP GPCI})] \times \text{CF}$$

The wRVU component 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.

The PE RVU 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. To determine the direct PE, CMS uses a bottom up methodology by adding costs of resources typically required to provide each service, based on recommendations by the American Medical Association's (AMA's) Relative Value Update Committee (RUC). To determine the indirect portion of the PE RVU, CMS uses actual PE survey data indicating the indirect practice expenses incurred per hour worked (PE/HR).

MP RVUs correspond to the relative malpractice practice expenses for medical procedures.[40] These values are updated at least every five years and typically comprise the smallest component of the RVU.[41] Due to the variation in malpractice costs among states and specialties, the malpractice component must be weighted geographically and across specialties.[42]

The CF is a monetary amount that is multiplied by the RVU from a locality to determine the payment amount for a given service.[43] This CF is updated yearly by a formula that takes into account: (1) the previous year's CF; (2) the estimated percentage increase in the Medicare Economic Index (MEI) for the year (which accounts for inflationary changes in office expenses and physician earnings); and, (3) an update adjustment factor.[44] All physician services, except anesthesia services, use a single CF.[45] The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) contains a predetermined schedule of updates to the CF. However, these annual updates are relatively small, with an update of 0.5% from 2016 to 2019, and an update of 0% for years 2020 through 2025.[46] It should be noted that, although the annual updates to the MPFS will be stagnant for the next several years, MACRA includes several provisions related to financial rewards for providers who furnish efficient, high quality healthcare services.

In recent years, payors have attempted to reduce healthcare expenditures and raise the quality of healthcare services that beneficiaries receive through payment models that tie physician compensation to the "value" of care delivered. Typically, the "value" of healthcare services refers to the cost and quality associated with those services.[47] Notably, MACRA introduced the Quality Payment Program (QPP), under which physicians' reimbursement for Medicare Part B services may be increased, decreased, or kept neutral, based upon quality performance under one of two models: alternative payment models (APMs) or the Merit-based Incentive Payment System (MIPS),[48] which consolidated several historic VBR programs into a singular quality program beginning in 2019.[49]

The QPP allows for modifications to a given physician's "base payment rate" based on an individual provider's participation in an APM or MIPS.[50] From 2019 to 2024, providers utilizing APMs are eligible for a bonus payment in the amount of 5% of their estimated aggregate payment amounts for services furnished to Medicare beneficiaries during the preceding year.[51] Further, beginning in 2026, the annual update to Medicare payments to providers who do not qualify as APM participants will be 0.25%, while the annual update to Medicare payments for qualifying APM participants will be 0.75%.[52]

In addition to provider incentives based on APM participation, MACRA also incentivizes providers through MIPS, which increases, keeps neutral, or decreases payments to providers based on certain performance metrics in the fields of: (1) quality; (2) promoting interoperability; (3) improvement activities; and, (4) cost.[53]

An estimated 95.3% of eligible clinicians qualified for neutral or positive payment adjustments beginning in 2020.[54] Notably, the bonus payments and penalties under MIPS will be budget neutral, i.e., the total bonus payments paid out to high-scoring providers will be funded by the total penalties withheld from low-scoring providers.[55]

In addition to the above VBR initiatives, CMS has also focused specifically on primary care in its transition to VBR. In 2019, for example, CMS and the U.S.

Department of Health and Human Services (HHS) announced the CMS Primary Cares Initiative.[56] This model built on past, similar models and aimed to reduce administrative burdens and leverage primary care for better health outcomes and lower costs.[57] It offers five payment options under Primary Care First (PCF) and Direct Contracting (DC) paths.[58] The two PCF payment models incentivize providers to reduce hospital utilization by making performance-based payments based on quality of care, patient experience, and key clinical outcomes.[59] The DC path provides a fixed monthly rate, which allows for predictable revenue and reduces burdens commensurate to financial risk.[60]

While Medicare reimbursement base rates for all physician services are expected to be fairly stagnant in the near term (notwithstanding the aforementioned VBR initiatives) due to MACRA's predetermined schedule of updates to the CF, recent efforts by CMS may encourage those specialties that provide more preventative services. For example, in the 2021 MPFS, CMS increased the wRVUs for common evaluation and management (E&M) office visits, which in turn bolstered reimbursement for those primary care specialties where E&M visits comprise a significant portion of the provider's case mix. Indeed, the 2021 MPFS increased internal medicine reimbursement rates approximately 6%.[61] This acknowledgement by CMS that primary care services are vital in shifting the U.S. healthcare industry to value-based care may serve to motivate more physicians to enter into primary care specialties such as internal medicine.

Valuation of Internal Medicine Services: Regulatory

[This is the third article in a five-part series regarding Valuation of Internal Medicine This installment was published in November 2021.]

Introduction

This third installment of the internal medicine series will discuss the regulatory environment of the provision of internal medicine services. Healthcare providers face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. Fraud and abuse laws, specifically those related to the federal Anti-Kickback Statute (AKS) and physician self-referral laws (the "Stark Law"), may have the greatest impact on the operations of healthcare providers. It is crucial to understand these laws because violating them can result in criminal penalties, civil fines, and/or exclusion from federal healthcare programs.[62]

The AKS and Stark Law are generally concerned with the same issue – the financial motivation behind patient referrals. 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. In contrast, 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.[63] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[64]

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.[65] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[66] Congress amended the original statute with the passage of the Medicare and Medicaid Patient & Program Protection Act of 1987 to include exclusion from the Medicare and Medicaid program as an alternative civil remedy to criminal penalties.[67] The Balanced Budget Act of 1997 added a civil monetary penalty of treble damages, or three times the illegal remuneration, plus a fine of $50,000 per violation.[68] Additionally, 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 remuneration deemed illegal under the AKS.[69]

The Patient Protection and Affordable Care Act (ACA) made two noteworthy changes to the intent standards related to the AKS. First, the legislation amended the AKS by stating that a person need not have actual knowledge of the AKS or specific intent to commit a violation of the AKS for the government to prove a kickback violation.[70] Therefore, in order to prove a violation of the AKS, the government must show that the defendant was aware that the conduct in question was "generally unlawful," but not that the conduct specifically violated the AKS.[71] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the False Claims Act (FCA).[72] The amended AKS points out that liability under the FCA is "[i]n addition to the penalties provided for in [the AKS]…"[73] This suggests that, in addition to civil monetary penalties paid under the AKS, violation of the AKS would create additional liability under the FCA, which itself carries civil monetary penalties of over $21,500 plus treble damages.[74]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[75] 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.[76] 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.[77] Failure to meet all of the requirements of a safe harbor does not

necessarily render an arrangement illegal.[78] 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.[79]

Of note, in December 2020, the HHS Office of Inspector General (OIG) released new revisions to the AKS in a final rule.[80] Included 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).[81] See below for more information on those arrangements.

Stark Law

The Stark Law, originally passed as the Ethics in Patient Referral Act of 1989, as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989, prohibits physicians from referring Medicare or Medicaid patients to entities with which the physicians or their family members have a financial relationship for the provision of designated health services (DHS).[82] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[83] 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.[84]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities which then have an ownership interest in the entity that provides DHS.[85] 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.[86] 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.[87] 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.[88] 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.[89]

As previously mentioned, 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.[90]

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 10%[91] 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.[92]

Also of note is CMS's new exception for limited remuneration to a physician. Under this new exception, a physician may be paid an aggregate remuneration up to $5,000 within a calendar year without having the arrangement set forth in writing or the amount consistent with Fair Market Value; however, the arrangement must be commercially reasonable.[93]

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 False Claims Act (which law may be triggered by a violation of the AKS or Stark) will likely raise a hypothetical investor's estimate of the risk related to the valuation of the internal medicine services.

Valuation of Internal Medicine Services: Competition

[This is the fourth article in a five-part series regarding Valuation of Internal Medicine This installment was published in December 2021.]

Introduction

Internists are considered part of the primary care industry, a service sector of growing importance to the healthcare delivery system despite increasing physician shortages. According to data from the American Board of Medical Specialties (ABMS), there are nearly 245,000 board-certified physicians in internal medicine.[94] This fourth installment of the five-part series on the valuation of internal medicine services will discuss the competitive landscape of the providers of internal medicine.

Supply of Internists

Over the next two decades, physician demand is anticipated to grow faster than supply, leading to a projected overall total shortage between 37,800 and 124,000 physicians by 2034.[95] A large proportion of the overall physician workforce is nearing traditional retirement age, indicated by the fact that more than two of every five active physicians in the U.S will be 65 or older in the next decade.[96] Combined with the strong growth in demand from the number of Americans over the age of 65 and the number of Americans with multiple chronic conditions, this indicates that the U.S. may soon face a serious shortage of internists. While the number of medical students in primary care is increasing, it is not sufficient to replace the number of retiring physicians, which means that there likely not be enough primary care (including internal medicine) physicians to treat the aging Baby Boomer population.[97] In fact, only about 25% of medical school graduates every year go into primary care fields.[98] Consequently, by 2034, the shortfall of primary care physicians, including internists, is estimated to be somewhere between 17,800 and 48,000 full-time equivalents (FTEs).[99]

In 2017, there were 2,758 individuals per internal medicine physician in the U.S.[100] Family and general practice physicians had a similar ratio of 2,804 patients per physician, while pediatricians had a much lower ratio of 1,429 patients per physician.[101] Recent studies indicate that primary care physicians generally have patient panel sizes ranging from 1,200 to 1,900 patients per physician.[102] This estimate is much lower than the 2,500 patients per physician often previously cited as the standard for panel size, and indicates a need for, and lack of, internal medicine and other primary care physicians to achieve optimum coverage of patients.[103] Further, the number of U.S. adults with a primary care physician has been falling in recent years, from 77% in 2002 to 75% in 2015, resulting in millions of Americans without a primary care physician.[104] The issue is much more pronounced in the younger adult population, where the rate declined from 71% to 64% over those years.[105]

The physician shortage has impacted those living in rural areas the most. Health Professional Shortage Areas (HPSAs) identify areas and populations that have a shortage of primary, dental, or mental healthcare providers primarily based on the number of healthcare professionals relative to the population.[106] Medically underserved areas/populations (MUA/P) are areas or populations designated by the Health Resources Services Administration (HRSA) as having too few primary care health services or having "economic, cultural, or language barriers" to healthcare.[107] As of December 2021, there were over 7,500 primary care HPSAs in the U.S. with California, Texas, Missouri, and Alaska having the greatest number of those designations.[108] Additionally, there were over 3,400 MUAs and 482 MUPs, which were concentrated in California, Texas, Illinois, Georgia, and Pennsylvania.[109]

In order to ameliorate the primary care shortage and meet the growing demand for healthcare services, healthcare enterprises are increasingly relying upon non-physician practitioners (NPPs), and have lobbied for an expansion in the

role of the non-physician workforce to provide services that support, supplement, and parallel physician services. In light of the fact that the gap between the supply and demand for physician services is projected to increase significantly, as the sources of physician manpower remain insufficient, and as the drivers of demand (i.e., the aging Baby Boomer population and the increased number of insured individuals) intensify, the NPP workforce is expected to see continued growth in both scope and volume in the future, as enterprises adopt care models that strategically allocate physician and non-physician manpower resources. According to the U.S. Bureau of Labor Statistics, nurse practitioner job growth is expected to be 45% from 2020 to 2030, much faster than the average for all occupations.[110] As of 2021, 24 states, including the District of Columbia, allow nurse practitioners full independent practicing authority, which includes the ability to: "evaluate patients; diagnose, order and interpret diagnostic tests; and initiate and manage treatments, including prescribing medications and controlled substances, under the exclusive licensure authority of the state board of nursing."[111] Those states effectively allow nurse practitioners the same scope of practice as physicians, showcasing the potential of NPPs to help ameliorate the coming physician shortage.[112]

Demand Drivers for Internal Medicine

The growing elderly patient population utilizes a greater proportion of (and expenditures related to) medical services relative to the rest of the general population, and as such may comprise a growing part of the patient population in future years. Specifically, the demand for internal medicine services come primarily from older adults (with internal medicine constituting a major share of visits for those over age 45) and those with multiple, complex, chronic conditions. As of 2018, the number of Americans age 45-64 increased by 7%, reaching a total of 83.9 million.[113] The prevalence of chronic disease nationwide has also been on the rise, with 60% of adults having one chronic disease and 40% having two or more chronic conditions.[114]

Increasing attention is also being paid to primary care, on both a research and legislation level, as a way to reduce costs and improve patient outcomes. U.S. health outcomes lag behind those of other wealthy countries, despite spending far more on healthcare than those countries.[115] Currently, only 5 - 7% of healthcare spending is devoted to primary care, with less than 5% of Medicare fee-for-service spending (i.e., spending related to patients aged 65+) going to primary care costs.[116] In contrast, countries with better health outcomes often spend two to three times more on their primary care systems.[117] Studies have shown that primary care significantly lowers patients' odds of premature death and save money by reducing unnecessary hospitalizations and by diagnosing and treating medical issues earlier.[118] With the U.S. healthcare industry's increasing focus on value-based reimbursement (VBR), which incentivizes the provision of higher-quality care at lower cost, some of this discrepancy between low spending and high proportions of office visits for primary care may ultimately be eliminated.[119]

Valuation of Internal Medicine Services: Technology

[This is the final article in a five-part series regarding Valuation of Internal Medicine This installment was published in January 2022.]

Introduction

There has been a rapid advancement, and subsequent adoption, of medical technological innovations in the U.S. over the last couple of decades, which has fundamentally changed the healthcare delivery system.[120] While internal medicine may not be considered a specialty in which technology plays a crucial role, advancements such as healthcare information technology (HIT), care coordination software, and telehealth are critical components of an internist's practice. This fifth and final installment of the five-part series on the valuation of internal medicine services will discuss technological advancements that impact the providers of internal medicine.

Health Information Technology

HIT includes a variety of software applications such as billing software; staffing models; and, electronic health records (EHR).[121] The effective use of HIT by internal medicine practices to facilitate quality improvement (QI) can help these practices improve their ability to deliver high quality care and improve patient outcomes.[122] Research indicates that implementation of HIT may lead to improved efficiency and quality management.[123] For example, use of EHRs have resulted in cost savings, improved quality, and better coordination of care.[124] Physician practices in particular may experience the benefits of EHRs, as they have been shown to increase efficiencies and cost savings.[125] Further, EHRs are linked to clinical improvements, which could financially benefit the operations of internal medicine physicians and their associated practices. [126] Providers using EHRs can access a comprehensive view of each patient's history to gain a better understanding of patients' needs, and the content of every provider-to-provider and provider-to-patient telephone exchange and fax is captured electronically within this system.[127] Providers also have access to progress notes from specialist visits and are notified of emergency department visits or hospitalizations.[128] Such benefits become more crucial for internists who participate in value-based reimbursement (VBR) models, as these models require physicians to eliminate fragmented care and work with other providers in their model to provide streamlined, efficient care for a defined patient population.

Despite the potential benefits of HIT, adoption of this technology poses significant administrative and cost burdens to independent internal medicine physician practices.[129] However, there are some exceptions to the Stark Law that protect:

(1) The sharing of HIT with "community providers and practitioners, in order to enhance the community's overall health…;"[130]

(2) The donation of EHR items and services to a physician by an entity (e.g., hospital);[131] and,

(3) The donation of cybersecurity technology and related services "necessary and used predominately to implement, maintain, or reestablish cybersecurity."[132]

So long as all of the factors contained within a given exception are met, the donation of these items and services by a hospital or other entity to an internist would be found to be compliant with the Stark Law, eliminating those aforementioned administrative and cost burdens.

Care Coordination Software

Care coordination software (also referred to as care coordination information technology, or CCIT) refers to software applications designed to enable various functions related to managing the care of a provider's patients.[133] This technology has been the focus of many digital healthcare companies, with the U.S. care coordination software market expected to grow to $3.18 billion by 2022 (up from $1.55 billion in 2019).[134] The components and capabilities of such software vary widely, but may perform tasks as automating: referral management; communication to a patient's care team (e.g., automated email updates to patient status and patient hospital admission/discharge); delivery of discharge instructions and next steps to a patient's primary care provider; and, reports that provide real-time utilization trends, outreach success rates, and no-show rates.[135] These technologies are also being aided by artificial intelligence and blockchain technology, "which support data interoperability and normalization within a defined clinical network."[136] Among other capabilities, these technologies allow for constant, two-way communication among providers in the acute, post-acute, and internal medicine spaces. This is significant as communication (or lack thereof) among providers in these spaces tends to be the root of many care coordination issues. Besides automating referral management and boosting patient revenue and satisfaction, CCIT offers potential to communicate patient outcomes in real time and realize savings from improved chronic disease management and community health efforts. Internal medicine practices can benefit from utilizing CCIT because providers often care for patients with multiple chronic diseases.

Similar to HIT, CCIT, as well as other data analytics, will be needed by participants in VBR models, which typically rely on pre-established benchmarks and require participants to report on patient outcomes.[137] However, much like HIT, adoption of these technologies poses significant administrative and cost burdens to small providers.[138]

Telehealth

Telehealth facilitates the delivery of health-related services via telecommunications technology.[139] Telehealth services can supplement or replace face-to-face encounters with physicians. Telehealth services show great

potential for helping to meet the growing demand for medical services and the shortage of physicians. Moreover, telehealth services can be more cost efficient for both the patient and the provider than face-to-face encounters.[140] As more studies validate the efficacy of telehealth services, more payors are offering coverage of telehealth services.[141] The COVID-19 public health emergency (PHE), which began in March 2020, was a catalyst for unprecedented increases in telehealth utilization across the U.S.[142] Several policies and developments have helped to fuel this rapid expansion. A number of relaxations and flexibilities for telehealth reimbursement and coverage were put in place by the Centers for Medicare & Medicaid Services (CMS), including allowing beneficiaries to receive care wherever they were located – even from out-of-state providers.[143] These measures represented dramatic changes from the previous policies, which only covered telehealth for rural patients, had stringent restrictions on the originating site for the care, and only allowed internal medicine physicians to utilize the technology to provide care to established patients (i.e., not new patients) in the same state in which they were licensed.

In addition to relaxing the originating site requirements, CMS also expanded the number of services that could be provided through telehealth. An additional 135 services, including emergency department visits, were added to the list of covered (and thus reimbursable) services for Medicare beneficiaries.[144] While all of these flexibilities and expansions were originally only valid for the length of the PHE (which is ongoing as of the publication of this article), CMS has been considering the extension of some expansions in covered services and reimbursement semi-permanently or permanently. For example, CMS's 2021 MPFS final rule included expansions to reimbursement for telehealth services.[145] Under the final rule, nine codes were covered permanently and 59 will be covered through the calendar year in which the PHE ends.[146] The 2022 MPFS final rule included an extension for those services that were temporarily added to the telehealth list during the PHE to 2023 (previously, coverage for these services would end at the conclusion of the PHE).[147] This will provide CMS additional time to gather sufficient data for those services, with the intent that they may be added on a permanent basis.[148]

As it increases in ubiquity (and coverage), telehealth will likely augment care coordination activities, leading to new opportunities for internal medicine providers to reduce healthcare expenditures.

Conclusion

One of the keys to advancing the healthcare delivery system's shift toward VBR models is technological advancement. These models, which require providers to provide cost effective, high quality care and report numerous patient care metrics, require the use of EHRs, CCIT, and other HIT. Further, the ability to connect with patients quickly through telehealth, before a medical condition advances to the point of requiring hospitalization, will help internal medicine providers achieve VBR benchmarks, i.e., provide higher quality patient care at lower cost to more patients, the "trifecta" of healthcare.

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Valuation of Home Health Agencies: Introduction

[This is the first article in a five-part series regarding Valuation of Home Health Agencies. This installment was published in February 2022.]

Home health agencies (HHAs) are primarily engaged in providing "*a wide range of health care services that can be given in [a] home for an illness or injury*."[1] There are three types of services that typically fall under the umbrella of home healthcare: (1) *home healthcare enterprises*, which provide medical and supportive care; (2) *home care aide enterprises*, which provide nonmedical care or custodial/non-meal care; and (3) *hospice enterprises*, which provide end-of-life care.[2] Additionally, two of the main types of home healthcare services are: (1) *infusion therapy* and (2) *respiratory therapy*.[3] Utilization of home healthcare services "*rises with the number of chronic conditions and the functional impairments that people have*," with approximately two-thirds of all Medicare home healthcare users managing at least four chronic conditions and at least one functional impairment.[4] While the elderly are frequent recipients of home healthcare services, chronically ill persons of all ages may also utilize home healthcare services.[5]

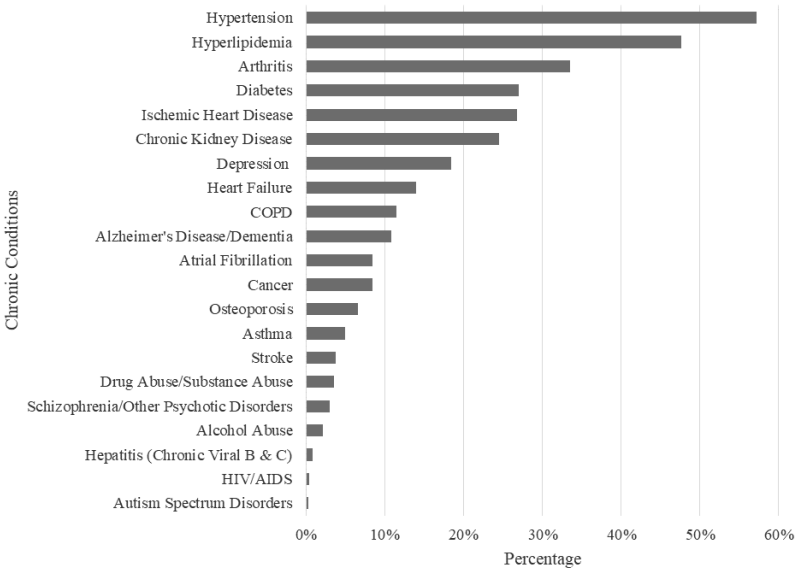
Lawmakers and regulators have historically viewed home health services with apprehension, largely due to the high potential for fraud and abuse.[6] These concerns have led to Medicare payment cuts and new regulatory hurdles for home health providers at a time when home healthcare is becoming more popular with the elderly population.[7] Further complicating the healthcare landscape, approximately 10,000 *Baby Boomers* will reach retirement age every day through 2030,[8] which will affect how policy makers and healthcare providers shape the healthcare delivery system.[9] As these *Baby Boomers* retire, not only may it increase demand for home healthcare services, but it may also decrease the supply of healthcare providers, as a number of HHAs are simply ceasing operations when their owners retire, and home care workers (also known as direct care workers) are difficult to recruit due to the profession's low pay, inconsistent schedule, and lack of advancement opportunities.[10] As the *Baby Boomer* generation retires, competition between HHAs, skilled nursing facilities (SNFs), and hospital outpatient facilities may increase due to an increasing patient pool.[11] However, given the growing interest in home health utilization among the elderly population, due to its cost-effective means of delivering care while allowing them to stay in their homes, the future of home health may be bright for providers able to leverage finite resources to advance high value care.[12]

A growing number of elderly persons seeking skilled care are finding value in receiving care at home. Individuals age 45+ have exhibited strong preference for independent living in their homes versus other alternatives.[13] Patient-centered care, as defined by the Institute of Medicine, is "*providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions*."[14] For many patients, receiving treatment in their home allows the care to be tailored to their

specific needs,[15] including being individualized to their home settings, daily behaviors, and specialized needs, which can improve quality of care and patient satisfaction.[16]

The aging *Baby Boomers* population, coupled with increased utilization of healthcare services (given that this population segment has higher rates of diabetes and obesity than their parents),[17] will likely increase the patient pool for healthcare services relating to chronic disease management. Two-thirds (66%) of Medicare beneficiaries suffer from at least two chronic conditions, and of that portion, 15% suffer from six or more chronic conditions;[18] the most common conditions among Medicare beneficiaries, as of 2018, are represented in the below exhibit.

Exhibit: Percentage of Medicare Fee-For-Service (FFS) Beneficiaries with Chronic Conditions, 2018[19]



Patients with chronic conditions under the age of 65 have also become strong advocates for receiving care in their home. Chronic diseases are among the most prevalent health problems in the U.S., with approximately 60% of the U.S. population having at least one chronic condition, and approximately 40% having multiple chronic conditions (predictably, the prevalence of multiple chronic conditions are highest in older adults).[20] Seven out of ten deaths among Americans every year result from chronic diseases, including: (1) heart disease; (2) cancer; and, (3) diabetes.[21]

Patient preference for home health is being increasingly matched by payors, who have recognized the cost effectiveness of home healthcare. As national healthcare expenditures per capita continue to rise,[22] a shift toward cost

effective healthcare delivery may be imminent. In 2019, the average cost for an in-home health visit was $13,012, which was roughly $7,000 less than the same visit at an in-patient facility ($20,325).[23] Extrapolating home health services nationwide for just five conditions could result in $3.7 billion in overall cost savings and $3 billion in Medicare savings.[24] Further, home healthcare represents 13% of all Medicare episodes utilizing post-acute care after hospital discharge.[25] While not as costly as *skilled nursing facilities* (SNFs), *inpatient rehabilitation facilities* (IRFs), or *long-term acute care hospitals* (LTCHs), 84% of Medicare home health patients rate their overall care a "9" or "10" on a ten-point scale.[26] Additionally, 92% of home health patients receiving wound care noted improvement or healing after an operation, 82% bathed more easily after a home health regimen, and 83% of home health patients noted improved breathing after a home health regimen.[27]

As the healthcare system evolves and is reformed to meet the future needs of the rapidly aging U.S. population, the value of healthcare delivery at home may grow due to patients' familiarity with technology, their preference to be treated at home, and home health's cost effective means of delivering high-quality care. However, with the continuing intense regulatory scrutiny of these healthcare organizations, HHAs should be cognizant of the potential for over-utilization of home health services that may subject them to fraud and abuse inquiry. The second installment of this five-part series will therefore cover the regulatory environment in which home health agencies operate.

Valuation of Home Health Agencies: Regulatory

[This is the second article in a five-part series regarding Valuation of Home Health Agencies. This installment was published in March 2022.]

Home healthcare in the U.S. is highly regulated, creating a complex system, especially for home health agencies (HHAs) that operate across multiple states. HHAs face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and ability to engage in transactions. The second installment of this home health valuation series will discuss the regulatory environment in which these organizations operate.

Certificate of Need

At its core, a state certificate of need (CON) program is one in which a government determines where, when, and how major capital expenditures (e.g., funds spent on public healthcare facilities, services, and key equipment) will be made.[28] The theory behind CON regulations is that, in an unregulated market, healthcare providers will provide the latest costly technology and equipment, regardless of duplication or need, resulting in increased costs for consumers.[29]

For example, hospitals may raise prices to pay for underused services, equipment, or empty beds.[30] Proponents of this system argue that CON programs are necessary to limit healthcare spending because healthcare consumers are unable to "shop" for goods and services, as most of these are ordered by physicians.[31] Opponents of the system assert that restricting new entrants to the market may reduce competition, and encourage construction and other additional spending, all of which ultimately results in higher healthcare prices.[32] Ideally, though, CON programs would not prevent change in the healthcare market but merely provide a way for the public and stakeholders to give input and allow for an evaluation process.[33] This regulatory scheme may serve to distribute care to disadvantaged or underserved populations and block low-volume facilities, which may provide a lower quality of care.[34]

Currently, 35 states and Washington D.C. have a CON program in place, and most of those programs regulate HHAs.[35] Therefore, a prospective HHA operator must apply for and be granted a CON through the applicable state agency prior to commencing operations. The process for obtaining a CON varies from state to state.

Licensure & Accreditation

At their inception, HHAs must satisfy state licensing requirements in order to begin operation. In addition, HHAs must be certified by Medicare in order to receive reimbursement for services provided to patients who are Medicare or Medicaid beneficiaries. HHAs may meet the requisite Medicare certification requirements by obtaining accreditation through an accepted national accreditation organization such as: (1) the Joint Commission on Accreditation of Healthcare Organizations; (2) the Accreditation Commission for Home Care, Inc.; or, (3) the Community Health Accreditation Program.[36] Once operational, HHAs must also maintain compliance with applicable federal fraud and abuse laws, such as the Anti-Kickback Statute and the Stark Law.

Fraud & Abuse

Fraud and abuse laws, specifically those related to the federal Anti-Kickback Statute (AKS) and Stark Law, may have the greatest impact on the operations of HHAs. 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.

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.[37] Violations

of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[38] Congress amended the original statute in 1987 to include exclusion from the Medicare and Medicaid program as an alternative civil remedy to criminal penalties[39] and again in 1997 to add a civil monetary penalty of treble damages, or three times the illegal remuneration, plus a fine of $50,000 per violation.[40] Additionally, 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 remuneration deemed illegal under the AKS.[41]

The *Patient Protection and Affordable Care Act* (ACA) made two noteworthy changes to the intent standards related to the AKS. First, the legislation amended the AKS by stating that a person need not have *actual knowledge* of the AKS or *specific intent* to commit a violation of the AKS for the government to prove a kickback violation.[42] However, the ACA did not remove the requirement that a person must "*knowingly and willfully*" offer or pay remuneration for referrals in order to violate the AKS.[43] Therefore, in order to prove a violation of the AKS, the government must show that the defendant was aware that the conduct in question was "*generally unlawful*," but not that the conduct specifically violated the AKS.[44] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the False Claims Act (FCA).[45] The amended AKS points out that liability under the FCA is "*[i]n addition to the penalties provided for in [the AKS]…*"[46] This suggests that, in addition to civil monetary penalties paid under the AKS, violation of the AKS would create additional liability under the FCA, which itself carries civil monetary penalties of over $21,500 plus treble damages.[47]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[48] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to the HHS to protect certain business arrangements by means of promulgating several *safe harbors*.[49] 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.[50] Failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[51] 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.

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).[52] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[53] Under the Stark Law, DHS include, but are not limited to:

(1) Home health services;

(2) Certain therapy services, such as physical, occupational, and outpatient speech-language pathology services;

(3) Durable medical equipment and supplies;

(4) Prosthetics, orthotics, and prosthetic devices and supplies;

(5) Inpatient and outpatient hospital services; and,

(6) Outpatient prescription drugs.[54]

Under the Stark Law, financial relationships include *ownership interests* through equity, debt, other means, and ownership interests in entities which then have an ownership interest in the entity that provides DHS.[55] 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.[56] 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.[57] 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.[58]

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, 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 investing in an HHA. For example, in September 2021, BAYADA Home Health Care Inc., BAYADA Health LLC, and BAYADA Home Care settled allegations they had violated the AKS for $17 million.[59] BAYADA was alleged to have paid kickbacks to a retirement home operator by purchasing two of its Arizona HHAs, and subsequently filing false claims to Medicare from 2014 to 2020.[60] Additionally, in November 2021, PruittHealth settled FCA claims for $4.2 million.[61] PruittHealth allegedly submitted claims to Medicare and Medicaid without conducting the requisite face-to-face certifications or plans of care or without documenting the patient's need for home health services.[62] The HHA also allegedly failed to refund overpayments received from CMS as reimbursement for other legitimate services provided.[63]

Conclusion

HHAs face many obstacles within the regulatory environment that can prohibit their formation, growth, and development. Understanding state CON and licensing laws as well as fraud and abuse laws, among other statutes and regulations, are integral to the success of an HHA. The next installment in this series will discuss the competitive environment in which HHAs operate.

Valuation of Home Health Agencies: Reimbursement

[This is the third article in a five-part series regarding Valuation of Home Health Agencies. This installment was published in April 2022.]

The U.S. government is the largest payor of medical costs, through Medicare and Medicaid, and has a strong influence on reimbursement for home healthcare services. In 2020, Medicare and Medicaid accounted for an estimated $829.5 billion and $671.2 billion in healthcare spending, respectively.[64] The outsized 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.[65] This effect may be even stronger in the home health industry. Out of the $109.6 billion in revenue received by home care providers in 2021, nearly 74% came from government programs (approximately 40% Medicare and 34% Medicaid), with only 12% from private insurance and 10% from out-of-pocket payments.[66] This may be combined by the large number of individuals retiring each year, triggering switches from commercial health insurance plans to Medicare, which may exacerbate the government's influence on effecting change in the home health industry through revisions to its reimbursement models.[67]

Medicare beneficiaries who are restricted to their homes and require skilled care on an intermittent basis are eligible to receive specific medical services at home, including:

(1) Skilled Nursing Care;
(2) Physical, Occupational, and Speech Therapy;
(3) Home Health Aide Services; and,
(4) Medical Social Work.[68]

From 2000 to 2019, the Centers for Medicare and Medicaid Services (CMS) reimbursed HHAs for these services through a *home healthcare prospective payment system* (HH PPS).[69] This system utilized a 60-day episode of care period with a base payment ($3,154.27 in 2019[70]) that was adjusted based on 153 category case-mixes.[71] This model saw profit margins for HHAs rise to historic levels due to an overestimated base payment and a decline in home health services utilization, which meant HHAs often received more in payments than the costs they incurred.[72] As a result, the Medicare Payment Advisory Commission (MedPAC) recommended CMS lower the base payment closer to the actual costs of providing home health services.[73]

Following MedPAC's recommendation, CMS and the *Health Center Program Bipartisan Budget Act of 2018* (BBA) changed the way HHAs are reimbursed and how home health services are delivered.[74] The BBA established the *Patient-Driven Groupings Model* (PDGM), which went into effect January 1, 2020 (replacing the 153 category case mix adjustment), to improve the quality of care provided by HHAs.[75]

The main focus of the PDGM is to remove the incentive to overserve patients. To prevent over-utilization of services, CMS reduced the payment period from 60 days to 30 and required the HHA re-certify that a patient needs additional care after each period.[76]

The biggest change for HHAs to navigate under the new PDGM is their payment methods. The PDGM increased the number of case mix groupings, from 153 to 432, and placed an increased reliance on technology to provide care and monitor patients.[77] These changes make it more difficult for HHAs to maintain the high margins experienced over the previous two decades.

For 2022, the base payment is $2,013.43, which is down 67% from the 2017 HH PPS model base payment, but up 108% since 2020, the first year of the PDGM.[78] As noted above, this base payment is adjusted using the 432 case mix groupings under the PDGM. The new case mix groupings include: (1) period timing, (2) referral source, (3) clinical category, (4) functional impairments, and (5) presence of comorbidities.

The new PDGM also introduced low- and high-use categories. A patient is considered low-use if they use 2-6 visits during a 30-day period, with the actual visit number varying by the accompanying case-mix grouping.[79] HHAs are reimbursed on a per-visit basis for low-use patients, but HHAs that provide more than the case-adjusted number of visits during a 30-day period will be reimbursed for a full 30-day period.[80] High-use patients typically utilize more than the average number of visits per period, thus costing the HHA more money. Under these new provisions, CMS will reimburse HHAs up to 80% of the difference on any high-use utilization.[81]

In addition to the home health reimbursement model discussed above, the *Patient Protection and Affordable Care Act* (ACA) included a 3% add-on payment for home health episodes in rural areas.[82] Originally effective from April 2010 through 2015, the ACA rural add-on payment was subsequently extended (most recently through the BBA) through 2022.[83] The add-on percentage for 2022 is 1%.[84] MedPAC has suggested that this add-on payment may have led to fraud and abuse in certain rural counties based on their atypical patterns of utilization.[85] In 2019, approximately 77% of those that received the add-on payments were in rural counties with higher utilization than the median utilization for all counties; further, 21 of the 25 highest utilization counties in the U.S. are in rural areas.[86] MedPAC has argued that the rural add-on payment has done little to improve the quality of care for home health beneficiaries, with the high level of utilization in many rural areas resulting in payments made to areas with higher-than-average utilization.[87] MedPAC supports more targeted approaches in order to limit the rural add-on payments to combat fraud and abuse.[88]

As the healthcare system evolves and is reformed to meet the future needs of the rapidly aging U.S. population, the value of healthcare delivery at home may grow due to patients' familiarity with technology, their preference to be treated at home, and home health's cost effective means of delivering high-quality care. However, unlike in most industries, increasing demand does not result in

higher payments, due to the government's prevalence as a payor in the marketplace, requiring HHAs to remain clinically and economically efficient in order to survive. The outlook for home healthcare's competitive environment will be discussed in the next installment in this series.

Valuation of Home Health Agencies: Competition

[This is the fourth article in a five-part series regarding Valuation of Home Health Agencies. This installment was published in May 2022.]

As of 2020, nearly 11,500 Medicare-certified home health agencies (HHAs) were operating in the US.[89] As the Baby Boomer cohort ages, competition among HHAs (and other entities that provide similar services) may increase due to a growing patient pool requiring chronic disease management.[90] This competition for patients, in addition to a shift in patient preference for home-based care over institutional care, may create a gap between the demand for home healthcare services and the supply of adequate personnel to meet that demand.[91] The fourth installment of this home health valuation series will discuss the competitive environment in which HHAs operate by examining the supply of, and demand for, home health services, competitive forces, and the future outlook for the industry.

To qualify for the Medicare home healthcare benefit, beneficiaries must need "*intermittent*" or part-time skilled care, totaling fewer than eight hours per day.[92] In 2020, approximately 3.1 million Medicare beneficiaries received home healthcare services, resulting in Medicare spending approximately $17.1 billion on these services (an average of $5,591 per patient).[93]

Demand for home healthcare services revolves around the need for five types of healthcare services: (1) skilled nursing; (2) therapy services such as physical therapy, occupational therapy, and speech language pathology; (3) home health aide services; (4) medical social services; and, (5) the use of medical supplies, such as wound dressings.[94] In 2020, 50% of all (in-person) home healthcare visits included skilled nursing services; 42% of visits utilized various therapy services; 6% utilized home health aide services; and, 1% utilized medical social services.[95] However, when the COVID-19 pandemic resulted in cancelled elective procedures and moving care out of the hospital and into patients' homes, physicians (who must prescribe home health services in order to trigger an episode of care) and patients both became more comfortable with home healthcare, resulting in what one HHA executive characterized as "pent-up demand" for home health services.[96] While demand is increasing, it started out fairly low, with "[o]nly about 15% of frail older adults receiv[ing] medical care at home."[97] This indicates that there is a large number of patients not currently receiving home health services that could receive them in the future. Further,

the number of overall people who may need care is increasing, with the number of Americans over the age of 65 totaling approximately 81 million by 2040.[98]

While demand may increase for home health services, patient access to home healthcare is reportedly quite high currently. Over 99% of Medicare FFS beneficiaries live in a county served by at least one HHA, and 87.9% live in a county served by 5+ HHAs.[99] However, other anecdotal reports indicate that there is already a shortage of home healthcare services, with providers across the country turning away patients because of insufficient staff.[100] This shortage will only become more critical as the Baby Boomers continue to age, resulting in an estimated national workforce shortage of 151,000 by 2030 and 355,000 by 2040.[101]

The home healthcare industry is quite fragmented, with the three largest HHAs only generating 10% of total industry revenue in 2021.[102] Further, the large majority of HHAs operate as sole proprietorships.[103] The supply of HHAs has been steadily decreasing since 2013 (at a rate of approximately 1.7% per year), although the decrease in the number of HHAs was lower between 2019 and 2020 compared to other years. This indicates that the COVID-19 pandemic and the implementation of a new reimbursement model did not affect the overall HHA industry as predicted.[104] The concentration of HHAs varies widely by state. For example, New Jersey had less than 1 HHA per 10,000 Medicare fee-for-service (FFS) beneficiaries, while Texas had 8.4 per 10,000, in 2020.[105]

Supply for home health services is also driven by the number of providers rendering those services, principally home health aides, personal care aides, and registered nurses (RNs). Consequently, an adequate supply of labor to provide home healthcare services, in particular home health aides, is essential to meet a growing preference for home healthcare services. Over the past 12 years, the size of the home health workforce more than doubled, with over 2.4 million home health workers in 2020.[106] Home health aides are expected to be one of the fastest-growing professions over the next 10 years, with the number of job openings expected to grow nearly 33% between 2020 and 2030, with over 1.23 million jobs projected to be added to the industry.[107] However, likely due to the relatively low annual wages for home health aides ($29,430 per year),[108] it is challenging to fill these roles and keep them filled. Evidence suggests that staffing shortages may be ameliorated by sidelined workers returning to work and/or travel nurses who are looking for a more permanent position.[109]

Competition among home healthcare providers is largely variable, due to the wide spectrum in the scope of services that may be provided by a given HHA. For example, HHAs may provide services that require a licensed provider, such as home infusion therapy; respiratory care; physical, occupational, and speech therapy; behavioral care; and, skilled nursing services, or may provide services that do not require a licensed provider, such as those provided by a home healthcare aide. In addition to competition from other HHAs, providers of home healthcare services face external competition from hospital outpatient departments (HOPDs), skilled nursing facilities (SNFs), and hospices.[110] In 2020, approximately 3.1 million Medicare beneficiaries received care from an

HHA, while approximately 1.2 million beneficiaries experienced a SNF stay.[111] However, patients utilizing home healthcare services may also utilize (concurrently or consecutively) institutional-based post-acute care services, such as SNFs, as both home healthcare services and institutional-based post-acute care services can assist patients with activities of daily living, such as bathing and dressing, while recovering from an injury or illness.[112]

The competition among HHAs will continue to rise as the industry grows and the widespread adoption of telehealth allow for more potential patients and visits. The final installment in this home health valuation series will discuss: the technological environment in which HHAs operate.

Valuation of Home Health Agencies: Technology

[This is the final article in a five-part series regarding Valuation of Home Health Agencies. This installment was published in June 2022.]

With home healthcare providers increasingly being viewed as a critical link in the array of patient-centered healthcare services aimed to bring care back into the community, technology will likely play a more prominent role in managing patient populations in need of home healthcare services. The final installment of this five-part series on the valuation of home health agencies (HHAs) will discuss the growing role of technology in home healthcare and the challenges of utilizing this technology post-COVID-19.

Seniors increasingly want to use home healthcare technology, with a 2020 University of Michigan survey reporting that 72% of seniors want to access healthcare services from home, while a more recent report from AccentCare and Home Health Care News highlighted the ease of adaptation for both providers and patients.[113] New technological advances have made delivering home healthcare easier by removing barriers between physicians and their patients. These technological advances serve two main functions: (1) to provide more efficient healthcare delivery; and, (2) to allow better safety monitoring.[114]

First, technological advancements in home healthcare have increased healthcare access and the efficient delivery of healthcare services by allowing more patients to receive medical care in their homes, rather than at an inpatient or outpatient facility. For example, *infusion therapy*, or the receipt of medication intravenously, can now be completed at a patient's home by a skilled nurse or home health aide. Additionally, mobile health (mHealth) device[115] advancements have allowed for wider remote patient monitoring (RPM) for conditions such as: (1) high blood pressure, (2) diabetes, (3) weight loss/gain, (4) heart conditions, (5) chronic obstructive pulmonary disease (COPD), (6) sleep apnea, and (7) asthma,[116] which have permitted some patients to remain in their homes unless a need for acute healthcare services

arises. These and other medical devices are also becoming widely used for remote therapeutic monitoring (RTM), a complement to RPM which uses devices to collect and report non-physiologic data related to musculoskeletal and respiratory conditions.[117]

Second, safety is an important concern for adults age 65 and older, as injuries resulting from falls is one of the most common causes of death for elderly individuals.[118] Motion detectors, webcams, and audio monitors can be used to monitor an individual's safety at home, and emergency response technologies such as Life Alert can be used in case of an emergency.[119]

As much of the technology discussed falls under the broader umbrella of telehealth, telehealth technology will be discussed in more depth herein. According to the *Health Resources Services Administration* (HRSA), telehealth is defined as:

> "*the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration*."[120]

Telehealth can also describe the monitoring of medical devices; health status data collection and analysis via smart devices; or, virtual visits between physicians and patients.[121]

The terms "*telehealth*" and "*telemedicine*" are distinguished by some in the healthcare industry, including HRSA, which differentiates *telemedicine* (which only includes remote clinical services), from *telehealth* (which can encompasses a broad scope of remote healthcare services, including provider training, administrative meetings, and medical education, in addition to clinical services).[122] In contrast, the *American Telemedicine Association* (ATA) considers the terms to be synonymous and largely interchangeable.[123] For the purposes of this article, the terms will be considered to be synonymous, and may be used interchangeably.

As mentioned above, telehealth services are provided utilizing two-way video, as well as email, smart phones, wireless tools, or other methods of telecommunication technology.[124] These technologies allow virtual consultations with distant specialists, patient monitoring without having to leave the home or office, and, consequently, less expensive healthcare.[125] Utilizing telemedicine services are equally as effective in obtaining clinical information, making an accurate diagnosis, and developing treatment plans as they are during in-person care.[126]

The COVID-19 public health emergency (PHE), which commenced in March 2020, forced the Centers for Medicare & Medicaid Services (CMS) to extend reimbursement for telemedicine services (e.g., patients may currently receive telehealth services from home). This resulted in a drastic increase in utilization, with a 2021 McKinsey and Co. report finding that telehealth utilization has grown 38% from its pre-pandemic levels.[127] Further, 40% of people surveyed believed they would continue to use telehealth services after COVID-19.[128]

Over the last year, telehealth has comprised an average of 4.75% of all medical claim lines.[129]

However, it is uncertain whether CMS will continue to reimburse for telehealth after the PHE ends. The *Choose Home Care Act* bill, which was introduced in Congress in 2021, aims to make COVID-19-related changes to telehealth access and reimbursement under Medicare permanent.[130] This bill seeks to increase the ability for Medicare beneficiaries to receive in-home care, reducing their reliance on skilled nursing facilities and other post-acute care facilities.[131] The bill's sponsors project a $250 million in savings annually as a result of increasing telemedicine reimbursement and accompanying utilization, benefiting both patients and providers.[132] However, this bill has not progressed forward, in either chamber of Congress, for nearly a year.[133] Nevertheless, as of June 2022, there were a number of proposed telehealth bills in Congress, including proposals to extend telehealth options for behavioral health services and to generally expand telehealth offerings under Medicare and other federal healthcare programs.[134]

Despite the immediate future of telehealth coverage being uncertain, it is evident that healthcare technology – including RPM, RTM, and telehealth – will continue to change (and augment) the way HHAs provide care.

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II. REIMBURSEMENT TOPICS

New Research Explores Benefits of Participation in Multiple Payment Models

[Excerpted from the article published in September 2021.]

An August 2021 study published in the Journal of the American Medical Association (JAMA) analyzed medical and surgical episodes of care in U.S. hospitals to determine whether outcomes differed in hospitals that participated in Medicare's Bundled Payments for Care Improvement (BPCI) Initiative depending on whether the patient being treated was attributed to a Medicare Shared Savings Program (MSSP) accountable care organization (ACO).[1] This Health Capital Topics article will discuss the study's findings and potential policy implications.

The BPCI is a demonstration program established by the Centers for Medicare & Medicaid Services (CMS) whereby healthcare organizations are compensated with a single payment for both the hospital ancillary and technical component services and the physician professional component services related to a single episode of care (rather than reimbursing each provider on a fee-for-service basis).[2] The goal of BPCI was to "align incentives" among hospitals, physicians, and other providers, as well as achieve "higher quality, more coordinated care at a lower cost to Medicare."[3] There were four (4) models under BPCI, each of which include different types of services to be included in the model's bundled payment. Participation in the model commenced in April 2013 and concluded in 2018.[4]

The MSSP was created by the Patient Protection and Affordable Care Act (ACA) and provides for the creation of ACOs, organized networks of providers who coordinate care in order to lower costs and increase quality to achieve financial incentives established through a contract with CMS. Under the program, which has undergone several iterations over the last decade, shared savings incentive payments are distributed to ACO participants that achieve established quality metrics and expenditure reductions for Medicare beneficiaries. The MSSP commenced in 2012 with the Pioneer ACO Model[5] and was revamped in 2019 to include five participation options (called "tracks") that have generally higher financial risks than the predecessor tracks and models.[6]

As the researchers noted, while BPCI and the MSSP have generally similar goals of improving coordination across the care continuum, the mechanisms for achieving these goals differ, which led the researchers to wonder whether models may "complement each other in ways that could produce additive benefits…[or, c]onversely, because they both encompass the period spanning hospitalization and discharge to post-acute care, [whether] the 2 payment models could lead to duplicative services."[7]

In reviewing data for over 9.8 million Medicare beneficiaries between 2011 and 2016, researchers compared costs and quality across 48 episodes of care (24 medical and 24 surgical) and categorized those episodes depending on whether

or not the hospital participated in BPCI, and whether or not the patient was attributed to an MSSP ACO.[8] Additionally, researchers analyzed the data before versus after the start of BPCI in October 2013. The outcomes on which the research focused included 90-day post-discharge institutional spending (i.e., skilled nursing facility [SNF], inpatient rehabilitation facility, long-term acute care, and readmissions spending), as well as readmission rates, 90-day morality rates, discharge to institutional post-acute care and home health, and SNF length of stay.[9] The goal of reviewing this data was to determine whether outcomes in BPCI differed depending on whether patients were attributed to ACOs in the MSSP, i.e., is there benefit to participating in both bundled payment and value-based payment programs simultaneously.

Specific to medical episodes, researchers found that in the non-ACO group, patients in bundled payment programs had differentially lower post-discharge institutional spending than patients not in bundled payment programs.[10] In the ACO group, patients in bundled payment programs had lower 90-day readmissions rates, a higher discharge to home health, and a lower SNF length of stay than patients not in bundled payment programs.[11] Further, patients in both bundled payment programs and ACOs had greater decreases in SNF length of stay and 90-day unplanned readmissions than those patients in BPCI or the MSSP only.[12]

In surgical episodes, the research similarly found that in the non-ACO group, patients in bundled payment programs had differentially lower post-discharge institutional spending than patients not in bundled payment programs.[13] In the ACO group, patients in bundled payment programs also had differentially lower post-discharge institutional spending compared with patients not in bundled payment programs.[14] Patients in bundled payment programs in the ACO and non-ACO groups did not differ with respect to changes in spending.[15]

In contrast to policymaker concerns that participating in multiple alternative payment models are counterproductive,[16] the study found that "simultaneous inclusion in both ACOs and bundled payment programs was associated with lower institutional postacute care spending and readmissions for medical episodes and lower readmissions but not spending for surgical episodes."[17] The research asserted that the "study results suggest three possible policy implications":

(1) Potential additive benefits when bundled payments and other alternative payment models overlap;

(2) Policymakers may now be motivated to revisit "the existing approach for handing ACO-bundled payment program overlap, as the MSSP currently "effectively penalizes ACOs whose patients receive care from rapidly improving bundled payment participants"; and,

(3) Undertaking further research to "evaluate outcomes when different payment models overlap in patients' care."[18]

This study provides the first evidence related to outcomes when participating in overlapping payment models[19] and indicates that, contrary to policymakers'

beliefs, participating in multiple value-based and bundled payment initiatives may have additive benefits for patients, providers, and payors (i.e., Medicare) alike. It is the researchers' hope (and likely the hope of healthcare industry stakeholders) that these findings will translate to CMS initiating additional payment program participation options.

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CMS Innovation Center Launches "Bold New" Strategy

[Excerpted from the article published in October 2021.]

When President Joe Biden was elected in 2020, there was much anticipation and speculation regarding what his election would mean for the U.S. healthcare industry in the coming years. As an ardent supporter of the *Patient Protection and Affordable Care Act* (ACA) who campaigned on offering a public insurance option similar to Medicare, many in the healthcare industry assumed that the Biden Administration would be a strong proponent of continuing the shift to value-based care, which shift was largely spurred by his predecessor and former boss, Barack Obama, with the passage of the ACA.[1] However, due to the COVID-19 pandemic and other healthcare priorities, Medicare's value-based payment models have largely taken a backseat in the administration's first year in office. Nevertheless, recent statements from leaders of the Center of Medicare & Medicaid Innovation (CMMI) indicate that value-based reimbursement (VBR) is becoming a priority once more.

CMMI was created by the ACA,[2] "with the goal of transitioning the health system to value-based care by developing, testing, and evaluating new payment and service delivery models in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP)."[3] CMMI "has a growing portfolio testing various payment and service delivery models that aim to achieve" higher quality care at lower costs, reaching almost 28 million patients and over 528,000 healthcare providers and plans between 2018 and 2020.[4] Although the agency has tested nearly 50 models over the past decade, very few of which have resulted in higher quality or better cost savings.[5]

Early in his term, President Biden announced that Elizabeth Fowler, an Obama Administration alumna who helped draft and implement the ACA, would be the new director of CMMI.[6] One week later, on March 10, 2021, the administration paused a number of CMMI VBR models, including the Geographic Direct Contracting Model, Primary Care First Model's Seriously Ill Population option, and the Kidney Care Choices Model, to "review model details."[7] The effect of this "review" (the length of which review was not disclosed) was to delay the timelines for these models, by pushing back the participation application deadlines and performance periods.[8] While this decision was not necessarily indicative of plans to eliminate the models – as one commentator noted, "It's natural for the administration to want to take a close look at the programs that are on the verge of being implemented to satisfy for themselves that this is not a disaster in the making where they'll be left holding the bag for something they did not conceptualize nor approve on their own")[9] – it certainly did not instill confidence that VBR was a priority for the administration. Subsequently, Fowler confirmed that the pause or termination of some CMMI models was not due to a change in course, stating, "I understand that collectively these announcements may have raised questions about where the center is headed next…True innovation means failing until we get things right."[10] In reviewing those models, CMMI was supposedly revamping the

agency's strategy and thinking more creatively about how the models would work in tandem going forward, perhaps in response to the Medicare Payment Advisory Commission's (MedPAC's) October 2020 recommendation that CMMI "condense the sheer number of models" and reimagine the program.[11]

The focus of CMMI's review became clearer recently, due to statements by CMMI leaders at various healthcare industry conferences. On September 30, 2021, CMMI's chief operating officer stated at the National Association of Accountable Care Organizations (ACOs) conference that he did not "think that [the Centers for Medicare & Medicaid Services (CMS)] will be promoting models that have more risk just for the sake of having more risk."[12] Healthcare industry commentators have interpreted this statement as a "signal that CMMI aims to restructure payment models to crack down on inappropriate coding, shift the focus of value-based programs to reduce patient inequities and cut down on initiatives that only serve to empower dominant providers with large market share."[13] This is a shift from the previous administration, which prioritized financial risk in their models, resulting in many healthcare providers choosing not to participate.[14] On October 20, 2021, CMMI's chief strategy officer indicated at the Better Medicare Alliance conference that the Biden Administration wants to "accelerate" the shift to VBR by increasing participation (specifically in ACOs), stating that "[w]e need to recognize we need to increase the number of ACOs and the beneficiaries assigned to them, increase opportunities for providers who want to participate and deliver whole-person, integrated care."[15]

On the same day as the speech at the Better Medicare Alliance conference, CMS published a white paper describing CMMI's vision for the next ten years.[16] The white paper listed five strategic objectives in implementing its vision of "a health system that achieves equitable outcomes through high quality, affordable, person-centered care":

(1) Drive accountable care, i.e., "[i]ncrease the number of beneficiaries in a care relationship with accountability for quality and total cost of care";

(2) Advance health equity, i.e., "[e]mbed health equity in every aspect of CMS Innovation Center models and increase focus on underserved populations";

(3) Support innovation, i.e., "[l]everage a range of supports that enable integrated, person-centered care – such as actionable, practice-specific data, technology, dissemination of best practices, peer-to-peer learning collaboratives, and payment flexibilities";

(4) Address affordability, i.e., "[p]ursue strategies to address health care prices, affordability, and reduce unnecessary or duplicative care"; and,

(5) Partner to achieve system transformation, i.e., "[a]lign priorities and policies across CMS and aggressively engage payers, purchasers[,] states, and beneficiaries to improve quality, to achieve equitable outcomes, to reduce health care costs."[17]

For each of the strategic objectives, CMS also listed certain measures of progress, meant to quantify advancement toward a given objective. Notably, pursuant to the achievement of the "drive accountable care" objective, CMS aims to move all Medicare Part A and B beneficiaries, and a vast majority of Medicaid beneficiaries, to a "care relationship with accountability for quality and total cost of care by 2030."[18] As of 2020, 67% of Medicare Part A and B beneficiaries were in Medicare Advantage plans or attributed to an ACO; this means that approximately 30 million additional beneficiaries would need be attributed to an ACO or other VBR model over the next 10 years.[19] Whether or not CMS and CMMI's new strategies can achieve this lofty goal remains to be seen.

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New Study Compares Medicare-Commercial Payment Gaps by Specialty

[Excerpted from the article published in October 2021.]

An October 2021 study conducted by the Urban Institute assessed the gap between commercial insurance payments and Medicare payments for professional physician services to determine whether the payment gap between Medicare and commercial insurance differs by specialty. This Health Capital Topics article will discuss this latest research on the payment differences.

Utilizing data from FAIR Health, the Urban Institute reviewed commercial insurance claims across the U.S. (for approximately 60 insurers and third-party administrators covering over 150 million Americans under age 65) from March 2019 through February 2020.[1] In one of the first studies to look at the commercial-to-Medicare payment ratio on a specialty level, and across such a large number of procedure codes, the researchers reviewed the payment gap across 17 non-pediatric and non-geriatric specialties:

(1) Internal Medicine;
(2) Family Medicine;
(3) Urology;
(4) Obstetrics & Gynecology;
(5) Psychiatry;
(6) Dermatology;
(7) Gastroenterology ;
(8) Ophthalmology;
(9) General Surgery;
(10) Cardiology;
(11) Cardiovascular Surgery;
(12) Emergency & Critical Care;
(13) Surgical and Radiation Oncology;
(14) Radiology;
(15) Neurosurgery;
(16) Anesthesiology; and,
(17) Orthopedics.[2]

The researchers reviewed the top 20 Current Procedural Terminology (CPT) codes for each specialty based on: (1) the frequency of the procedures; and (2) the expenditure amount for the procedures.[3] In totality, these codes represented approximately 41% of all of the FAIR Health professional spending data.[4] While the Urban Institute largely used the expenditure amount procedures (termed the expenditure-weighted ratios) in their comparisons, the researchers noted that the trends were largely the same for the high-frequency procedures.

In determining the commercial-to-Medicare payment ratio for each procedure code, FAIR Health utilized rates from the 2020 Medicare physician fee schedule (MPFS) after adjustment for the geographic practice cost index (GPCI).[5] The researchers also constructed a weighted average among MPFS non-facility and facility rates for applicable procedures, to control for the fact that "Medicare pays physicians higher rates for certain physician services provided in an office-based setting."[6] FAIR Health then compared those MPFS rates for each code to the national and state-specific average *imputed allowed amounts* for the commercial claims.[7] Because FAIR Health does not share actual contracted rates (i.e., allowed amounts), so as to "protect the confidentiality of proprietary rates negotiated between individual payers and providers," it instead constructs imputed allowed amounts for each claim line

by calculating the ratio of the actually allowed amount to the provider charge for each claim, then averages those ratios across claim lines and geographies; the average of those ratios is subsequently "applied to the actual charge on each claim line within the region and service group to calculate an imputed allowed amount for each claim line."[8] FAIR Health did confirm that the imputed allowed amounts and actual allowed amounts were very similar (with a correlation of approximately 0.9).[9]

In comparing the various specialties, the researchers found that family medicine, obstetrics and gynecology, dermatology, ophthalmology, and psychiatry had the lowest commercial-to-Medicare payment ratios[10] – 1.1 of Medicare or less.[11] Nine of the 17 specialties had ratios between 1.2 and 1.5, including gastroenterology, cardiology, general surgery, and orthopedics.[12] The specialties with the highest commercial-to-Medicare payment ratios were: radiology (1.8); neurosurgery (2.2); emergency department/critical care specialties (2.5); and anesthesia (3.3).[13] Across all codes and specialties, the average ratio was approximately 1.6.[14]

The researchers analyzed and compared the data in a couple of different ways. First, the procedure codes were classified into six broad service categories: (1) Procedures; (2) Evaluation & Management; (3) Tests; (4) Treatments; (5) Imaging; and, (6) Anesthesia.[15] When the national average ratios were compared across these service categories, the categories largely ranged between 1.4 and 1.6 with one exception – anesthesia (3.3).[16]

Second, the researchers compared the data across the 12 states to analyze geographic variation. Because the data sample only had data for all specialties for 12 states, those were the states analyzed. This comparison found that commercial-to-Medicare payment ratios varied fairly widely, from 1.2 in Pennsylvania to 2.6 in Wisconsin; as mentioned above, the U.S. average was 1.6.[17] Additionally, while researchers admitted that comparing data across both geographic location and type of service (i.e., physician price versus hospital prices) was difficult, they noted that "some evidence suggests wider geographic variation in physician prices than in hospital prices," based on their data as well as the findings of past studies.[18]

This study is not the first to review the payment gaps between Medicare and commercial payors.[19] In fact, the researchers reviewed a number of past studies to confirm the reasonableness of their commercial-to-Medicare payment ratios. A 2018 Congressional Budget Office (CBO) study reviewed 2012-2017 data for a single payor to construct average annual commercial and Medicare prices for 20 common services in each core-based statistical area in the U.S.[20] The author found that "average commercial prices were substantially higher than Medicare [fee-for-service] prices and were up to three times higher out of network than in network…[Further,] commercial prices varied widely among and within geographic areas."[21] Additionally a 2019 study utilized 2016 data from Truven's MarketScan database to estimate a national average commercial price for each service and compared it to MPFS rates; while this study is very similar to the October 2021 Urban Institute study (and had similar findings),

the 2019 study did not adjust the Medicare comparison price for geography or place of service.[22]

The Urban Institute researchers discussed some potential policy implications for their findings. Notably, any physician payment reforms wherein commercial payment rates become tied to the Medicare rate or a Medicare benchmark (e.g., a rate no more than a certain percentage of Medicare) could result in large payment cuts – but only to a small number of physician specialties – resulting in large income losses for those providers.[23] However, the researchers noted that "many specialties receive more modest commercial markups over Medicare rates, around 130 to 150 percent...[t]hus, these specialties would see smaller payment reductions in the face of proposed policies."[24]

While reforming commercial insurance rates for physicians is not likely to be at the top of the federal government's priority list anytime soon, other governmental initiatives may serve to force the commercial insurance industry to change (i.e., reduce payment rates). For example, effective January 1, 2021, every U.S. hospital is required to "provide clear, accessible pricing information online about the items and services they provide."[25] The pricing information that must be publicly disclosed includes certain standard charges for hospital's services, such as commercial payor-specific negotiated charges.[26] Because approximately 40% of hospitals had yet to comply with the rule as of June 2021,[27] and the data posted by hospitals vary widely in quality and comprehensibility, "the data…hasn't delivered meaningful transparency, [but] it has raised awareness of the issue."[28] However, with some tweaks to the rule, as well as harsher penalties for noncompliant hospitals,[29] perhaps this new rule could serve to reduce commercial insurance payment rates for those specialties with the greatest markups to Medicare and help constrain healthcare costs.

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22 "The Pricing of Care Under Medicare for All: Implications and Policy Choices" By Zirui Song, Journal of the American Medical Association, Vol. 322, No. 5 (2019), available at: https://mfprac.com/web2021/07literature/literature/Health_Costs/MedicareAllPricing_Song.pdf (Accessed 10/21/21); McMorrow, Berenson, and Holahan, Urban Institute, October 2021, p. 6.

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24 *Ibid.*

25 "Hospital Price Transparency" Centers for Medicare & Medicaid Services, https://www.cms.gov/hospital-price-transparency (Accessed 10/20/21).

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MedPAC's Next Iteration of Alternative Payment Models

[Excerpted from the article published in Janruary 2022.]

Recent meetings of the Medicare Payment Advisory Commission (MedPAC) have provided a glimpse into the next iteration of Medicare alternative payment models (APMs). This Health Capital Topics article will discuss MedPAC's discussion regarding the form such an APM may take, the commission's resulting reactions and recommendations, and what these recommendations may ultimately mean for providers.

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."[1] Comprised of 17 members (commissioners) that serve three-year terms, as well as a career staff with "backgrounds in economics, health policy, public health, or medicine,"[2] MedPAC makes recommendations to Congress and to the Secretary of Health and Human Services (HHS).[3] Those recommendations are typically included in one of the two annual reports published by the commission in March and June.

In June 2021, MedPAC recommended that Centers of Medicare & Medicaid Services (CMS) "streamline and harmonize its portfolio of advanced [APMs]."[4] In line with that recommendation, MedPAC began discussing the development of a new multi-track, population-based APM in October 2021, the same month that CMS set a goal for all Medicare beneficiaries to be under a value-based payment arrangement by 2030.[5] In its October meeting, MedPAC commissioners expressed "broad interest in centering CMS's APM strategy around a single multi-track, population-based payment model," with various tracks and financial risk options.[6]

In November 2021, MedPAC commissioners specifically explored developing administratively-set benchmarks for accountable care organizations (ACOs). Historically, ACO benchmarks have been "based on spending for beneficiaries who would've been eligible for the ACO in the baseline years, along with the growth in an ACO's spending between the baseline and performance years."[7] If an ACO comes in below that year's benchmark, they share in those realized savings with Medicare (in some instances, the ACO also shares in the losses if it comes in above the benchmark).[8] This benchmark is reset each year based on the ACO's past performance, meaning that the ACO must perform better each year in order to achieve savings, resulting in benchmarks that become increasingly harder to exceed. This so-called "ratcheting effect" puts long-term ACO participation at risk, as the longer ACOs participate, the smaller the margin is in which to create savings.[9]

In order to address the ratcheting effect, MedPAC proposed during its November 2021 meeting using "an administratively-set trend factor, which could be based on a number of [external] metrics including a discounted

projection of Medicare fee-for-service spending growth or projected gross domestic product growth."[10] Certainly, this path has its own issues, such as inaccurate spending projections; random variation in spending, which may "create unwarranted shared savings"; and, other one-time changes by smaller ACOs that may be due to random variation rather than patient care improvements.[11] Additionally, industry stakeholders have questioned the value of such a shift when ACO participation is still voluntary, as it may make administratively-setting benchmarks more difficult.[12] MedPAC's vice chair stated that he "envisions a set up where ACO participation would be mandatory for certain types of providers, with strong incentives in the form of higher fee-for-service rates for other providers to participate as well."[13] However, MedPAC's chair has indicated his aversion to mandatory ACO models and has suggested that ACOs should instead be incentivized to participate.[14]

In its January 2022 meeting, MedPAC staff presented a proposal for a potential three-track APM, (with administratively-set benchmarks using external factors), which tracks would be as follows:

(1) No financial risk track – For independent physician practices, small safety net providers, or rural providers, wherein providers could keep up to 50% of savings generated after meeting a minimum savings rate;

(2) Some financial risk track – For mid-sized organizations (e.g., multispecialty physician practices, small community hospitals), wherein providers could keep up to 75% of savings generated after meeting a minimum savings rate, or repay 75% of losses; and,

(3) Full financial risk track – For large organizations (e.g., health systems with multiple locations), wherein providers would have a 100% shared savings/loss rate.[15]

Several questions were raised regarding this potential APM, including whether an organization's size is determinate of its ability to take on risk (as smaller organizations are often more nimble), and how soon a provider should have to take on risk (e.g., could small organizations stay in the no financial risk track indefinitely).[16] Other issues that need to be addressed, according to MedPAC commissioners, include how to encourage participation in APMs and setting future dates for mandatory participation (which transparency may provide some certainty to providers as to "where things are going").[17] The next steps in moving this APM blueprint to reality was not clear from the meeting, although the MedPAC vice chair did state that such APM reform will likely need to be made via legislation.[18] While the agenda for the upcoming MedPAC meeting in March 2022 has not yet been released,[19] providers would be well-served to stay abreast of MedPAC's ultimate recommendations as to the next iteration of value-based care, as they will likely be directly affected by any changes to current programs.

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3 "Commission Recommendations" Medicare Payment Advisory Commission, https://www.medpac.gov/recommendation/ (Accessed 11/18/22).
4 "January 13-14, 2022: Public Meeting" Medicare Payment Advisory Commission, https://www.medpac.gov/meeting/january-13-14-2022/ (Accessed 11/18/22).
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8 *Ibid.*
9 *Ibid.*
10 *Ibid.*
11 *Ibid*; Burton, et al., Medicare Payment Advisory Commission, January 14, 2022, p. 4.
12 Goldman, Modern Healthcare, November 8, 2021.
13 *Ibid.*
14 *Ibid.*
15 Goldman, Modern Healthcare, January 14, 2022.
16 *Ibid.*
17 *Ibid.*
18 *Ibid.*
19 "Public Meetings" Medicare Payment Advisory Commission, https://www.medpac.gov/meeting/ (Accessed 1/18/22).

MedPAC Recommends Payment Updates for 2023

[Excerpted from the article published in Janruary 2022.]

In a January 2022 meeting of the Medicare Payment Advisory Commission (MedPAC), commissioners reviewed various recommendations related to the Medicare fee schedule for various health sectors, and unanimously agreed to update Medicare payments to hospitals and keep physician payment rates the same for 2023. This Health Capital Topics article will review the recommendations made by MedPAC for each of the health sectors and their respective payment systems.

As noted in another article in this Health Capital Topics issue,[1] 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] During their January 13-14, 2022 meeting, MedPAC reviewed the payment adequacy of:

(1) Hospital inpatient and outpatient services;
(2) Physician and other health professional services;
(3) Ambulatory surgical center (ASC) services;
(4) Outpatient dialysis services
(5) Hospice services;
(6) Skilled nursing facility (SNF) services;
(7) Home health agency services;
(8) Inpatient rehabilitation facility services; and,
(9) Long-term care hospital services.[5]

Regarding hospital inpatient and outpatient services, the commissioners approved the recommendation by MedPAC staff to update the base payment rates for acute care hospitals.[6] While MedPAC staff acknowledged that the COVID-19 public health emergency (PHE) has had "material effects on payment adequacy indicators, making them more difficult to interpret," they stated that "[t]emporary or highly variable coronavirus effects are best addressed through targeted, short-term funding policies rather than permanent changes to all providers' payment rates in 2023 and future years."[7] Commissioners ultimately approved an update of 2% for both inpatient and outpatient payments for hospitals for fiscal year 2023, in accordance with current law,[8] but expressed concerns that the recommended payment update "may not be adequately reflected in the FY 2023 market basket update" due to the disruptions emanating from COVID-19.[9]

However, when it came to payment rates to physicians, MedPAC commissioners were not as generous. Commissioners voted, despite "concerns about the long-term viability of the current physician fee schedule model" to recommend keeping the physician fee schedule payment stagnant for 2023.[10] This recommendation is consistent with the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which dictates a 0% update for physician pay (although physicians can receive enhanced reimbursement through participation in quality payment programs).[11] Despite this vote, commissioners expressed concern that the physician payment update is not "keeping up with inflation during a particularly volatile time for healthcare providers," which may "lead to underpaying providers in the current high-inflation environment."[12] Many of the commissioners' comments regarding the physician fee schedule centered on the prospective need for more wholesale changes to the physician payment system. For example, nearly half of physician fee schedule payments are comprised of the practice expense (the overhead involved in providing a given service), but that practice expense is not tied to a market basket update (similar to the payment system for hospitals) that accounts for inflation. This could lead to the two payment systems experiencing payment update differentials in coming years.[13]

Provider organizations quickly spoke out in opposition to MedPAC's recommendation, asserting that keeping physician payments unchanged (not even keeping payments on par with inflation) ignores the reality that "[p]hysician practices are dealing with massive staffing shortages and skyrocketing expenses."[14]

For SNFs, home health agencies, and inpatient rehabilitation facilities, MedPAC agreed to recommend a base payment decrease of 5% to those organizations.[15] Further, MedPAC recommended that home health agencies be required to report telehealth services provided during a 30-day care period. For long-term care hospitals and dialysis facilities, however, MedPAC voted to suggest an increase in reimbursement.[16] MedPAC did not recommend a payment increase or decrease for ASCs or hospices, but it did recommend an elimination of the 2022 ASC conversion factor.[17]

The recommendations made by MedPAC during its January 2022 meeting will be included in its annual March report to Congress on Medicare payment policy.[18]

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1 See the article entitled, "MedPAC's Next Iteration of Alternative Payment Models."

2 "What We Do" Medicare Payment Advisory Commission, https://www.medpac.gov/what-we-do/ (Accessed 1/18/22).

3 "January 13-14, 2022: Public Meeting" Medicare Payment Advisory Commission, https://www.medpac.gov/meeting/january-13-14-2022/ (Accessed 1/10/22).

4 "MedPAC: Increase hospital pay, no change for physicians in 2023" By Maya Goldman, Modern Healthcare, January 13, 2022, https://www.modernhealthcare.com/medicare/medpac-increase-hospital-pay-no-change-physicians-2023 (Accessed 1/20/22) ; "MedPAC votes on 2023 payment recommendations"

American Hospital Association, https://www.aha.org/news/headline/2022-01-13-medpac-votes-2023-payment-recommendations (Accessed 11/20/22).

5 Medicare Payment Advisory Commission, https://www.medpac.gov/meeting/january-13-14-2022/ (Accessed 1/10/22).

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7 *Ibid*, p. 3.

8 Notably, "[i]npatient rates will also be subject to an additional statutory 0.5 percent," which bumps the inpatient hospital rates increase to 2.5%. "MedPAC: Increase hospital pay, no change for physicians in 2023" By Maya Goldman, Modern Healthcare, January 13, 2022, https://www.modernhealthcare.com/medicare/medpac-increase-hospital-pay-no-change-physicians-2023 (Accessed 1/20/22); American Hospital Association, https://www.aha.org/news/headline/2022-01-13-medpac-votes-2023-payment-recommendations (Accessed 11/20/22); "Medicare Payment Advisory Commission Public Meeting" Transcript, January 13, 2022, Medicare Payment Advisory Commission, available at: https://www.medpac.gov/wp-content/uploads/2021/10/Jan22_MedPAC_Meeting_Transcript_SEC.pdf (Accessed 1/21/22), p. 10.

9 "MedPAC Votes on Updates to Hospital Base Payment Rates and Physician Payments" Association of American Medical Colleges, January 14, 2022, https://www.aamc.org/advocacy-policy/washington-highlights/medpac-votes-updates-hospital-base-payment-rates-and-physician-payments (Accessed 1/20/22).

10 Goldman, Modern Healthcare, January 13, 2022.

11 *Ibid.*

12 *Ibid.*

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Exorbitant Healthcare Spending in 2020 due to COVID-19

[Excerpted from the article published in Janruary 2022.]

On December 15, 2021, the Centers for Medicare & Medicaid Services (CMS) released a report detailing healthcare spending in the U.S. in 2020, which confirmed the outsized impact the COVID-19 pandemic has had on the nation's healthcare industry and on federal spending. Overall, healthcare spending increased 9.7% in 2020 (to $4.1 trillion), double the 2019 increase of 4.3%.[1] Healthcare spending also became a larger share of the U.S. gross domestic product (GDP) in 2020. In addition to the increase in spending, the GDP declined by 2.2% (the largest decrease since 1938), resulting in healthcare comprising 19.7% of the national GDP, compared to 17.6% in 2019.[2] This *Health Capital Topics* article will review the notable findings included in CMS's report.

The healthcare spending acceleration in 2020 (the fastest growth rate since 2002) was largely attributable to a 36% increase in federal healthcare expenditures in response to the COVID-19 pandemic.[3] In comparison, federal healthcare expenditures grew only 5.9% in 2019.[4] Interestingly, much of this spending was not directly related to patient care, but rather to the more than $175 billion in financial support to healthcare providers (e.g., the Provider Relief Fund and Paycheck Protection Program), as well as increased public health activities (e.g., contact tracing and vaccination services).

Examining expenditures across service categories, hospital expenditures grew 6.4% in 2020 (comprising 31% of national health spending), barely faster than its 6.3% growth in 2019.[5] This growth was largely attributed to the substantial funding from federal programs, which more than offset the moratoria on elective procedures as well as other voluntarily-forgone healthcare services.[6] Expenditures on physician and clinical services similarly grew by 5.4% (comprising 20% of national health spending), faster than the 4.2% rate seen in 2019.[7] Retail drug spending also increased 3% in 2020 (comprising 8% of national health spending), a slower rate than its 2019 growth of 4.3%.[8] This deceleration was due to less utilization (i.e., fewer physician visits resulted in fewer new prescriptions), but also to the increase in consumers' use of coupons, which decreased their expenditures.[9]

Analyzing expenditures by sponsor, the federal government understandably accounted for the largest portion of healthcare spending (36%), followed by households (26%), private businesses (17%), state and local government (14%), and other private revenues (7%).[10] The federal government was the only sponsor for whom expenditures increased in 2020 – expenditures by all other sponsors declined, due to the decreased utilization and reductions in retail prescription drug purchases.[11] Similarly, although federal healthcare spending increased rapidly, spending for those individuals with health insurance (both governmental and commercial) grew much slower in 2020 than in the year prior (3% in 2020 compared to 4.3% in 2019), and out-of-pocket spending decreased by 3.7%.[12] This was largely due to Americans seeking fewer medical services

and goods,[13] likely because of the decrease in the number of uninsured individuals, as well as the number of individuals who stayed home instead of risking infection by going to a healthcare facility.

In terms of insurance coverage, the number of uninsured individuals decreased, while the proportion of the various types of coverage shifted. The number of uninsured individuals decreased from 31.8 million in 2019 to 31.2 million in 2020, as enrollment increases in Medicaid and Affordable Care Act (ACA) Marketplace plans more than offset the pandemic's significant effect on employment and the resulting reduction in employer-sponsored coverage (a decline of 0.8%).[14]

Looking ahead to what these trends may mean for 2021 healthcare spending, CMS expects that the COVID-19 pandemic will still have a significant influence on national health expenditures, due to the national vaccination campaign and the virus surges as a result of the Delta and Omicron variants. While the data is currently incomplete in order to make any conclusions, CMS does know "that the story that unfolded in 2020 and continues today is unlike anything that has happened in the past 100 years."[15]

Projecting healthcare spending post-COVID, a 2020 spending report projected national healthcare spending to grow at 5.4% per year, reaching $6.19 trillion by 2028 (a 54% increase from 2020 expenditures) and accounting for 19.7% of the U.S. GDP.[16] CMS predicts that prices for medical goods and services will grow at an average annual rate of 2.4% from 2019 to 2028, accounting for 43% of total projected growth in personal healthcare spending during that time period.[17] CMS states "this acceleration in price growth largely reflects faster expected growth in health-sector wages and follows the unusually slow rate of personal health care inflation observed in 2014-18, when price growth for medical goods and services was 1.2% and represented 25% of expenditure growth."[18] Significantly, the government "is projected to pay a larger share (nearly half) of the nation's total health bill by 2028, as the baby boomers continue aging into Medicare…"[19]

Many healthcare finance and economics experts assert that these spending trends highlight a key concern – price inflation.[20] 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."[21]

1 "National Healthcare Spending In 2020: Growth Driven By Federal Spending In Response To The COVID-19 Pandemic" By Michah Hartman, et al., Health Affairs, December 15, 2021, https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01763 (Accessed 1/14/21).
2 *Ibid.*
3 *Ibid.*
4 *Ibid.*
5 *Ibid.*; "NHE Fact Sheet" Centers for Medicare & Medicaid Services, December 15, 2021, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet (Accessed 12/23/21).
6 Hartman, et al., Health Affairs, December 15, 2021.
7 Centers for Medicare & Medicaid Services, December 15, 2021.
8 Hartman, et al., Health Affairs, December 15, 2021.
9 *Ibid.*
10 *Ibid.*
11 *Ibid.*
12 *Ibid.*
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14 Centers for Medicare & Medicaid Services, December 15, 2021.
15 Hartman, et al., Health Affairs, December 15, 2021.
16 "CMS: US health care spending will reach $4T in 2020" Advisory Board, April 3, 2020, https://www.advisory.com/en/daily-briefing/2020/04/03/health-spending (Accessed 12/23/21); "Healthcare spending to consume 20% of GDP by 2028" By Alex Kacik, Modern Healthcare, March 24, 2020, modernhealthcare.com/healthcare-economics/healthcare-spending-consume-20-gdp-2028 (Accessed 11/14/21).
17 Advisory Board, April 3, 2020.
18 *Ibid.*
19 *Ibid.*
20 *Ibid.*
21 *Ibid.*

Gap Between Medicare and Commercial Hospital Prices Increases

[Excerpted from the article published in April 2022.]

A recent study examined the growth in hospital prices paid by commercial health insurance companies compared to Medicare over a seven-year period and found that commercial health plan rates were, on average, 180% higher than Medicare rates as of 2019.[1] While the national ratio between commercial and Medicare hospital payment growth rates remained relatively stable during the seven-year study period, ratios varied widely on a regional basis. This Health Capital Topics article will discuss this recent study and its implications.

In evaluating "the extent to which trends in commercial hospital prices have differed across the" U.S., researchers obtained cost report data submitted by hospitals to the Healthcare Provider Cost Reporting Information System (HCRIS) between 2012 and 2019. After going through several "data cleaning steps and sample restrictions," the data contained information from 3,612 hospitals across 306 hospital referral regions (HRRs).[2] This data was then applied to Medicare rates to create commercial-to-Medicare payment rate ratios.

This analysis indicated that commercial-to-Medicare price ratios were fairly steady overall between 2012 and 2019, increasing approximately 7%, from an average of 173% of Medicare in 2012 to 180% of Medicare in 2019; however, these ratios varied significantly across HRRs.[3] For example, in HRRs that had high ratios (i.e., wide gaps between commercial and Medicare rates) in 2012, they had large swings (increases and decreases) in those ratios – both increases and decreases averaged around 38 percentage points (i.e., in places with large increases, that increase was an average of 38%, while places with large decreases saw an average decrease of 38%).[4]

Between 2012 and 2019, the top five HRRs that had high ratios at the beginning of the study period and experienced large increases during the study period were:

(1) Tacoma, WA (increase of 115%, to 337% of Medicare);
(2) Chico, CA (increase of 101%, to 338% of Medicare);
(3) San Mateo County, CA (increase of 83%, to 329% of Medicare);
(4) Santa Barbara, CA (increase of 80%, to 362% of Medicare); and
(5) Salinas, CA (increase of 69%, to 290% of Medicare).

At the other end, the top five HRRs that had high ratios at the beginning of the study period but experienced large decreases during the study period were:

(1) Gulfport, MS (decrease of 109%, to 158% of Medicare);
(2) Lafayette, IN (decrease of 78%, to 279% of Medicare);
(3) Pueblo, CO (decrease of 78%, to 197% of Medicare);
(4) Lawton, OK (decrease of 54%, to 167% of Medicare); and
(5) Casper, WY (decrease of 52%, to 193% of Medicare).[5]

As highlighted by these lists, the large ratios and large increases occurred largely in California (of the 19 HRRs with large increases, 11 of them were in California), while the large ratios with large decreases were more geographically diverse.[6] Interestingly, some of the HRRs with the largest price increases were adjacent to HRRs with the lowest ratios or largest decreases.[7]

At the other end of the spectrum, those HRRs that had low ratios (i.e., commercial and Medicare rates were more similar), their large increases averaged 31% while their large decreases only averaged 16%.[8] In both circumstances, this resulted in some HRRs trending up or down closer to the national average, while some trended in the other direction, creating more extreme outliers.[9]

Overall, researchers attributed these observed trends to changes in the commercial prices set by hospitals.[10] Although researchers did not specifically identify the reasons for why the ratios increased in some areas while decreasing in others, they did assert that some of their results aligned with anecdotal changes in various markets. For example, the Seattle-Tacoma area saw a number of health system mergers over the past several years.[11] Alternatively, the low price ratios in Massachusetts, with "only modest" growth, may be attributed to the 2012 establishment of the Health Policy Commission "to monitor and reduce health care spending, with the objective of limiting growth to the state gross domestic product."[12]

Nevertheless, the study's authors believe that the price ratio variation across HRRs may indicate an opportunity to constrain growth: "Had the HRR-level percentage-point increases in commercial-to-Medicare price ratios been capped at the increase observed at the national level (7 percentage points), then the average ratio would have been 164 percent in 2019—that is, 9 percent less than the level observed (180 percent).."[13] In other words, "restraining the growth rate of HRR commercial hospital price ratios to the national average during [the] sample period would have reduced aggregate spending by $39 billion in 2019."[14]

The study's authors identified a number of possible options to tackle high prices, and price growth, among hospitals, including: directly regulating prices similar to Rhode Island, which put a cap on commercial price inflation based on Medicare growth rates plus 1%; capping price levels rather than price growth; and, enhancing competition through increased antitrust scrutiny and/or price transparency.[15]

The U.S. spent $1.2 trillion on hospital care in 2019, accounting for 32% of all healthcare expenditures and over 5% of the U.S. gross domestic product.[16] Consequently, any changes made to hospital prices could have a significant impact on overall spending. Numerous efforts toward that end are in the works, including the recently-finalized price transparency rule for hospitals[17] and recent comments by the Federal Trade Commission and Department of Justice indicating forthcoming changes to horizontal and vertical merger guidelines.[18] Whether these initiatives can stem the tide of ever-increasing hospital prices remains to be seen.

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3 *Ibid.*
4 *Ibid.*
5 *Ibid.*
6 *Ibid.*
7 "Hospital prices for health plans vary widely across the U.S., study finds" By Mari Devereaux, Modern Healthcare, April 4, 2022, https://www.modernhealthcare.com/payment/hospital-prices-health-plans-vary-widely-across-us-study-finds (Accessed 4/20/22).
8 Levinson, et al., Health Affairs, April 2022.
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11 Devereaux, Modern Healthcare, April 4, 2022.
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14 *Ibid.*
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16 *Ibid.*
17 "2022 OPPS Final Rule Overview: CMS Finalizes Policies on 340B, Hospital Price Transparency, and Inpatient-Only List" National Law Review, November 8, 2021, https://www.natlawreview.com/article/2022-opps-final-rule-overview-cms-finalizes-policies-340b-hospital-price (Accessed 11/8/21).
18 "FTC, DOJ ask for public input in antitrust 'overhaul'" By Alex Kacik, Modern Healthcare, January 18, 2022, https://www.modernhealthcare.com/mergers-acquisitions/ftc-doj-ask-public-input-antitrust-overhaul (Accessed 3/31/22).

CMS Finalizes 2022 Physician Fee Schedule

[Excerpted from the article published in November 2021.]

On November 2, 2021, the Centers for Medicare & Medicaid Services (CMS) released the final rule for the calendar year (CY) 2022 Medicare Physician Fee Schedule (MPFS). The final rule generally remained unchanged from the proposed version. This *Health Capital Topics* article will briefly review CMS's 2022 MPFS final rule, which will go into effect on January 1, 2022, as well as its potential impacts.

Payment Rate Update

CMS finalized the 2022 MPFS conversion factor at $33.59, $0.01 higher than what was proposed, but a $1.30 decrease from the 2021 MPFS conversion factor (a 3.73% reduction).[1] The upcoming year rate reductions are largely due to the end of the temporary 3.75% payment increase for 2021, which was the result of pandemic-related legislation passed by Congress in December 2020.[2] While the final conversion factor decrease is not as drastic as the over-10% cut between 2020 and 2021, other budget enforcement tools could result in payment decreases of up to 9.75%, barring congressional intervention.[3] Due to the increase in the federal deficit following passage of the American Rescue Plan Act of 2021, the Pay-As-You-Go Act (PAYGO) was triggered. This law requires that "all new legislation changing taxes, fees, or mandatory expenditures, taken together…not increase projected deficits" and "is enforced by the threat of automatic across-the-board cuts in selected mandatory programs [including most Medicare payments] in the event that legislation taken as a whole does not meet the PAYGO standard."[4] Consequently, Medicare payments would be cut by 4% (the maximum amount allowed by law) for the next several years, barring congressional intervention.[5] However, it is worth noting that the PAYGO sequester has never gone into effect.[6] Therefore, it is likely that Congress will take action to avoid this 4% cut before it goes into effect in mid-January 2022.[7] An additional 2% Medicare payment cut is also set to begin again with the expiration of the moratorium on sequestration at the end of 2021.[8] Legislation in 2020 and 2021 suspended the sequestration between May 1, 2020 and December 31, 2021, [9] but there does not appear to be any active legislation in development to delay the return of this payment cut.

As set forth in the table below, the change in the conversion rate (as well as changes to the relative value unit weightings) resulted in relatively small payment changes to various specialties for 2022.

Table: 2022 MPFS Estimated Impact on Total Allowed Charges by Specialty (Proposed and Final Rule)[10]

Physician Specialty	Percent Change from CY 2021 (Proposed Rule)	Percent Change from CY 2021 (Final Rule)
Interventional Radiology	-5%	-5%
Oral Surgery	-4%	**-1%**
Portable X-Ray Supplier	+10%	**+2%**
Radiation Oncology	-5%	**-1%**
Vascular Surgery	-4%	**-5%**

Telehealth Changes

Similar to the proposed rule, the final rule included regulatory restrictions (or relaxations to those restrictions) related to some telehealth services. Most notably, the final rule significantly expands access to behavioral healthcare, particularly for underserved communities.[11] The rule eliminates geographic barriers for patients utilizing telehealth for behavioral healthcare, allowing them to access services at home for the diagnosis, evaluation, and treatment of mental health disorders.[12] Further, for the first time outside of the COVID-19 public health emergency (PHE), Medicare will begin paying for mental health visits furnished by rural health clinics (RHCs) and federally qualified health centers (FQHC) through telehealth, including audio-only telephone calls.[13] The final rule also includes an extension for those services that were temporarily added to the telehealth list during the COVID-19 PHE to CY 2023.[14] This will provide CMS additional time to gather sufficient data for those services, with the intent that they may be added on a permanent basis.[15]

Quality Payment Program Updates

The Quality Payment Program (QPP) is an incentive program that includes two participation tracks: the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs).[16] MIPS determines Medicare payment adjustments to clinicians based on their performance in a number of categories, which results in a payment bonus, penalty, or no adjustment. CMS finalized the proposed rule changes to performance category weighting as follows:

(1) 30% for the Cost category (previously 20%);
(2) 30% for the Quality category (previously 40%);
(3) 15% for the Improvement Activities category (same as prior year); and,
(4) 25% for the Promoting Interoperability category (same as prior year).[17]

The total MIPS score (i.e., the performance threshold) is determined from these weighted categories, and any score above or below the threshold results in positive or negative payment adjustments, respectively. For the 2022 performance year/2024 payment year, CMS finalized increasing the threshold to 75 points from the previous 60 points, consequently making it more difficult for clinicians to receive a positive payment adjustment.[18]

In the CY 2021 final rule, CMS introduced a replacement to the current MIPS framework – the new MIPS Value Pathways (MVPs) – with the intent of moving away from siloed reporting measures to focusing on activities that are meaningful to a clinician's practice.[19] The final rule confirmed that CMS will be moving forward with implementing seven optional MVPs in 2023, as was previously proposed.[20] The first seven optional MVPs will be in the areas of: rheumatology; stroke care and prevention; heart disease; chronic disease management; lower extremity joint repair; emergency medicine; and, anesthesia.[21] Additionally, the final rule expanded the eligible clinician definition for those participating in MIPS to include both clinical social workers and certified nurse-midwives.[22]

Other Changes

CMS is making the first changes to clinical labor pricing in almost twenty years, updating the clinical labor rates used to calculate expenses under the MPFS. These rate updates are expected to increase payments for family practice, internal medicine, and geriatric specialties.[23] The pricing update will take place over a four-year transition period.[24] CMS finalized authorization for Medicare to make direct payments to physician assistants (PAs), rather than through the PA's employer or independent contractor, for professional services delivered under Medicare Part B starting January 1, 2022,[25] which will allow Medicare patients better access to PA services specifically and healthcare services generally.

Second, CMS finalized changes to its Medicare Shared Savings Program (MSSP) to give accountable care organization (ACO) participants more time to prepare for reporting electronic clinical quality measures (eCQMs). Originally set to begin in 2022, CMS proposed a transition period of two years, but added a third year in the final rule, giving ACOs until 2024, in response to concerns expressed by ACOs.[26] Further, CMS finalized an additional year delay to the commencement of the phase-in of the increase to the MSSP ACO quality performance standard, which ACOs must meet in order to share in savings and avoid maximum losses; this heightened standard will not begin until 2024.[27]

Third, CMS finalized steps to improve its Medicare Diabetes Prevention Program (MDPP) expanded model. CMS is now waiving the enrollment fees for all organizations that enroll as an MDPP supplier on or after January 1, 2022.[28] MDPP services will also be shortened from a two-year period to just one.[29] CMS expects that these changes will usher in more suppliers, increase access to MDPP services for rural patients, and ultimately decrease the overall number of individuals with diabetes in both rural and urban areas.[30]

Fourth, following CMS's request for information regarding the update to payment rates for the administration of preventative vaccines in the proposed rule, CMS finalized updated payment rates for these services. Beginning January 1, 2022, CMS will pay $30 per dose for the administration of influenza, pneumococcal, and hepatitis B vaccines (nearly double the former $17 per dose).[31] The COVID-19 vaccine payment rate will remain at the current $40 per dose until the end of the calendar year in which the COVID-19 PHE ends.[32]

Stakeholder Reactions

Stakeholders generally oppose the conversion factor changes in the 2022 MPFS final rule. Coupled with the looming 4% cut to PAYGO and the 2% cut from the ending moratorium on sequestration, physician payments may see a total decrease of 9.75%.[33] The American Medical Association (AMA) made a statement expressing their disapproval, stating:

"The final rule includes a reduction in the 2022 Medicare conversion factor of about 3.85 percent. The AMA is strongly advocating for Congress to avert this and other looming cuts to Medicare physician payments that, overall, will produce a combined 9.75 percent cut for 2022. This comes at a time when physician practices are still recovering from the personal and financial impacts of the COVID public health emergency. Congress is beginning to recognize that this financial instability could limit health care access for Medicare patients. The clock is ticking."[34]

American Medical Group Association (AMGA) President and CEO Jerry Penso echoed the AMA, stating, "The decrease in the Medicare conversion factor, along with the looming sequester and PAYGO cuts, will undermine the ability of AMGA members to care for their patients."[35]

The National Association of ACOs (NAACOS) commended CMS for the extended delay on eCQM reporting for MSSP ACOs.[36] Additionally, the American Academy of Family Physicians (AAFP) praised CMS for modernizing clinical labor pricing, increasing payment rates for vaccine administration, and expanding telehealth services.[37] The AAFP stated its further interest in working with CMS toward ongoing coverage of primary care telehealth services after the end of the PHE.[38]

Conclusion

While not all of the final payment changes in the CY 2022 MPFS were well received by stakeholders, many praised rule changes made to vaccine administration payment updates and further expansion of telehealth services, allowing for greater patient access. Payment concerns were generally focused on the looming physician cuts, with many calling for congressional intervention to prevent limiting patient access to services. However, some of those payment cuts, such as those related to PAYGO and the end of sequestration, are out of the hands of CMS, and require congressional action. Whether Congress will act, however, remains to be seen.

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CMS Finalizes 2022 OPPS/ASC Final Rule

[Excerpted from the article published in November 2021.]

On November 2, 2021, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2022 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system final rule, in which the agency finalized several of the policies it proposed in July 2021.[1] In summary, the final rule updated payment rates and addressed issues such as health equity and patient-centered care, increasing price transparency, patient safety, and access to quality care generally.[2] This *Health Capital Topics* article will briefly review those major updates and changes to, as well as the possible impacts of, CMS's 2022 final rule, which will go into effect on January 1, 2022.

Payment Rate Updates for Hospital Outpatient Departments (HOPDs)

Each year, CMS updates the payment rates that affect the way physicians are paid by Medicare. In the proposed rule, CMS suggested a 2.3% increase in OPPS payment rates to hospital outpatient departments (HOPDs) that meet specific quality reporting criteria.[3] The final rule backed off that amount, increasing the payment rates by only 2.0%, comprised of a 2.7% market basket increase *minus* a productivity adjusment of 0.7%.[4] The 2021 conversion factor of $82.797 will be increased to $84.177 for CY 2022.[5] Further, because of the COVID-19 pandemic (and related quality integrity concerns related to the claims during that year), CMS will continue using CY 2019 data to set the CY 2022 OPPS and ASC payment system rates, rather than CY 2020 data.[6] CMS estimates that this will extrapolate to nearly $82.08 billion in total payments to HOPDs in 2022, an increase of approximately $1.3 billion from 2021 Medicare payments.[7]

Payment Rate Updates for Ambulatory Surgical Centers (ASCs)

Similar to the OPPS, CMS also updates the payment rates for ASCs on a yearly basis. In the proposed rule, CMS suggested a 2.3% increase in payment rates to those ASCs that meet specific quality reporting criteria.[8] The final rule backed off that amount, increasing the payment rates at the same rate as for HOPDs – an update of 2.0%, comprised of a 2.7% market basket increase *minus* a productivity adjustment of 0.7%.[9] CMS estimates that this will extrapolate to approximately $5.41 billion in total payments to ASCs in 2022, an approximately $40 million increase from 2021 Medicare payments.[10]

Price Transparency of Hospital Standard Changes

On January 1, 2021, the Hospital Price Transparency final rule went into effect, wherein all U.S. hospitals are required to provide online pricing information in a clear, accessible manner.[11] Under the OPPS/ASC final rule, CMS substantially increased financial penalties for noncompliance under the hospital price transparency rules.[12] The final rule maintained a minimum civil monetary penalty (CMP) of $300 per day for hospitals with 30 or fewer beds,[13] but increased the amount for larger hospitals. Starting January 1, 2022, a penalty of $10 per bed per day would apply to hospitals with more than 30 beds, not to

exceed a maximum daily dollar amount of $5,500.[14] Under this approach, for a full calendar year of noncompliance, the minimum total penalty amount would be $109,500 per hospital, and the maximum total penalty amount would be $2,007,500 per hospital that fails to provide the charge information.[15]

340B Drug Pricing Program Reimbursement

The federal 340B Drug Pricing Program is a drug price control program that allows qualifying providers, generally hospitals, specialty clinics, and their associated outpatient facilities serving uninsured and low-income patients in rural communities, to purchase outpatient drugs from manufacturers at discounted prices.[16] The CY 2021 rule reduced Part B reimbursement for separately payable, non-pass-through Part B drugs purchased through the 340B Program from average sales price (ASP) *plus* 6% to ASP *minus* 22.5%.[17] CMS's reasons for the reimbursement cut included increases in patient copayment amounts, the number of 340B covered entities, and Part B drug prices.[18] The final rule maintained this reduced payment rate for 2022, and continued its exemption of rural community hospitals, prospective payment-exempt cancer hospitals, and children's hospitals from the reduced payment policy.[19]

Inpatient Only (IPO) List

The IPO list, established as part of the initial implementation of the OPPS, contains approximately 1,740 services for which Medicare will make payment only when they are furnished in the inpatient hospital setting.[20] In the 2021 OPPS/ASC final rule, CMS eliminated the IPO list over a three-year transitional period.[21] In response to stakeholder concerns, the 2022 final rule reversed course and halted this elimination, reinstating most of the services removed in CY 2021, except for CPT codes 22630 (lumbar spinal fusion), 23472 (reconstruct shoulder joint), and 27702 (reconstruct ankle joint), as well as their corresponding anesthesia codes.[22] The final rule also codifies longstanding criteria for removal of procedures from the IPO list to clarify how future procedures will be evaluated for removal.[23]

Conclusion

Overall, CMS furthered its overarching goal of moving care from high-cost inpatient treatment to ASCs and other outpatient facilities.[24] While providers will generally receive slightly higher reimbursement in 2022 due to the payment rate updates, some of them will continue to receive reduced 340B drug discount payments and others will face stricter penalties if they do not comply with hospital price transparency rules. Further, those providers who invested in their outpatient facilities over the past year in anticipation of performing a plethora of new surgeries as a result of the IPO list elimination will not be able to recognize those investments with the CMS reversing its position on the IPO list. Therefore, whether or not these updates and changes will be financially positive for outpatient providers in the aggregate remains to be seen.

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IPPS and LTCH PPS Proposed for 2023

[Excerpted from the article published in May 2022.]

On April 18, 2022, the Centers for Medicare & Medicaid Services (CMS) released its proposed rules for payment and policy updates to the *Medicare Inpatient Prospective Payment System* (IPPS) and the *Long-Term Care Hospital* (LTCH) *Prospective Payment System* (PPS) for fiscal year (FY) 2023.[1] This Health Capital Topics article discusses the various provisions outlined in CMS's proposed rule.

IPPS Payment Rate Updates

For 2023, CMS proposes an estimated 3.2% total increase in IPPS payments for general acute care hospitals that participate in the *Hospital Inpatient Quality Reporting* (IQR) *Program* and are meaningful users of electronic health records (EHRs).[2] This payment increase is higher than the FY 2022 increase of 2.5%[3] and translates to a growth in Medicare spending on inpatient hospital services of approximately $1.6 billion in 2023, before adjusting for Medicare *disproportionate share hospital* (DSH) payments and uncompensated Medicare payments.[4] CMS predicts that Medicare DSH and uncompensated care payments will decrease by approximately $300 million, resulting in an overall hospital payment increase of $1.1 billion.[5]

Other changes to the IPPS for 2023, as a result of the COVID-19 pandemic, include:

(1) A return to using the most recent data for price-setting (FY 2021 for claims and FY 2020 for cost reports), with modifications to account for the COVID-19 pandemic;

(2) Discounting value-based purchasing measures in the Hospital-Acquired Condition Reduction Program;

(3) Establishing new policies to better address any future epidemics or pandemics by requiring the continued reporting of COVID-19, seasonal flu, and other illnesses by hospitals; and

(4) Putting the Hospital Readmissions Reduction Program, adapted in 2020, on hold until 2024.[6]

LTCH PPS Payment Rate Updates

For 2023, CMS proposes increasing overall LTCH PPS payments by approximately $25 million, only half of FY 2022's increase of $52 million.[7] Further, for FY 2023, LTCH discharges paid the standard payment rate are expected to increase by 1.2%, while LTCH discharges paid the site neutral payment are expected to increase by 3%.[8] LTCH discharges can be paid in one of two ways:

(1) A standard rate – In order to be paid this rate upon discharge, the patient must have been directly admitted to the LTCH from an IPPS hospital after: (a) spending at least three days in an intensive or

coronary care unit or (b) having been admitted to the LTCH after having been on a ventilator for at least 96 hours, and must not have been assigned to psychiatric or rehabilitation services upon discharge; or,

(2) A site neutral rate – For all other discharges that do not meet the above criteria.[9]

New Technology Add-On Payments (NTAP)

NTAP is additional reimbursement that provides "add-on" payments (up to 65%) to hospitals for the use of technology that may not be included in the *diagnosis-related group* (DRG) bundled payment due to the novelty of that technology. For FY 2021, CMS proposed 24 applications for the NTAP program and approved 13 technologies in the final rule.[10] For FY 2022, CMS proposed extending NTAP for 14 technologies that would otherwise be discontinued.[1112] For FY 2023, CMS proposes extending add-on payments for 15 technologies.[13] Further, CMS approved 13 alternative pathway applications (out of the 19 received) for NTAP in FY 2023.[14]

Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program is a quality reporting program that may reduce payments to hospitals that fail to meet quality reporting requirements.[15] CMS is looking to adopt 10 new measures for adoption, which are in line with the Biden Administration's commitment to health equity and include:

(1) Proposed hospital commitment to health equity measure beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years;

(2) Proposed adoption of two social drivers of health measures beginning with voluntary reporting in CY 2023 and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years;

(3) Screen positive rate for social drivers of health measure, beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination;

(4) Proposed cesarean birth electronic clinic quality measure (eCQM), beginning with voluntary reporting in the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years;

(5) Proposed severe obstetric complications eCQM beginning with the CY 2023 voluntary reporting period/FY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years;

(6) Proposed hospital-harm—opioid-related adverse events eCQM beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years;

(7) Proposed global malnutrition composite score eCQM beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years;

(8) Proposed hospital-level, risk standardized patient-reported outcomes following elective *primary total hip arthroplasty* (THA) and/or *total knee arthroplasty* (TKA), beginning with two voluntary reporting periods in CYs 2025 and 2026, followed by mandatory reporting for eligible elective procedures occurring July 1, 2025 through June 30, 2026, impacting the FY 2028 payment determination and for subsequent years;

(9) Proposed Medicare spending per beneficiary (MSPB) hospital measure beginning with the FY 2024 payment determination; and

(10) Proposed hospital-level risk-standardized complication rate (RSCR) following elective primary THA and/or TKA measure beginning with the FY 2024 payment determination.[16]

Conclusion

The American Hospital Association (AHA) immediately expressed concern regarding CMS's proposed payment update of only 3.2%.[17] The trade organization also highlighted the fact that hospitals will see a net decrease in payments from CMS through 2023 as a result of cuts to other payment structures, primarily DSHs.[18] AHA did, however, acknowledge CMS's recognition of COVID-19-related challenges still facing hospitals, especially pertaining to quality and value.[19] Formal comments from industry stakeholders on the IPPS and LTCH PPS Proposed Rule are due to CMS by June 17, 2022.[20] Once approved, the IPPS FY 23 update will go into effect on October 1, 2022.

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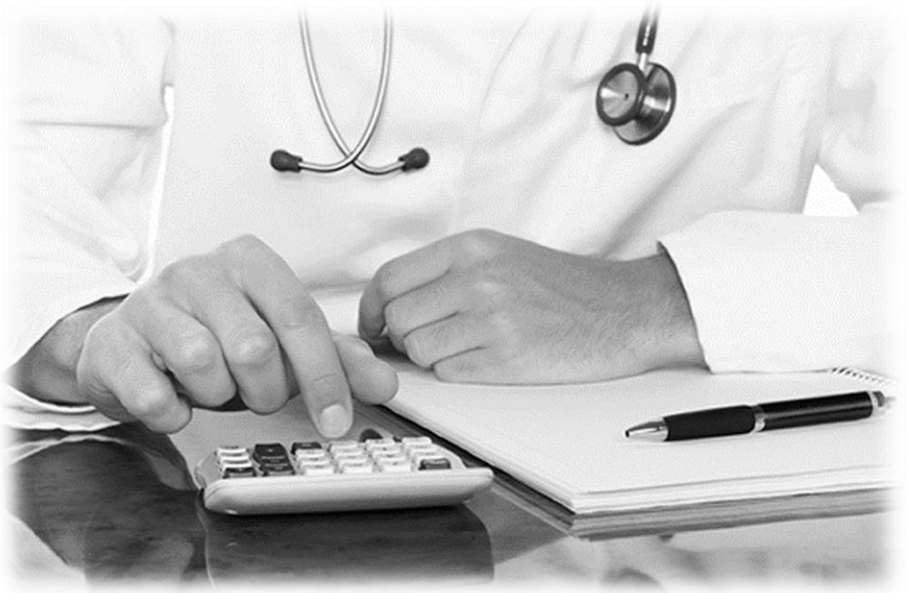

Home Health Payment Cuts Proposed for 2023

[Excerpted from the article published in June 2022.]

On June 17, 2022, the Centers for Medicare & Medicaid Services (CMS) published its proposed Home Health Prospective Payment System (HH PPS) for calendar year (CY) 2023. If CMS's proposed rule is finalized as is, home health agencies (HHAs) will experience an $810 million pay cut from Medicare next year. This Health Capital Topics article will review the proposed rule and discuss industry response.

Much of the decrease in home health payments proposed for 2023 is due to pay adjustments "to account for increased expenditures CMS contends resulted from a recently implemented payment system," i.e., the Payment-Driven Groupings Model (PDGM).[1] The PDGM was implemented in 2020 as required by the Bipartisan Budget Act of 2018 (BBA), with the goal of better aligning payments with patient care needs, particularly for more clinically-complex beneficiaries that require more skilled nursing services than therapy services.[2] Toward that end, CMS eliminated the incentive to overserve patients by paying HHAs "based on patient characteristics instead of the number of therapy hours provided."[3] To prevent over-utilization of services, CMS reduced the payment period from 60 days to 30 and required HHAs re-certify that a patient needs additional care after each period.[4] The PDGM also increased the number of case mix groupings from 153 to 432 and introduced low- and high-use thresholds for each.[5] A patient is considered low-use if they use 2-6 visits during a 30-day period, with the actual visit number varying by case mix grouping.[6] HHAs are reimbursed on a per-visit basis for low-use patients, but HHAs that provide more than the case-adjusted number of visits during a 30-day period will be reimbursed for a full 30-day period.[7] High-use patients typically utilize more than the average number of visits per period, thus costing the HHA more money. Under these new provisions, CMS will reimburse HHAs up to 80% of the difference on any high-use utilization.[8]

The PDGM is budget neutral, meaning it may not cause higher Medicare spending. Consequently, CMS reduced HHA payments starting in 2020 in anticipation of the reduced utilization as a result of PDGM implementation. The BBA requires CMS, for the first 7 years of the PDGM, to "make assumptions about behavior changes that could occur because of the implementation of the 30-day unit of payment and the" PDGM and annually assess the impact of the differences between (1) the behavioral changes that CMS assumed and (2) the actual behavioral changes, on estimated aggregate expenditures; CMS must then make any indicated temporary/permanent increases or decreases to the 30-day payment amount.[9] Toward that end, CMS proposes a way to determine the impact of those differences between the assumed and actual behavior changes, by calculating what Medicare would have spent had PDGM not been implemented in 2020 and 2021 and comparing that to what was actually spent during the same timeframe.[10] As a result, CMS proposed a -7.69% payment adjustment for 2023, "to ensure that aggregate expenditures under the new

payment system model would be equal to what they would have been under the old payment system."[11] In addition to these retrospective, temporary payment adjustments, CMS proposed to apply a prospective, permanent payment adjustment, for the same reason.[12]

Therefore, the aforementioned proposed payment decrease of $810 million for 2023 is the combination of a proposed 2.9% home health payment update, the -7.69% budget neutrality adjustment, and an estimated 0.2% decrease "that reflects the effects of a proposed update to the fixed-dollar loss ratio (FDL) used in determining outlier payments," as well as some other minor adjustments.[13]

Additional measures proposed by CMS include:

(1) Reweighting each of the PDGM payment group's case mix weights (including the low utilization thresholds), utilizing 2021 data.

(2) Implementing a permanent 5% cap on any negative changes to the hospital wage index (on which the geographic factors of the base rate are adjusted), regardless of the reason for the decline. The agency contends that smoothing out year-to-year changes will help increase the predictability of home health payments.

(3) Updating the home infusion therapy services payment rates for 2023. However, the amount of that update was not disclosed by CMS, because the law requires those rates to be updated by the June 2022 Consumer Price Index for all urban customers (CPI-U), which was not available at the time the proposed rule was released.[14]

CMS is also seeking comment on how it may collect data from HHAs related to the use of telecommunications technology for the purpose of analyzing the characteristics of Medicare beneficiaries utilizing the remote services. This may serve to give CMS, and HHAs, a better understanding "of the social determinants that affect who benefits most from those services, including what barriers may potentially exist for certain subsets of beneficiaries."[15]

Home health industry representatives have expressed their significant dismay with the proposed rule. The National Association for Home Care & Hospice (NAHC) is "very disappointed in the CMS proposed rule…The stability of home health care is at risk as a consequence of CMS proposing the application [of] a fatally flawed methodology for assessing whether the PDGM payment model led to budget neutral spending in 2020…With significantly rising costs for staff, transportation, and more, home health agencies across the country cannot withstand the impact of the proposed rate cut."[16] The Partnership for Quality Home Healthcare also expressed displeasure: "Considering that access to home-based care has become increasingly important to the health and safety of American seniors, it is very troubling that CMS would propose such steep rate cuts for next year and potentially even deeper cuts in the future. If implemented as proposed, this payment adjustment will jeopardize the stability of this vital sector and risk seniors' access to Medicare home health services."[17]

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CMS Issues 2023 Physician Fee Schedule Proposed Rule

[Excerpted from the article published in July 2022.]

On July 7, 2022, the Centers for Medicare & Medicaid Services (CMS) released its proposed Medicare Physician Fee Schedule (MPFS) for calendar year (CY) 2023. Arguably the most noteworthy provision in the proposed rule is the agency's suggested cut to physician payments. However, the rule also includes a number of other policy proposals, including changes to Medicare accountable care organizations (ACOs), behavioral health care, cancer screening, and dental care. According to CMS, "[i]f finalized, the proposals in this rule will advance equity, lead to better care, support healthier populations, and drive smarter spending of the Medicare dollar."[1]

Payment Rate Updates for MPFS

For 2023, CMS proposes to decrease the conversion factor by $1.53, to $33.08 (a 4.4% reduction from the 2022 conversion factor of $34.61).[2] Conversion factors are applied to relative value units (RVUs), i.e., the resources required to furnish a service, to become payment rates. Payment rate decreases for CY 2023 emanate from the 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]

The proposed conversion factor decrease for 2023 results from a March 2022 Medicare Payment Assessment Commission (MedPAC) report, which stated that Medicare payments to physicians do not need to be increased for 2022. This assertion is, expectedly, hotly contested by provider groups, as discussed further below.

Proposed Updates to Accountable Care Organizations

In an effort to combat stagnant growth in the program over the past few years, CMS included in the proposed rule several suggested changes to the Medicare Shared Savings Program (MSSP) that, if finalized, will "represent some of the most significant reforms since the final rule that established the program was finalized in November 2011 and ACOs began participating in 2012."[4]

In order to provide smaller providers with no previous ACO experience more time to acclimate to two-sided risk, CMS proposes extending the amount of time during which these providers may participate in one-sided (no risk) shared savings models. If finalized, these ACOs would be able to spend up to seven years in a one-sided model.[5]

In furtherance of its focus on health equity,[6] CMS proposes incorporating advance shared savings payments (a $250,000 one-time payment and quarterly payments for two years thereafter based on "enrollee neediness") to low-revenue ACOs, which can be used to address social needs of Medicare beneficiaries.[7] For example, the funds could be used to improve provider infrastructure, increase staffing, or care for underserved enrollees.[8] These funds would then be repaid to CMS through the ACO's shared savings (if it earns

any). If finalized, this will be one of the first times traditional Medicare payments would be permitted for such uses.[9]

Additionally, CMS seeks to fix "glitches" in the MSSP's benchmarks that make it progressively harder to top the previous year's metrics. Toward that end, the agency proposes adding a prospective (rather than an historical) external factor, and including a prior savings adjustment in historical benchmarks. CMS also proposes reducing the cap on negative regional adjustments, from 5% to 1.5% of national per capita expenditures, for Parts A and B services.[10]

In total, these proposed changes could 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).[11]

Other Proposals

First, CMS recommends the removal of various barriers to behavioral healthcare, such as by allowing certain types of behavioral health practitioners to provide services under general, rather than direct, supervision. CMS also proposes bundling "certain chronic pain management and treatment services into new monthly payments" to facilitate team-based care and covering opioid treatment and recovery services that are provided from mobile units.[12]

Second, CMS introduced a number of ideas for improving access to screening for colon cancer, the second leading cause of cancer deaths in 2020.[13] CMS is proposing that colonoscopies performed as a follow up to an at-home test be classified as a preventative service, which allows cost sharing to be waived for Medicare beneficiaries. Additionally, CMS is seeking to cover colonoscopies for individuals age 45+.[14]

Third, CMS plans to extend coverage for some dental services, including dental exams and treatment prior to an organ transplant. The agency is also seeking comment regarding other medical conditions for which Medicare should pay for dental services.[15] Currently, Part B only pays for dental services that are "integral to medically necessary services required to treat a beneficiary's primary medical condition."[16]

Comments from Stakeholders

Many stakeholders have sharply criticized CMS for the over-4% reduction in the proposed conversion factor. The president of the American Medical Association (AMA) stated that:

"It is immediately apparent that the rule not only fails to account for inflation in practice costs and COVID-related challenges to practice sustainability, but also includes a significant and damaging across-the-board reduction in payment rates. Such a move would create long-term financial instability in the Medicare physician payment system and threaten patient access to Medicare-participating physicians."[17]

The Surgical Care Coalition, led by the American College of Surgeons (ACS), claimed that CMS "once again jeopardizes seniors' access to critical treatments and procedures."[18] The organization urged Congress "to immediately stop these

cuts to protect patients and work toward finding a long-term solution that promotes quality care and investment."[19]

Similarly, the Medical Group Management Association (MGMA) is concerned about the likely impact of the proposed reduction to the conversion factor, especially in light of the financial uncertainty which medical groups have faced over the past two years stemming from the COVID-19 pandemic, inflation, and the staffing crisis."[20] MGMA also made the important point that these cuts could be compounded by the Pay-As-You-Go Act (PAYGO) sequestration scheduled to take effect on January 1, 2023. This law requires that "all new legislation changing taxes, fees, or mandatory expenditures, taken together…not increase projected deficits" and "is enforced by the threat of automatic across-the-board cuts in selected mandatory programs [including most Medicare payments] in the event that legislation taken as a whole does not meet the PAYGO standard."[21] Consequently, Medicare payments could be cut by an additional 4% (the maximum amount allowed by law) for the next several years, barring congressional intervention; it is worth noting, however, that the PAYGO sequester has never gone into effect.[22] Therefore, it is likely that Congress will take action to avoid this cut before it goes into effect in January.

In contrast, the National Association of Accountable Care Organizations (NAACOs) commended CMS for "taking steps to reach its goal of creating a stronger Medicare by strengthening accountable care models and speed the movement toward value for all patients."[23]

Conclusion

While proposed payment changes in the CY 2023 MPFS were not well-accepted by stakeholders given the current healthcare environment, many applauded CMS for the other proposed changes. CMS is open to comments and information on requested topics until September 6, 2022; the final rule will be released sometime thereafter.[24]

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2023 OPPS Proposed Rule Released

[Excerpted from the article published in July 2022.]

On July 15, 2022, the Centers for Medicare & Medicaid Services (CMS) released the proposed rule for the Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Centers (ASCs) for calendar year (CY) 2023. The agency proposes an increase in payments to outpatient providers and offers insight on the new rural emergency hospital program, as well as to how it might respond to the recent U.S. Supreme Court decision on the 340B Program.

Payment Rate Updates

For CY 2023, CMS proposes to increase OPPS payment rates to hospital outpatient departments (HOPDs) that meet specific quality reporting criteria by 2.7% – calculated from the proposed hospital inpatient market basket percentage increase of 3.1% *minus* the proposed productivity adjustment of 0.4%.[1] This results in a proposed OPPS conversion factor of $86.785.[2] However, CMS proposes to continue the 2% statutory reduction for hospitals that fail to meet certain quality reporting requirements by utilizing a reduced conversion factor of $85.093.[3] CMS estimates that it will provide approximately $86.2 billion in total payments to OPPS providers in 2023, a $6.2 billion increase from 2022.[4]

ASCs that meet the required quality criteria will also receive proposed payment rate increases of 2.7%, by way of the same calculation described above for OPPS payment rates.[5] Consequently, the proposed ASC conversion factor for 2023 is $50.315.[6] CMS estimates that it will provide approximately $5.4 billion in total payments to 5,500 ASCs in 2023, a $130 million increase from 2022 Medicare payments.[7]

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).[8] On June 30, 2022, CMS released the proposed Conditions for Participation for these new provider types.[9] The OPPS proposed rule also expounds upon this new program. 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 and receive an additional 5% on top of the OPPS payment rate for each service, as well as a monthly facility payment.[10] CMS also proposes "(1) a new exception for ownership or investment interests in an REH; and (2) revisions to certain existing exceptions to make them applicable to compensation arrangements to which an REH is a party."[11] REHs will be required "to accept Medicare, have average lengths of stay of 24 hours or shorter, eliminate acute care inpatient services, have transfer

agreements with Level I or Level II trauma centers and meet federal employee training and certification requirements."[12]

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.[13] 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.[14] 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%.[15] In the 2018 OPPS, however, CMS instead finalized a reduction to this reimbursement rate, specific to 340B participants only, of ASP *minus* 22.5%.[16]

Hospitals and hospital associations subsequently sued CMS to challenge the cuts and asserted 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).[17] 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.[18] While the Supreme Court decision was released too late for CMS to change the 340B reimbursement rate in the proposed rule, the agency did state that they "fully anticipate applying a rate of ASP plus 6% to such drugs and biologicals in the final rule for CY 2023...[and] are still evaluating how to apply the Supreme Court's recent decision to prior calendar years."[19]

Other Proposals

Other proposals included in the rule include:

(1) Removing 10 maxillofacial procedures from the inpatient-only (IPO) list[20] for 2023;

(2) Adding one procedure – lymph node biopsy or excision – to the ASC covered procedure list;[21]

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

(4) Paying for behavioral telehealth services (including audio-only care) after the end of the public health emergency, provided that the provider has seen the patient within six months prior to the remote services and sees them in person once annually thereafter.[22]

Stakeholder Responses

Stakeholders' reactions to the changes in the 2022 OPPS proposed rule were somewhat mixed. The American Hospital Association (AHA) stated that it was "deeply concerned about CMS' proposed payment update of only 2.7%, given the extraordinary inflationary environment and continued labor and supply cost pressures hospitals and health systems face," arguing that "[a] much higher update is warranted."[23] However, the AHA, as well as America's Essential Hospitals, noted their appreciation that the 340B cuts would end.[24] The Ambulatory Surgery Center Association (ASCA) noted its continuing displeasure at the lack of procedures being added to the IPO List and ASC covered procedures list, asserting that the "proposed rule misses an opportunity to lower costs and improve access to care to beneficiaries by not adding many viable procedures that ASCs are safely performing on commercial patients."[25]

CMS will receive comments and information on requested topics until September 13, 2022, and the final rule will be issued in early November.[26]

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President Biden Signs the Inflation Reduction Act into Law

[Excerpted from the article published in September 2022.]

On August 16, 2022, one week after Congress passed the Inflation Reduction Act of 2022 (IRA), President Joseph Biden signed the bill into law. The broad bill, which covers healthcare, taxes, and climate change, had been passed around Congress in assorted versions with varying support for months, but under the specter of a record 40-year-high inflation rate, congressional Democrats ultimately came together to pass the IRA; no Republicans voted for the bill.[1] The IRA aims, among other things, to fight against ever-increasing healthcare costs, by lowering prescription drug prices and extending federal health insurance subsidies.

Although this omnibus law is anticipated to result in $485 billion in total spending, the law actually stands to lower the U.S. deficit by approximately $300 billion across the next ten years.[2] By levying a tax on certain stock buybacks and imposing a 15% minimum corporate tax on large corporations, the new law will generate hundreds of billions of dollars in tax revenue in the coming decade.[3] Of these totals, $98 billion is expected to be spent on healthcare provisions, while savings of over $320 billion will principally come from reduced Medicare drug prices.[4]

Prescription Drug Costs

Among the bill's numerous healthcare provisions, the IRA allows the federal government to negotiate on behalf of seniors to reduce Medicare prescription drug costs.[5] To determine which drugs for which the government may negotiate prices, the Centers for Medicare & Medicaid Services (CMS) is directed to publish a list of eligible high-cost drugs, which must be single source (i.e., there is no generic or biosimilar version) and must have been on the market for at least seven years.[6] From that list, the U.S. Department of Health & Human Services (HHS) can select a total of 100 drugs (50 Part B drugs and 50 Part D drugs) over a six year period to negotiate for a "maximum fair price."[7] The "maximum fair price" is capped at: "75 percent of the Average Manufacturer Price for those [drugs] on the market for nine to 11 years (25 percent discount offered by the drug maker); or 65 percent for 12 to 15 years (35 percent discount offered by the drug maker); or 40 percent for 16 years or longer (60 percent discount offered by the drug maker)."[8]

In an effort to maintain drug price levels going forward, the IRA discourages pharmaceutical companies from arbitrarily inflating prices on certain drugs.[9] Between 2019 and 2021, 50% of Medicare-covered drugs saw price increases higher than the rate of inflation.[10] 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.[11]

In addition to reducing the prices of certain prescription drugs, the bill will lessen the prescription drug costs directly incurred by patients. In 2020 alone,

Americans paid $388.6 billion in out-of-pocket healthcare costs generally;[7] to combat this, the IRA establishes a maximum cap on beneficiary spending. First, 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.[12] Second, starting in 2025, beneficiaries' out-of-pocket costs under Part D will be capped at $2,000 per year.[13] Third, 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.[14]

Healthcare Coverage Costs

Since 2010, the average American family has seen a 60% increase in their yearly health insurance premium.[15] The Patient Protection and Affordable Care Act (ACA), among other things, created an open marketplace where patients could find affordable and subsidized health insurance (dependent on income level).[16] Under the ACA, if a person's income level is between 150% and 400% of the federal poverty level (FPL), they may receive a premium tax credit to subsidize the cost of insurance premiums.[17] These subsidies were subsequently extended and enhanced by the American Rescue Plan Act (ARPA), so that in 2021 and 2022:

(1) Individuals with incomes below 150% of the FPL (who are not Medicaid eligible) could access zero-premium coverage;

(2) Individuals with incomes between 150% and 400% of the FPL received enhanced subsidies; and

(3) Individuals with incomes above 400% of the FPL could receive premium subsidies if the premium payment would be more than 8.5% of their income.[18]

These expanded and enhanced subsidies were set to expire at the end of 2022. Consequently, the IRA extends these subsidies for an additional three years, through 2025.[19] This ensures that the 13 million Americans who already rely on subsidized monthly premiums through the ACA will continue to save $800 per year on average, and 3 million more Americans (who otherwise would be uninsured due to affordability concerns) are anticipated to obtain insurance coverage.[20]

Stakeholder Reactions

A number of government officials released statements in support of the IRA's healthcare provisions. U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra called the law "one of the most consequential pieces of legislation in our lifetimes that will lower healthcare costs for millions of Americans."[21] CMS Administrator Chiquita Brooks-LaSure believes the bill will "meaningfully lower health care costs for people across the country" and highlighted the fact that the bill fought to enact "a $35 monthly co-pay cap for insulin, a limit on out-of-pocket expenses in Medicare Part D, and reduced costs under Medicare's new ability to negotiate drug prices in the years ahead."[22]

The American Medical Association (AMA) released a statement extolling the bill's benefits to Medicare beneficiaries and ACA tax credit recipients, but also noted that the IRA "does nothing to address Medicare physician payment reform or to halt payment cuts set to take effect next year."[23]

In contrast, the pharmaceutical industry, which spent $187 million on lobbying in the first seven and a half months of 2022 alone, was largely displeased with the IRA's healthcare provisions.[24] Stephen Ubl, CEO of the Pharmaceutical Research and Manufacturers of America (PhRMA), called the bill "partisan" and claimed it would "lead to fewer cures and treatments," while simultaneously not doing "nearly enough to make medicines more affordable for most Americans."[25]

Conclusion

The varied provisions of the IRA is likely to significantly impact some of the largest segments of the U.S. economy and will have far-reaching implications for the healthcare industry. Paid for in large part by increases in tax revenue generated by stricter enforcement and a minimum corporate rate, the IRA allows the federal government to spend more to lower out-of-pocket healthcare costs and expand access to health insurance coverage.

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Physician Compensation Surveys: Is the "New Normal" Here?

[Excerpted from the article published in the The Value Examiner.]

Beginning in late May, numerous industry normative benchmark production and compensation surveys, including those conducted by the Medical Group Medical Association (MGMA), American Medical Group Association (AMGA), SullivanCotter, and Gallagher (f/k/a Integrated Health Strategies), published the most recent year's reports. These surveys annually report specific types of physician compensation and productivity metrics across the country for various specialties and are widely used by valuation professionals in valuing compensation arrangements. While the surveys have shown that, historically, physician compensation has generally increased year-over-year, the COVID-19 pandemic, coupled with changes to the Medicare Physician Fee Schedule (MPFS), resulted in physician compensation aberrations in 2020 and 2021. While these aberrations raised significant concern in the valuation industry, as basing physician compensation valuations on compensation surveys resulted in potential overcompensation for productivity-based compensation arrangements, these concerns may end up being short-lived, according to initial indications from the first of the recently-published 2022 compensation surveys (reporting 2021 data).

The valuation implications of the use of and reliance upon these surveys are significant, because in business valuation, many of the businesses that are appraised require the normalization of business earnings, which involve the normalization of owner compensation. In healthcare, owners are often physicians, so the normalization process includes the determination of the Fair Market Value compensation, or replacement cost, of the physician owners.

The COVID-19 global pandemic wreaked havoc on the U.S. healthcare delivery system, negatively affecting most every healthcare provider. Surgical specialists saw decreases in their work with the cancellation of non-elective procedures, and office-based physicians saw a substantial decrease in office visits.[1] However, this productivity decrease was largely short-term, as physician productivity appears to have rebounded by the end of 2020 and continued into 2021.

To add insult to injury, the Centers for Medicare & Medicaid Services (CMS) then made changes to the MPFS, effective 2021. The MPFS is the payment system by which Medicare reimburses physicians, according to an annually-updated fee schedule. Each procedure in the MPFS is assigned a number of relative value units (RVUs) based on the resources required to perform each procedure. There are three categories of resources: (1) physician work (wRVUs); (2) practice expense; and, (3) malpractice expense. Pertinent to the subject of this article, the wRVU component 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.

The 2021 MPFS final rule increased the wRVUs for common evaluation and management (E/M) office visits. CMS's final rule, and the subsequent *Consolidated Appropriations Act of 2021*, not only reduced the Medicare conversion factor 3.3% (from $36.09 to $34.89), but, maybe more importantly, rebased (increased) wRVU values for the following E/M office visits:

Table 1: Comparison of 2020 & 2021 MPFS wRVU Values

CPT	Description	2020 wRVUs	2021 wRVUs	% Change
99203	Office/Outpatient Visit New	1.42	1.6	12.70%
99204	Office/Outpatient Visit New	2.43	2.6	7.00%
99205	Office/Outpatient Visit New	3.17	3.5	10.40%
99212	Office/Outpatient Visit Est.	0.48	0.7	45.80%
99213	Office/Outpatient Visit Est.	0.97	1.3	34.00%
99214	Office/Outpatient Visit Est.	1.5	1.92	28.00%
99215	Office/Outpatient Visit Est.	2.11	2.8	32.70%

As illustrated above in Table 1, beginning in 2021, physicians performing the same volume of E/M office visits in 2021 as they did in 2020 generated anywhere from 7.0% to 45.8% more wRVUs. This rebasing more significantly affected primary care providers, whose work is largely based on E/M office visits, than surgical specialists, whose work is largely procedure based.

Despite the shift toward value-based reimbursement, the majority of physician compensation models are still productivity-based.[2] Therefore, physicians' decreased productivity due to COVID-19, and the rebased RVU rates had the possibility of resulting in much lower compensation for these providers, had their employers (largely hospitals) not taken measures to ensure these front-line workers were made whole for the provision of medical care during a global pandemic, e.g., by freezing compensation at 2019 levels, continuing to utilize 2020 MPFS RVU weights, and other changes.

Further, the combination of the COVID-19 pandemic's effects on healthcare delivery and the 2021 MFPS resulted in a spike in the compensation-to-wRVU ratios (both in reality and as reported in the 2021 compensation surveys) due to the steady compensation (numerator) and the reduced wRVU productivity (denominator), a departure from historical ratios, which had risen steadily year over year.[3] As an illustration of this issue, see below the three exhibits that report the past seven years of physician compensation (numerator), productivity, measured in wRVUs (denominator), and compensation per productivity unit (quotient) for family medicine, per MGMA:

Exhibit 1: Total Compensation

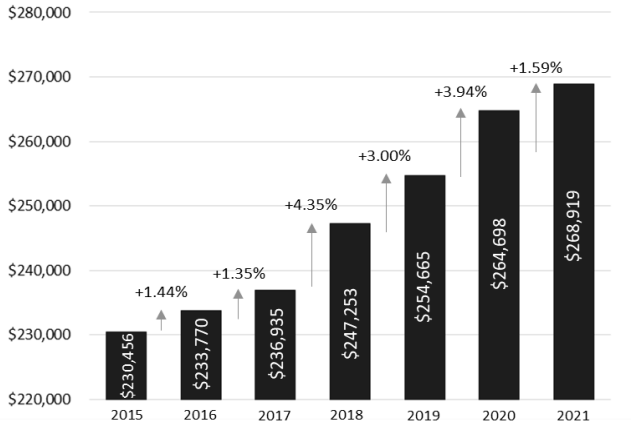


Exhibit 2: wRVU Production

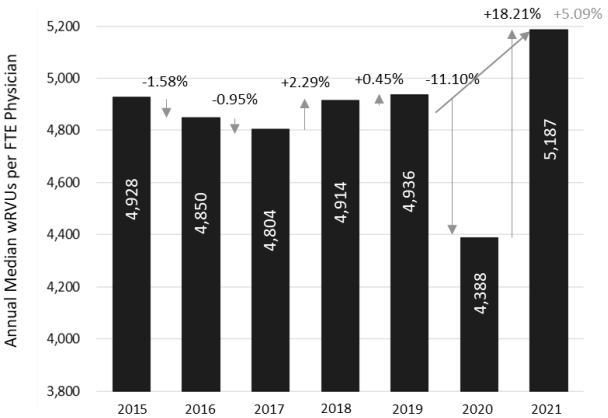
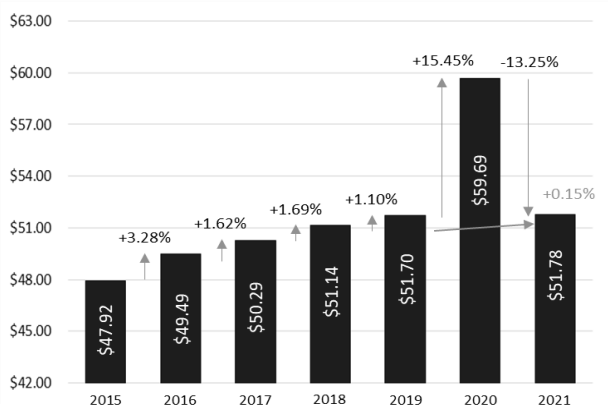


Exhibit 3: Compensation per wRVU Ratio



Looking at the change over the last two years across multiple specialties shows that while there were significant changes across the board between 2019 and 2020, the compensation and change in median wRVUs for most specialties has largely right-sized:[4]

Specialty	2019-2020		2019-2021	
	Change in median total compensation	Change in median wRVUs	Change in median total compensation	Change in median wRVUs
Cardiology: Invasive	2.61%	-5.45%	2.82%	3.57%
Family Medicine (without OB)	3.94%	-11.10%	5.60%	5.09%
Gastroenterology	0.67%	-13.70%	4.66%	1.81%
Hospitalist: Internal Medicine	0.14%	-6.79%	2.55%	0.37%
Internal Medicine: General	2.73%	-10.93%	4.57%	2.44%
Neurology	1.44%	-11.68%	3.48%	-0.85%
Obstetrics/Gynecology: General	0.35%	-7.24%	3.64%	0.69%
Orthopedic surgery: General	1.67%	-11.65%	6.88%	7.31%
Pediatrics: General	6.00%	-11.76%	1.77%	-3.50%
Surgery: General	0.40%	-11.19%	3.15%	-0.53%

Notably, the 2022 MGMA survey instrument required survey participants to report 2021 wRVUs utilizing the new MPFS weights.

In reviewing these compensation surveys and utilizing them in your valuation engagements, it is important to understand what wRVU weighting the physician compensation model utilizes. As 88% of medical practices had not modified their physician contracts to account for the MPFS E/M updates as of 2021,[5] it may be necessary to convert their wRVU weights to the 2021 MPFS weights, in order to make an apples-to-apples comparison.

The first indications from the 2022 surveys (reporting 2021 data) are that the healthcare industry is returning to the production and compensation trends that were exhibited prior to the COVID-19 pandemic. This may mark the beginning of the "new normal." While the normalization process continues to be an important function of healthcare valuation engagements, the process itself has become more difficult. Valuation professionals still need to remember that these salaries are just a starting point. Valuation professionals in the healthcare industry would be well-served to understand the survey data (and survey instrument) they rely upon; utilize an evidence-driven methodology that includes both qualitative and quantitative assessments of the specific facts and circumstances related to the transaction; document their consideration of these facts and circumstances; and, articulate their ultimate applicability to the transaction in support of their opinion.

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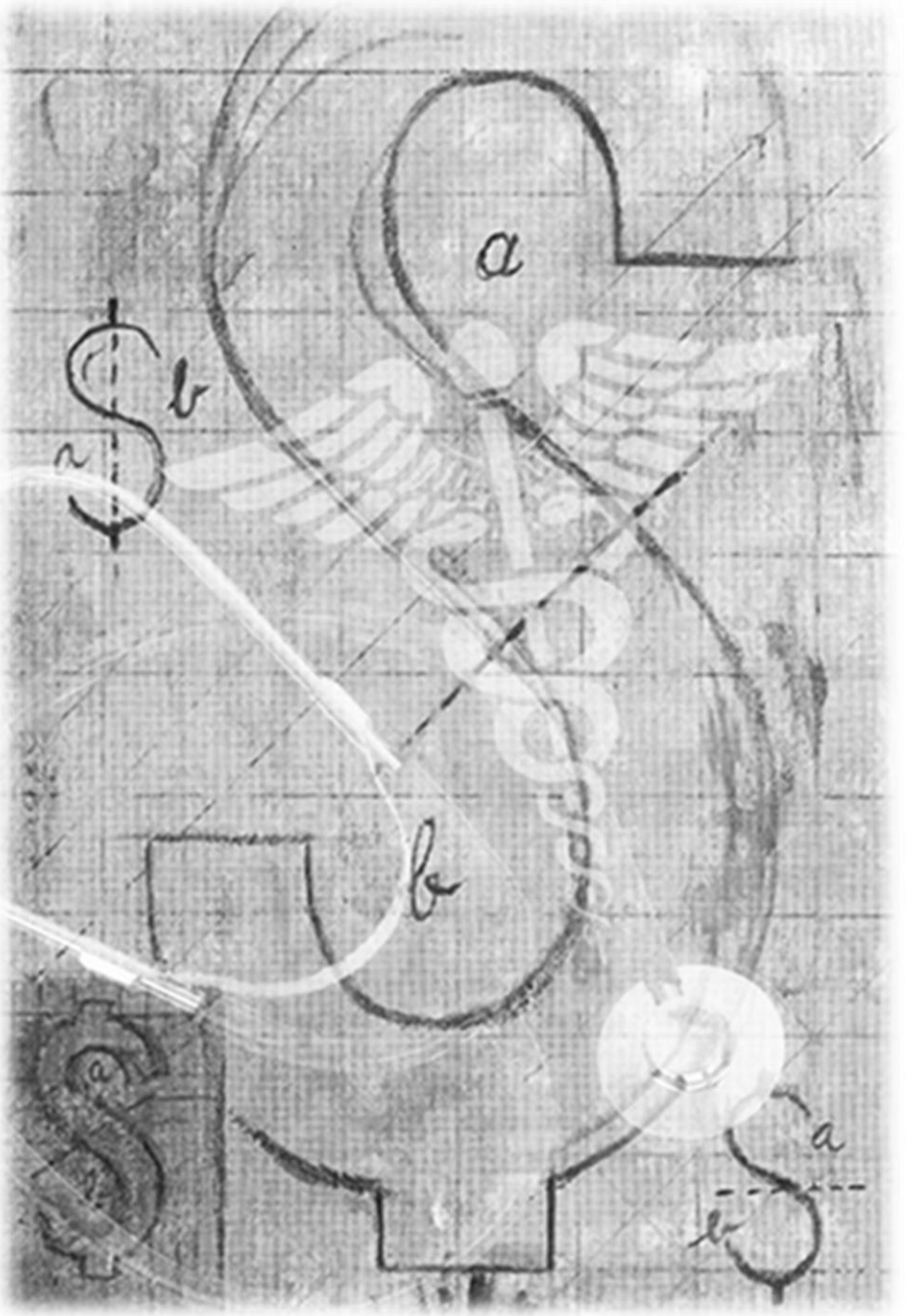
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III. REGULATORY TOPICS

Federal ACO Performance Results for 2020 Released

[Excerpted from the article published in November 2021.]

The 2020 performance year (PY) results for two of Medicare's accountable care organization (ACO) programs, the Medicare Shared Savings Program (MSSP) and the Next Generation ACO (NGACO) model, have been released. This Health Capital Topics article will examine the key highlights of the 2020 MSSP and NGACO model performance results.

The MSSP was established by the Centers for Medicare & Medicaid Services (CMS) to achieve savings in how providers delivered healthcare services while maintaining the quality of those services. Providers could share in those savings by participating in the MSSP through an ACO, i.e., a group of healthcare providers who come together to provide coordinated high-quality care to patients.[1] Established in 2012, the MSSP was fundamentally changed in 2018 based on the program's first six years of experience. Under this new "Pathways to Success" model, all ACOs (both new and current) had to choose between the new Basic Track and Enhanced Track.[2] Under the Basic Track, which is further divided into five levels – A, B, C, D, and E – an ACO is automatically advanced to the next track level at the start of each subsequent performance year.[3] While levels A and B are one-sided risk models, levels C, D, and E are two-sided risk models, which progressively increase in risk (as well as in potential shared savings) up to 50% of savings and 30% of losses.[4] The Enhanced Track is a two-sided model with much higher financial risk – up to 75% of shared savings or losses.[5] For each ACO, CMS sets annual financial targets (termed benchmarks) under which the ACO must fall in order to be eligible for shared savings. The MSSP is the largest alternative payment model offered by CMS, with 513 participating ACOs reaching approximately 10.6 million patients in 2020.[6]

The NGACO model was built upon CMS's experience from previous ACO initiatives such as the MSSP. Established in 2016, this model sought to set predictable financial targets, give providers more opportunities to coordinate care to beneficiaries, and ensure high quality care and examine whether the combination of financial incentives coupled with increased patient care interaction/management can lower expenditures for fee-for-service recipients.[7] Toward that end, the NGACO model allows physicians to take on higher financial risks than the MSSP. There were only 37 NGACOs in the program in 2020, serving 1.1 million patients.[8]

CMS's report on the MSSP's performance results for 2020 (the program's eighth performance year) found that participating ACOs generated savings of approximately $4.145 billion above their benchmarks, the highest amount of program savings to date.[9] This resulted in the participants receiving a total shared savings of $2.3 billion, and Medicare experiencing net savings of approximately $1.9 billion; this was Medicare's fourth consecutive year of net savings.[10] In fact, 83% of all MSSP ACOs reduced spending relative to their own benchmarks (a record high), and 67% reduced their spending sufficient to

achieve shared savings.[11] Only six MSSP ACOs qualified for shared losses (which were waived in light of the COVID-19 public health emergency).[12] Notably, ACO benchmarks declined in 2020, requiring participants to spend less to potentially achieve savings, rendering these record-breaking figures all the more notable.[13]

CMS performance data showed that ACOs that take on financial risk are more likely to reduce costs and achieve savings. The grand majority (88%) of MSSP ACOs that operated under two-sided risk models (wherein they are on the hook for any losses) achieved shared savings, while just over half (55%) of one-sided risk models earned shared savings.[14] Further, two-sided risk models saved Medicare $211 per beneficiary, while one-sided risk models saved $152 per beneficiary (38% less).[15]

The data also indicated that more experienced ACOs are more likely to achieve savings. Approximately 80% of mature ACO participants (i.e., those who entered the program between 2012 and 2014) earned shared savings in 2020, compared to 59% of newer ACO participants (i.e., those who entered the program between 2018 and 2020).[16] This confirms that implementing the processes required to reduce costs and achieve shared savings is a years-long process.[17]

Further, the data showed that the type of provider leading the ACO may result in more savings. Physician-led ACOs saved Medicare $218 per beneficiary in 2020, compared to hospital-led ACOs, which saved $168 per beneficiary.[18] Interestingly, ACOs led by both physicians and hospitals saved even less – only $145 per beneficiary.[19] This dichotomy may indicate increased savings for Medicare going forward, as more and more ACOs are being led by physician groups.[20]

It is important to note that, despite streamlining costs, MSSP ACOs maintained high quality care, receiving an average quality score of 97.8%, the best score to date.[21] The 2020 MSSP performance results indicate that ACOs continue to have an impact in improving healthcare quality while lowering costs.[22] The report findings also suggest that MSSP ACOs might be better positioned to deliver care than other providers during public health emergencies and advance valuable healthcare delivery trends such as telehealth.[23]

Approximately two months after CMS released the MSSP performance report, the agency released 2020 performance data related to the NGACO model's fourth performance year. Similar to the MSSP, NGACOs also saved CMS money in 2020, with 35 of the 37 NGACOs generating savings compared to their benchmark.[24] NGACOs generated $637 million in gross savings, but Medicare netted only $230 million after doling out shared savings payments; both of these amounts were higher than a year prior.[25] Even while reducing spending, NGACOs provided high quality care, receiving an average quality score of 96.5% (a slightly lower average score than the MSSP ACOs).[26]

Further, the nonpartisan and objective research organization (NORC) at the University of Chicago utilized the 2020 NGACO data in evaluating the overall

performance of the NGACO model in its first four years.[27] Its recently-released report found that NGACOs reduced acute care hospital stays and spending, with acute care spending declining by 0.9%.[28] Importantly, NGACOs' total Medicare spending reductions were substantially larger for patients with eight or more chronic conditions (a reduction of approximately $755 per beneficiary) and for patients with prior hospitalizations (a reduction of approximately $410 per beneficiary), highlighting the success of the model's focus on care coordination.[29]

Despite this seemingly positive news (and the savings generated in 2020), the NGACO model has not been successful at reducing Medicare spending in aggregate. After accounting for the shared savings and coordinated care reward[30] payments of $909.6 million over the last four years, the NORC report found that the NGACO model actually *increased* net Medicare spending by 0.4% during the first four performance years.[31]

The results of the 2020 performance year for MSSP ACOs were overwhelmingly positive, despite having a difficult year in 2020 due to the COVID-19 pandemic. However, despite gross savings and a generally positive year, the short-lived NGACO model ultimately increased Medicare spending during its four-year program. This lack of aggregate savings is largely the reason for the model ending at the conclusion of 2021.[32] The model was originally set to end in 2020, but extended it for an additional year due to the pandemic, in order to give NGACO model participants sufficient time to transition to another two-sided risk payment model; in particular, CMS is encouraging NGACOs to transition to the Direct Contracting model.[33] The Direct Contracting Model is a voluntary, five-year Medicare ACO model that aims to reduce administrative burden though partially- and fully-capitated payments for Medicare Part A and B services.[34] Given the cancellation of the NGACO model, it is increasingly likely that CMS and its Center for Medicare and Medicaid Innovation (CMMI) could introduce a new advanced payment model for 2023, or at least significantly "tweak" the Medicare Direct Contracting model.[35]

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Hospital Settles False Claims Act Allegations for $18.2 Million

[Excerpted from the article published in December 2021.]

On December 2, 2021, the U.S. Department of Justice (DOJ) announced that it had entered into an $18.2 million settlement with Flower Mound Hospital, a 91-bed hospital located northwest of Dallas, to resolve claims that the hospital had violated the Stark Law, the Anti-Kickback Statute (AKS), and the False Claims Act (FCA) by making improper inducements to referring physicians.[1] This *Health Capital Topics* article will review the facts underlying the settlement.

The FCA imposes civil monetary penalties in an amount between $5,000 to $10,000 per claim, as well as treble damages, upon any individual who knowingly submits a false or fraudulent claim to, or uses false records to induce payment from, the U.S. government.[2] The FCA is a potent fraud and abuse enforcement tool, as it allows private individuals, also known as *qui tam* relators or whistleblowers, to bring suits on behalf of the government.[3]

A violation of the FCA can be triggered by violations of the AKS and/or Stark Law.[4] 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.[5] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[6] 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.[7] However, the AKS does contain certain *safe harbors* that 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.[8] The Stark Law governs those physicians (or their immediate family members) who have a financial relationship (i.e., an ownership interest, investment interest, or compensation arrangement) with an entity, and prohibits those individuals from making Medicare referrals to those entities for the provision of designated health services (DHS), unless the referral is protected by one or more of the numerous exceptions delineated by the statute.[9] Notable to the allegations against Flower Mound Hospital, ownership interests in a hospital are one of the financial relationships protected by the Stark Law exceptions, so long as:

(1) The referring physician is authorized to perform at the hospital; and,

(2) The ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.[10]

Texas Health Presbyterian Hospital Flower Mound (referred to as "Flower Mound Hospital" in the DOJ settlement filings), is located in Flower Mound, Texas, and is jointly owned by Texas Health Resources (a non-profit health system that serves patients throughout North Texas[11]) and several physicians. The government's underlying lawsuit was originally brought in 2019 by a

physician-owner at the hospital under the FCA's whistleblower provisions.[12] The lawsuit alleged that the hospital violated fraud and abuse laws when it "repurchased shares from physician-owners aged 63 or older [in 2019] and then resold those shares to younger physicians" in 2021 because the hospital took into account the volume or value of these physicians' referrals in determining: (1) to which physicians the shares would be resold and (2) the number of shares that each physician would receive.[13] In other words, the hospital allegedly conditioned their future ownership (and the extent of that ownership) on each physician's expected referrals.[14] While additional facts underlying the lawsuit are sparse, the government specifically alleged that the hospital's relationships with the physician-owners failed to satisfy the exception described above related to physician ownership interests in hospitals (generally known as the Whole Hospital Exception to the Stark Law).[15]

As a result of the settlement, Flower Mound Hospital will pay $18.2 million in restitution, of which:

(1) Over $17.7 million will be payable to the federal government to resolve the claims related to Medicare and TRICARE[16];

(2) Approximately $486,500 will be payable to the State of Texas to resolve the claims related to Medicaid; and,

(3) Approximately $3 million will be payable to the whistleblower for his efforts.[17]

Additionally, Flower Mound Hospital entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), which requires, among other items, that the hospital maintain a compliance program, hire an Independent Review Organization to review arrangements entered into by or on behalf of the hospital, and, for certain executives, obtain compliance-related certifications.[18]

While the number of FCA suits brought by whistleblowers stayed stagnant between 2019 and 2020 (potentially due to the COVID-19 pandemic), over the past five years, there has been a significant uptick in the number of FCA suits brought by whistleblowers (with 672 *qui tam* cases initiated in 2020 alone).[19] This trend, as well as the total number of new healthcare fraud and abuse enforcement actions initiated, suggest that regulatory scrutiny of healthcare transactions will remain high going forward.

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DOJ Recoveries for False Claims Act Cases Doubled in 2021

[Excerpted from the article published in February 2022.]

On February 1, 2022, the U.S. Department of Justice (DOJ) announced their recovery of $5.6 billion in settlements and judgments from civil cases involving fraud and false claims for *fiscal year* (FY) 2021.[1] Over $5 billion was recouped from the healthcare industry for federal losses alone, and included recoveries from drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians.[2] This figure is more than double the amount of healthcare-related recoveries secured in FY 2020, which totaled $1.8 billion.[3] Settlements received from the healthcare industry (approximately 93% of the total recovery amount) far outstripped recoveries from defense, energy, construction, and other industries.[4] In addition to the $5 billion recovered for federal losses, the DOJ also recovered tens of millions of dollars for state and Medicaid programs in FY 2021.[5]

The largest healthcare recoveries were related to settlements from opioid litigation. In the year's largest settlement, $2.8 billion was recovered from Purdue Pharma as part of its global resolutions of criminal and civil liability related to allegations that the company "promoted its opioid drugs to health care providers it knew were prescribing opioids for uses that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion."[6] In addition to the $2.8 billion, individual Purdue shareholders and board members agreed to pay $225 million to resolve allegations "that they approved a new marketing program that intensified marketing of OxyContin to extreme, high-volume prescribers, causing opioid prescriptions for uses that were unsafe, ineffective and medically unnecessary, and that often led to abuse and diversion."[7] In another settlement, $209 million was recovered from Indivior, as part of its global resolutions of criminal and civil liability related to allegations that the company "promoted the opioid-addiction-treatment drug Suboxone to physicians who were writing prescriptions that were not for a medically accepted indications and were often diverted."[8] These two cases accounted for nearly 75% of 2021 healthcare recoveries.

In addition to pursuing cases related to opioids, the DOJ settled two cases related to their 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. Sutter Health paid $90 million to resolve allegations that it "submitted invalid diagnoses and received inflated payments as a result."[9] Further, Kaiser Foundation Health Plan of Washington paid $6.3 million to resolve allegations that it submitted invalid diagnoses, which resulted in the receipt of inflated payments.[10] In addition to these settlements, the government intervened in lawsuits against

Independent Health Corporation and against members of the Kaiser Permanente consortium alleging that they submitted inaccurate information about the health status of enrolled beneficiaries in order to receive inflated Medicare reimbursement.[11]

Several lawsuits were resolved in 2021 related to unlawful kickbacks. For example:

(1) Arriva Medical LLC, a mail-order diabetic testing supply company, paid $160 million to settle allegations that Arriva paid kickbacks to Medicare beneficiaries via "free" or "no cost" glucometers and frequently waived or did not collect copayments for glucometers and diabetic testing supplies;[12]

(2) An individual who owned and operated pain management clinics and urine drug testing laboratories paid $9 million, and his clinic and laboratories paid $140 million to resolve allegations that the clinics and laboratories paid unlawful kickbacks to providers to induce referrals of urine tests;[13]

(3) Athenahealth Inc., an electronic health records technology (EHR) vendor, paid $18.35 million to resolve allegations that it "invited customers and prospective customers to lavish all-expense-paid sporting, entertainment, and recreational events to generate sales of its EHR product;[14] and,

(4) Three generic pharmaceutical manufacturers paid in excess of $400 million to resolve allegations that they paid and received illegal remuneration "through arrangements on price, supply and allocation of customers with other pharmaceutical manufacturers as part of a conspiracy to fix the price of certain generic drugs."[15]

Several other lawsuits brought or resolved by the DOJ in 2021 were related to billing for medically unnecessary services or services not rendered as billed. SavaSeniorCare LLC paid $11.2 million to resolve claims that it submitted false claims for rehabilitation therapy services in pursuit of corporate targets, rather than in accordance with a patient's medical needs.[16] Alere paid $38.75 million to resolve allegations of billing for "defective rapid point-of-care testing devices used by Medicare beneficiaries to monitor blood coagulation when taking anticoagulant drugs."[17] Apria Healthcare LLC paid $40.5 million to resolve allegations that it submitted false claims related to the provision of non-invasive ventilators to beneficiaries who had no need or use for the devices.[18] St. Jude Medical paid $27 million to resolve allegations that it "knowingly sold defective, implantable heart devices and failed to disclose serious adverse health events in connection with premature battery depletion in those devices."[19] Regency (and its owner) paid $20.3 million to resolve allegations of falsifying documentation in order to bill federal healthcare programs for medically unnecessary durable medical equipment.[20]

As in 2019 and 2020, the DOJ's FY 2021 press release included an additional section entitled, "*Holding Individuals Accountable*," wherein it reviewed

several cases in which the DOJ obtained substantial judgments from individuals, illustrating its continued commitment to the 2015 memorandum authored by then-Deputy Attorney General Sally Yates regarding holding individuals accountable for corporate wrongdoing (often referred to as the "Yates Memo").[21]

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.[22] Since 1986, recoveries made under civil FCA suits total more than $70 billion.[23] Over the past five years, there has been a significant uptick in the number of FCA suits brought on by both *whistleblowers* (also known as *qui tam* lawsuits) and the DOJ, with 598 qui tam cases and 203 *non*-qui tam cases initiated in FY 2021 alone.[24] The number of qui tam cases in 2020 was the lowest it had been since 2009, potentially indicating the government's decreasing reliance on whistleblower activity.[25] However, the total amount recovered in FY 2021 was the second largest ever recorded and the most since 2014.[26] However, if the $2.8 billion settlement with Purdue was removed, the total amount of recoveries would be more in line with past years. Nevertheless, the DOJ's continued active interest and involvement in fraud and abuse cases in 2021 suggests that FCA enforcement will remain high going forward.

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U.S. Intervenes in False Claims Act Case Against Hospital

[Excerpted from the article published in May 2022.]

On April 11, 2022, the U.S. Department of Justice (DOJ) intervened in an ongoing lawsuit against Methodist Le Bonheur Healthcare (Methodist). The lawsuit was originally filed in 2017 by two relators, a former Methodist executive leadership team member and the former CEO for Methodist University Hospital.[1] The crux of the relators' complaint was that Methodist induced the referrals of cancer patients to their facility through kickback payments made to The West Clinic (West), in violation of fraud and abuse laws.[2]

Methodist is a non-profit healthcare system consisting of five hospitals as well as outpatient and ancillary services.[3] West (also known as West Cancer Center) is a large oncology physician group with several outpatient oncology clinic locations in Tennessee, Mississippi, and Arkansas.[4] The lawsuit alleges that during the partnership between Methodist and West (2012 to 2018), over $400 million was allegedly paid by Methodist for referrals from West physicians in the form of kickbacks, "disguised thorough a sophisticated business integration."[5] Through the alleged illegal inducement of referrals from West physicians, Methodist received over $1.5 billion in increased revenues,[6] with over half of these increased revenues estimated to have been paid by Medicare and Medicaid.[7]

The Anti-Kickback Statute (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.[8] Similar to the Stark Law, the AKS contains several safe harbors, including protections for personal services and management contracts, which may shield an arrangement from regulatory liability if some or all of the requisite criteria is met.[9] Failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[10] However, for a payment to meet the requirements of many AKS safe harbors, the compensation must: (1) be consistent with FMV; (2) be commercially reasonable; and, (3) not take into account the value or volume of any referrals provided by the group practice physicians.[11]

Violations of the AKS can trigger a violation of the False Claims Act (FCA).[12] The FCA imposes civil monetary penalties in an amount between $5,000 to $10,000 per claim, as well as treble damages, upon any individual who knowingly submits a false or fraudulent claim to, or uses false records to induce payment from, the U.S. government.[13] The FCA is a potent fraud and abuse enforcement tool, as it allows private individuals, also known as *qui tam* relators or *whistleblowers*, to bring suits on behalf of the government.[14]

The DOJ's Complaint in Intervention alleges the same general facts (although with more specificity by the Government). The "sophisticated business

integration" between Methodist and West was memorialized through several agreements:

(1) An Asset Purchase Agreement (APA), wherein Methodist purchased almost all of West's outpatient locations and certain tangible and intangible assets of West;

(2) A Professional Services Agreement (PSA), wherein 28 West physicians were compensated by Methodist on a productivity basis for providing inpatient or outpatient oncology services;

(3) A Management Services Agreement (MSA), wherein West physicians were to "provide management services across the entire…adult oncology service line, inpatient and outpatient, at six of Methodist's facilities…, the Cancer Center Sites, and any other off-campus oncology care sites…where West provided services under the PSA;"[15]

(4) A Leased Employee Agreement, wherein "Methodist leased West's 193 non-physician employees," for which "Methodist paid West the same rate that West compensated these leased employees…on a pass-through basis"; and,

(5) An Unwind Agreement, wherein West could terminate the entire transaction and buy back what it had sold after the first six months of the arrangement.[16]

Beyond these transactions (and the payments made by Methodist for these services and assets from West), Methodist also allegedly made a separate $7 million investment in ACORN Research, LLC, in which West and its medical director had a personal financial interest.[17]

As a result of this arrangement, Methodist "was able to establish a new stream of income through reimbursements for outpatient treatment…[and] a huge increase in referrals for inpatient services from West, which previously referred the bulk of its patients to Methodist's competitors."[18] Further, Methodist was able to enroll in the 340B Drug Pricing Program to receive discounts on some of its drugs, including oncology infusion drugs; this resulted in the health system receiving $50 million in profit in one year alone.[19]

Notably, Methodist and West obtained Fair Market Value (FMV) opinions related to the APA, PSA, MSA, and the ACORN investment.[20] While the Government does not go into details on the opinions related to the first or last of those transactions, it does briefly discuss the FMV opinion on the PSA and goes into greater detail regarding the numerous FMV opinions related to the MSA. While the Government does not appear to assign fault to the FMV opinions (or the valuation firms that prepared them), it does note that, in regard to the PSA, the "opinion does not include any reference to the cost of benefits that Methodist paid…[t]he opinion also notes that there may be a need for a new opinion in 2014…[a] new opinion, however, was not obtained until 2016."[21] In regard to the MSA, which compensation was supposedly tied to a percentage of the oncology service line revenues, and manifested as a combination of base management fees and additional incentive compensation,

the Government noted that the first FMV opinion was rendered in late 2011.[22] Then, in 2014, to support an increase in management fees, West engaged two valuation firms, and ultimately accepted the higher of the two FMV opinions (which was over $1 million more).[23] Yet another FMV opinion was sought by West in 2016, for which the practice engaged a different valuation firm.[24] A fourth round of MSA fee increases necessitated an additional FMV opinion in 2017.[25] It appears that in most of these valuations, West allegedly provided inaccurate data to the valuation firms that had the effect of increasing the revenue, resulting in a higher range of fees.[26]

The Government alleges that although Methodist paid West management fees at a continually increasing rate between 2012 and 2018, the West physicians did not provide management services for Methodist, and in fact were paid management fees to grow West. The MSA was never overseen or audited as contemplated by the agreement and no time records or other documentation were ever provided as evidence that the management services were actually provided.[27]

In general, the government makes clear that their allegations center in large part on Methodist and West not following the terms of their various agreements.[28] To state another way, services were compensated by Methodist even though they were never performed by West. Further, the Government emphasizes that West, which had the largest market share of cancer patients in the area, had not provided many referrals to Methodist prior to its 2012 agreement, but subsequently referred practically all of its patients to Methodist during the term of their arrangement.

The suit is currently in the discovery phase.[29] Interestingly, the DOJ informed the court in September 2019 that "it was not intervening in the case 'at this time' but its investigation into the matter would continue."[30] The Government filed its motion to intervene in October 2021, which Methodist contested, arguing that the DOJ failed to show "good cause" for why it had waited so long to intervene.[31] While the DOJ "intervenes in fewer than 25% of whistleblower lawsuits,"[32] it is unclear from the court filings what prompted the DOJ to ultimately intervene in this case. Nevertheless, as the arrangements underlying this lawsuit are fairly ubiquitous in the healthcare industry, both hospitals and physicians would be well-served to follow the developments in this case.

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1 "United States and State of Tennessee ex rel. Jeffery H. Liebman and David M. Stern v. Methodist Le Bonheur Healthcare, et al." Case No: 3:17-cv-00902 (M.D. Tenn., December 13, 2019), Second Amended Complaint, p. 4.

2 *Ibid*, Notably, the Government only alleges violations of the FCA and AKS. "United States and State of Tennessee ex rel. Jeffery H. Liebman and David M. Stern v. Methodist Le Bonheur Healthcare, et al." Case No: 3:17-cv-00902 (M.D. Tenn., April 11, 2022), Complaint in Intervention, p. 68-71.

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5 *Ibid*, p. 4 and 12

6 *Ibid*, p. 6.

7 *Ibid*, p. 6.
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CMS Unveils New ACO Model

[Excerpted from the article published in March 2022.]

On February 24, 2022, the Centers for Medicare & Medicaid Services (CMS) announced a new accountable care organization (ACO) model, called ACO REACH.[1] REACH stands for "Realizing Equity, Access, and Community Health."[2] ACO REACH will replace the current Global and Professional Direct Contracting (GPDC) model, and terminate the current Geographic Direct Contracting (Geo Model) model, a subset of the GPDC model.[3] This Health Capital Topics article will discuss the new ACO REACH model and its implications for existing ACOs.

CMS's current Geo Model was introduced in December 2020 with the promise of advancing regional value-based care (VBC), reducing healthcare expenditures, and enhancing the quality of care provided to Medicare beneficiaries.[4] The Geo Model was suspended in March 2021, after stakeholders sent a letter to the Department of Health and Human Services (HHS) addressing their concerns regarding the model's effects on care quality, including that there were too many challenges for existing ACOs to get involved and too little incentive to provide quality care.[5] As a result of these concerns, CMS decided to redesign the entire GPDC model.

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]

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.[7] Because the GPDC model did not sufficiently meet the three objectives set forth above, CMS unveiled their new REACH model in an attempt to fix these problems.[8] According to CMS, the new REACH model meets these three criteria and addresses other areas of concern that exist in the GPDC model by supporting value-based initiatives and changing the governance structures of ACOs; specifically, it requires a minimum of 75% of a participating ACO's governing body to be held by participating providers, up from the 25% minimum under the GPDC model.[9] Further, the REACH model is more in line with CMS's recently released ten-year strategic plan, as it better supports care innovation and focuses more on the social determinants of health.[10] This is especially true as the REACH model does more than the GPDC model to advance health equity, increase access, and

drive affordable accountable care.[11] Specifically, the 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.[12]

Additionally, traditional Medicare beneficiaries may be entitled to more benefits under the new REACH model, such as telehealth and home care visits.[13] However, it should be noted that the REACH model is considered by CMS to be a "new and improved" GPDC model,[14] meaning that it will provide the same two voluntary risk-sharing options (a "professional" 50% shared savings/losses plus a primary care capitation payment and a "global" 100% shared savings/losses plus either a primary care capitation or a total care capitation payment) while allowing providers to earn more predictable revenue.[15] Overall, the REACH model's primary goal is to help many different kinds of healthcare organizations work together to ensure patients can obtain the care they need when and where they need it.[16]

The reaction to the GPDC model and the new REACH model has been mixed. In January 2022, 50 Democratic lawmakers sent a letter to HHS demanding the GPDC model (which they alleged incentivizes the privatization of traditional Medicare) be thrown out and replaced, which stance implies these lawmakers would support the new REACH model and its revised priorities.[17] However, there is strong pushback from other stakeholders, namely providers and other large, private companies that would benefit from the greater profits under the GPDC model. In early February 2022, over 200 healthcare organizations sent a letter to HHS asserting the GPDC model be fixed, not replaced.[18] The organizations praised the GPDC model, claiming there would be a slower shift to VBC if the model was scrapped.[19]

CMS has announced that the GPDC model will expire on December 31, 2022, and the new REACH model will be effective January 1, 2023, running through 2026.[20] The application window for the ACO REACH model will be open from March 7, 2022 until April 22, 2022.[21]

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New Initiatives Announced to Improve Nursing Home Quality & Safety

[Excerpted from the article published in March 2022.]

On February 28, 2022, President Joe Biden announced during his State of the Union address that the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) will establish increased standards in nursing homes to improve equality and safety.[1] In his address, President Biden cited the poor performance of nursing homes across the U.S. and the toll that the COVID-19 pandemic has had on them, particularly with regard to financial and personnel losses.[2]

More than 1.4 million Americans live in over 15,500 Medicare- and Medicaid-certified nursing homes across the U.S.[3] Since the onset of the COVID-19 pandemic in March 2020, over 200,000 nursing home residents and staff have died, while nearly 240,000 caregivers have left the industry.[4] Further, a White House fact sheet released the same day as the State of the Union cited Government Accountability Office (GAO) findings that 82% of nursing homes inspected since 2020 had an infection prevention and/or control deficiency, which was a major cause of illness and death among nursing home residents.[5] However, the Biden Administration's biggest concern with the industry is the increase in private equity (PE) firm investment in nursing homes.[6] The White House fact sheet cited several studies, stating nursing homes owned by PE had lower care quality, worse health outcomes, structurally-reduced staffing, and increased mortality rates.[7] These studies found that PE-owned and operated nursing homes have contributed to over 20,000 lives lost, resulting from their poor performance compared to traditional not-for-profit nursing homes.[8]

To combat the rising Medicare and Medicaid costs of care in nursing homes, the increasing tax-payer burden on poor-performing facilities, and the rise in PE-run facilities, the Biden Administration announced four new initiatives. They include: requiring minimum staffing loads, reducing room crowding, strengthening s*killed nursing facilities'* (SNFs') value-based purchasing programs, and reinforcing safeguards against providing unnecessary medications and treatments.[9] Beyond these initiatives, the Biden Administration is seeking to enhance accountability and oversight, increase transparency, and ensure future emergency preparedness.[10] Specific plans to accomplish these initiatives include phasing out rooms with occupancy greater than two residents and reducing the number of problematic diagnoses and prescriptions.[11] A larger, more important objective is for each facility to collect and submit verifiable data to CMS regarding staffing rates (including turnover) and other critical metrics.[12] This effort is largely designed to benefit the consumers by allowing families to make better decisions regarding the placement of a patient.[13] The proposed initiatives will have the greatest effects on the 97% of nursing homes that are Medicare- and Medicaid-certified.[14] These facilities, both for- and not-for-profit, will have to comply with the new requirements.[15]

The President will also ask Congress to provide CMS with an additional $500 million to support the increase in health and safety inspections at nursing homes.[16] This 25% budget increase will allow CMS to improve the *Special Focus Facility* (SFF) program to more efficiently identify and better enforce compliance and improve care at the worst-performing facilities.[17] For facilities that are not in compliance or fail to meet minimum standards, fines can now be assessed daily, instead of the one-time penalty used by the Trump Administration.[18] President Biden will also call on Congress to increase penalties up to $1 million per instance; other penalties may include being cut-off from CMS's funds and revocation of a facility's Medicare and Medicaid licenses.[19]

In order to enforce compliance, the use of additional data that will be required for nursing homes to report, predictive analytics, and other information processing tools will indicate to CMS whether facilities are improving and if they have met minimum standards.[20] This increased data transparency, including a facility's ownership status and detailed financial records will be made public (or, if already public, more accessible) via the Nursing Home Compare website.[21]

While many consider the President's plan to improve the safety and quality of care in nursing homes to be a positive announcement and long overdue, key industry stakeholders on both sides are unsure as to how well these initiatives will work and if attacking PE investors is the best path forward. Beth Martino, the senior Vice President of the *American Care Association and National Center for Assisted Living* (AHCA/NCAL) asserted the White House's initiatives should focus more on "chronically underfunded" Medicaid facilities, rather than PE-owned ones.[22] She cited the small number of PE-owned facilities and the long-lasting impact underfunding has had on nursing homes, which can be attributed to the extreme shortage in caregivers and the increase in closure or sale of not-for-profit facilities to PE investors.[23] Juan Sanabria of BMO Capital Markets notes that increased government oversight may lead to extra costs to meet requirements, particularly with regard to collecting data and meeting minimum staffing requirements.[24] Sanabria says this additional oversight may cause further complications when recovering from the financial and workforce losses resulting from the COVID-19 pandemic.[25]

Seema Verma, who served as CMS Administrator during the Trump Administration, echoed many of these concerns with the new initiatives, especially if precautions are not taken to consider the underlying issues of staffing shortages relating back to poor reimbursement and severe underfunding.[26] Verma also stated that more steps should be taken to facilitate the shift to *value-based care* (VBC). In doing so, she opposes increased government oversight and proposes a more collaborative approach to helping poor-performing facilities, rather than focusing only on punitive processes.[27]

The initiatives announced by the Biden Administration during the State of the Union address are meant to increase the quality and lower the cost of care in nursing homes. They are also designed to increase transparency of

organizations to help patients and families make better decisions, as well as to help CMS make critical funding and punitive decisions. It is clear this industry needs more attention; however, many stakeholders are concerned the attention is going to the wrong places, overlooking the root causes of poor performance among many facilities in the industry.

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Biden Announces Fix to ACA's "Family Glitch"

[Excerpted from the article published in April 2022.]

On April 5, 2022, the *Internal Revenue Service* (IRS) proposed a rule change to its eligibility requirements for families to receive premium tax credits toward purchasing high-quality health coverage on the insurance marketplaces established by the *Patient Protection and Affordable Care Act* (ACA).[1] This proposed change comes on the heels of two Biden Administration executive orders calling for improvements to the ACA and Medicaid. This Health Capital Topics article will discuss the proposed solution to a decade-long problem and how it will affect millions of Americans.

The ACA, which was passed in 2010 by then-President Barack Obama, was the most extensive change to the U.S. healthcare system since the establishment of Medicare/Medicaid in 1965, offering numerous rights and protections to consumers to help make healthcare coverage more fair and attainable.[2] The law also provides subsidies, tax credits, and cost-sharing reductions for consumers looking to purchase high-quality health coverage.[3] However, the law contains a clause intended to keep people with employer-provided insurance out of the ACA marketplaces, keeping the system fair and affordable for those without any coverage. The unintended consequences of this overly-restrictive clause has earned it the name "the Family Glitch."[4]

The Family Glitch clause states that individuals with employer-provided insurance are not eligible for tax credits or other subsidies to purchase high-quality health coverage.[5] The problem is that the definition of "affordable" refers only to the employed individual's self-coverage, not the cost of a family plan for his/her spouse and/or children (the cost of which can significantly differ from the employee's self coverage, depending on the amount of the premium that is subsidized by the employer).[6]

In an effort to fix some of the unintended results of various ACA provisions, President Biden signed an executive order in January 2021 calling for improvements to the ACA and Medicaid. In response, federal agencies took a number of actions, including:

(1) "[F]acilitating the expansion of Medicaid in Missouri and Oklahoma";

(2) "[E]extending Medicaid eligibility…in order to allow pregnant individuals to retain their Medicaid coverage for up to 1 year postpartum" through a number of state initiatives;

(3) Opening up a Special Enrollment Period "that allowed 2.8 million Americans to newly enroll in coverage under the ACA";

(4) "[E]xtending the length of the HealthCare.gov Open Enrollment Period by 1 month and operating the most successful Open Enrollment Period ever, with a historic 14.5 million Americans enrolling in coverage through the ACA Marketplaces and an additional 1 million people enrolling in Basic Health Program coverage, resulting in a 20 percent increase over the prior year"; and

(5) "[L]owering maximum out-of-pocket costs for consumers with employer and ACA coverage by $400 in 2022."[7]

Fifteen months later, on April 5, 2022, President Biden signed an additional executive order to continue strengthening access to affordable and high-quality health coverage.[8] Specifically, the order directs agencies to review agency actions and "identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage," including examining policies or practices that:

(1) "[M]ake it easier for all consumers to enroll in and retain coverage, understand their coverage options, and select appropriate coverage";

(2) "[S]trengthen benefits and improve access to healthcare providers";

(3) "[I]mprove the comprehensiveness of coverage and protect consumers from low-quality coverage;

(4) "[E]xpand eligibility and lower costs for coverage in the ACA Marketplaces, Medicaid, Medicare, and other programs";

(5) "[H]elp improve linkages between the healthcare system and other stakeholders to address health-related needs; and,

(6) "[H]elp reduce the burden of medical debt on households."[9]

On the same day that President Biden signed this newest healthcare executive order, the Treasury Department and the IRS announced a proposed rule amending the Family Glitch, as well as adding a minimum value rule for the family members of an individual who receives workplace coverage.[10] By revising the Family Glitch, the IRS intends to update the definition of "affordability" to mean an employee's share of the cost to cover additional family members, not an employee's individual coverage, as the definition states currently.[11] The proposed minimum value rule is intended to aid in defining "affordability" by lowering the percent threshold on what the ACA deems affordable. The new minimum value rule would reduce the percentage of household income spent on family coverage deemed affordable from 10% to 9.5%.[12] This means that any employee who has insurance through their workplace may be eligible for premium tax credits if the cost for family coverage through their workplace exceeds 9.5% of the employee's income.

The proposed elimination or revision of the Family Glitch would be the most significant change to the ACA since it was passed in 2010. This change would mean 200,000 currently-uninsured Americans would be able to gain coverage, while an additional 5 million Americans would see a reduction in the costs of coverage for plans purchased through the ACA's marketplaces.[13] The proposed rule change is particularly significant because an estimated 2.8 million children will be direct beneficiaries from increased access and reduced cost of marketplace health coverage.[14]

The reaction from healthcare industry stakeholders in response to the administration's announcement has been largely positive. The president of the

American Hospital Association stated that "Hospitals and health systems strongly support the Biden Administration's efforts to help more Americans secure affordable health insurance by proposing to eliminate the 'family glitch.'"[15] Additionally, the president of the American Medical Association stated:

"[T]he Biden Administration has taken a crucial step in the campaign to cover the five million uninsured people who fall into the family glitch. The family glitch is inconsistent with the goals of the Affordable Care Act and unfairly penalizes family members of lower-income workers. The American Medical Association has repeatedly asked Congress and administrations to fix the glitch, and the Biden Administration has made good on its promise to make healthcare coverage more affordable."[16]

Similarly, the president of the AHIP (formerly America's Health Insurance Plans) indicated the trade association's support for "proposals to fix the 'family glitch' in the ACA, and affordability and access both in the employer and individual markets will remain our core values as we review this proposed rule."[17]

The timing of this proposed rule is likely no coincidence, as the Biden Administration is most likely seeking changes to the Family Glitch now to allow for a sufficient comment and modification period prior to the next marketplace open enrollment period in December 2022.[18] In addition to the time constraint for the next enrollment period, the COVID-era open-enrollment policies expire at the end of 2022, meaning up to 2.8 million Americans will lose access to the marketplaces' coverage options in the absence of any new policy modifications.[19] As such, this newly-announced proposal could help keep hundreds of thousands of Americans eligible for marketplace coverage.[20]

The IRS has scheduled a public hearing for June 27, 2022, to hear commenters.[21] Further, any written comments must be received by June 6, 2022, whether or not they are to be included in the public hearing.[22] Pending approval, the proposed rule would take effect January 1, 2023, but Americans could sign up for financial assistance prior to that date, during the next open enrollment period.[23]

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Biden Administration to Overhaul Vertical Merger Guidelines

[Excerpted from the article published in April 2022.]

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), especially among physician groups integrating with health systems or insurers, as providers seek to fill gaps in their continuum of care. In 2010, only 28% of physicians were employed by hospitals or health systems, compared to nearly 40% in 2020;[1] by 2021, nearly 70% of physicians were employed by hospitals or corporations.[2] Further, approximately 90% of acute care markets in metropolitan areas are considered highly concentrated.[3] In response to these trends and resulting market imbalances, the Biden Administration is aggressively pursuing antitrust enforcement by updating and revising U.S. antitrust law guidance.[4] This Health Capital Topics article will discuss the vertical integration movement and the proposed changes to antitrust laws that may affect the future of healthcare.

Unlike *horizontal consolidation*, which is the acquisition or merger of two companies at the same level in the supply chain, *vertical integration* is the merger or acquisition of two or more companies that are in the same line of production, but not at the same level.[5] 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.[6] 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.[7] 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.[8]

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;[9] further, companies and individuals may not engage in deceptive business practices.[10] Violating one or more of these acts can result in fines up to $1 million for individuals and up to $100 million for corporations.[11] The purpose of antitrust laws is to maintain healthy competition and avoid price-fixing, rigged bids, and monopolization.[12]

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.[13] As such, the Biden Administration has begun investigating possible changes to antitrust law enforcement pertaining to vertical integration.[14] In September 2021, the *Federal Trade Commission* (FTC) voted to withdraw its approval of changes it had made to its vertical merger guidelines, jointly with the *Department of Justice* (DOJ), in 2020.[15] The merger

guidelines "outline the principal analytical techniques, practices, and enforcement policies" of the DOJ and the FTC.[16] The 2020 changes improved on the previous 1984 guidelines, but were rescinded in order to "prevent further reliance of flawed provisions."[17] Specifically, the 2020 guidelines inadvertently suggested pro-competitive effects or efficiencies are justifications for an otherwise unlawful merger.[18]

In addition to remedying inaccurate language in the 2020 guidelines, these recent steps by the FTC and DOJ are in line with the Biden Administration's July 2021 executive order to promote competition, which specifically directed the FTC and DOJ to work together to review and consider revising both the horizontal and vertical merger guidelines.[19] Toward that end, the FTC and DOJ commenced a joint review process in January 2022 and issued a request for information (RFI) seeking comment from industry stakeholders on "how the agencies can modernize enforcement of the antitrust laws regarding mergers."[20] The nature of the questions contained in the RFI suggest that the agencies may be looking to substantially change their current enforcement framework.[21]

The proposed guidelines are anticipated to address, among other things, "how markets are defined in merger analyses to factor in non-price related consequences, the breadth of the oversight, the separation of the vertical and horizontal guidelines, the presumption that vertical mergers are beneficial and worker-specific impacts of mergers."[22] Stakeholders and policy experts anticipate that any new changes to antitrust laws and vertical merger guidelines are likely to impact the competitive landscape of the healthcare industry by requiring greater government oversight, particularly when companies need to inform the government of a potential merger and whether or not the government will approve certain mergers.[23] Changes will also likely require pro-competitive benefits as a result of any deals and may reduce the internal benefits of such deals.[24] This could mean requiring merging companies to remain separate in at least one area, such as management. The overall goal of revised guidelines is to ensure fair and increased competition; however, it will likely do so by creating more bureaucratic hoops and limiting the scope of acquisitions. Additional consequences of changes to antitrust law enforcement could result in recent mergers being deemed unlawful, requiring the "break-up" of some companies.[25]

Both supporters and critics of the forthcoming changes are arguing many of the same points in defense of their positions, but for different reasons. Most stakeholders argue that increased competition is good, but some state that the problem the Biden Administration is attempting to fix does not exist. An attorney at Dickinson Wright and the CEO of Crux Strategies has said the commercial health insurance plan market is not concentrated, citing UnitedHealthcare, for example, only having 15% market share in 2020. Because "[a]ntitrust law is a blunt instrument for fixing [concentrated markets]…I am not convinced the government is going to do a good job. They are trying to fix a problem that, to a great extent, doesn't exist."[26]

Other stakeholders assert that vertical integration in healthcare is necessary for organizations to survive, with some adding that organizations need to come together to solve the complex problems facing the healthcare industry. A senior managing director at FTI Consulting noted that they "have certainly seen providers struggle mightily with setting up their own plans, taking on value-based arrangements and risk," when talking about the importance of vertical consolidation.[27] The president and CEO of Presbyterian Hospital added that, "[e]ach individual entity alone isn't going to solve it 100% correctly, but if we come together we could have better and more seamless care."[28] As highlighted by these statements, industry stakeholders view vertical integration and complex mergers as critical steps for hospitals and the healthcare industry to solve its most challenging problems, such as providing a full continuum of care to receive the benefits from value-based reimbursement (VBR) models.

Despite the opposition from industry leaders, the FTC and DOJ are determined to follow through with revamping the merger guidelines to help protect the American public from anticompetitive behavior, as Americans "historically have lost out, with diminished opportunity, higher prices, lower wages, and lagging innovation" as a result of industry consolidation and a lack of competition.[29]

The issue of rewriting the vertical merger guidelines is hotly contested between the healthcare industry and the Biden Administration. Oddly, both sides are arguing for more competition, but are hoping to achieve it by different means. Further, because the guidelines are only used for a prosecutor's discretion, it is unclear how changes will affect courts' decisions in antitrust cases.[30] The FTC and DOJ's changes are expected soon, as they are currently operating in a grey area, having revoked the 2020 changes and admitting that the 1984 original guidelines are outdated.[31] The public comment period for the RFI ended on March 21, 2022,[32] and the agencies have stated their intention to publish the proposed guidelines by the end of 2022.[33]

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Advisory Opinion Deals Another Blow to Clinical Labs

[Excerpted from the article published in May 2022.]

On April 18, 2022, the *Department of Health and Human Services* (HHS) *Office of Inspector General* (OIG) published *Advisory Opinion* (AO) No. 22-09 analyzing a proposed business arrangement involving a testing laboratory contracting with hospitals for specimen collection and testing. This AO is an extension on earlier opinions and guidance, and is yet another blow for laboratory arrangements.

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. In short, an AO is the OIG's position on whether a certain business arrangement is in conflict with the federal Anti-Kickback Statute (AKS), the law that 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.[1] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[2] Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[3] 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 transactional arrangements 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] Notably, for the purposes of this AO, one of the common safe harbors utilized by healthcare providers is the Personal Services and Management Contracts and Outcomes-Based Payment safe harbor. Under this safe harbor, compensation is allowed to be made "by a principal to an agent as compensation for the services of the agent, as long as all of the following standards are met":

(1) The agreement "is set out in writing and signed by the parties;"

(2) The agreement identifies the all of services to be provided to the agreement during the term;

(3) The agreement term must be at least one year;

(4) The methodology for determining the compensation to be paid to the agent "is set in advance, is consistent with fair market value in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part" by federal healthcare programs;

(5) The services to be performed "do not involve the counseling or promotion of a business arrangement;" and,

(6) "The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services."[7]

Under the proposed arrangement proposed to the OIG, the requestor of the AO, a group of clinical laboratories, would compensate hospitals on a per-patient-encounter basis for the collection, processing, and handling of those specimens sent to the labs for testing.[8] The labs would bill the payor (including Medicare, Medicaid, and commercial payors) and phlebotomists employed or contracted by the hospital would conduct the collection, processing, and handling services.[9] While the hospitals were free to choose a lab other than the requestor, if a physician's order did not specify the testing laboratory, the hospital could select the lab to which it would send the specimen.[10]

The OIG determined that such an arrangement "would generate prohibited remuneration under the [AKS], if the requisite intent were present"[11] because a fee would be paid, ultimately, for each patient encounter, which could incentivize the improper steering of patients to the labs. This is despite the labs certifying that the arrangement:

(1) Would be set out in writing and signed by the parties;

(2) Would be for a term of at least one year;

(3) Would cover all of the services to be provided, but would not exceed those reasonable and necessary to accomplish a reasonable business purpose;

(4) Fee would be consistent with Fair Market Value in an arm's-length transaction;

(5) Would prohibit double billing (i.e., the contracting hospitals could not separately bill any payors or patients for the services);

(6) Would prohibit the hospitals from requiring referrals to the labs from paying physicians based on their referrals to the labs; and,

(7) Would require the hospitals to certify that none of their employed or contracted physicians or affiliated parties would be required to refer to the labs and consequently the labs would not receive payments from the hospitals for any referrals.[12]

Further, the OIG noted that lab services are "particularly susceptible to the risk of steering under" the AKS. Additionally, the agency was concerned that the "per-click" fee structure, even if consistent with Fair Market Value, nonetheless fluctuates (i.e., reflects) the volume or value of referrals or other business sent to the labs, and thus does not fall under the Personal Services and Management Contracts and Outcomes-Based Payment safe harbor.[13]

As noted above, this AO builds upon previous agency guidance related to laboratory arrangements. In 1994, OIG published a Special Fraud Alert regarding joint venture arrangements, such as those for the provision of clinical lab services that may violate the AKS.[14] In this alert, the OIG stated that labs could station phlebotomists in physician offices, so long as the phlebotomists

did not render any additional services to the office.[15] In 2014, the OIG published another Special Fraud Alert addressing "compensation paid by laboratories to referring physicians and physician group practices…for blood specimen collection, processing, and packaging, and for submitting patient data to a registry or database."[16] The agency noted its concern with patient steering, stating that "the choice of laboratory, as well as the decision to order laboratory tests, typically is made or strongly influenced by the physician, with little or no input from patients."[17] An AO published that same year reviewed an arrangement wherein a lab would pay an electronic health record (EHR) vendor a fee of $1 per order to transmit orders to a lab (so that the physicians did not have to do so); the OIG found that there seemed to be "no reason" for the lab to pay these fees "other than to secure referrals."[18]

As noted by some legal experts, this AO may serve to effectively chill all arrangements for specimen collection between hospitals and laboratories, unless "the laboratory is certain that the hospital could not and would not refer, or influence referrals, to the laboratory."[19] This could make specimen collection particularly difficult going forward, as laboratories rely on hospitals and other providers to collect the specimens and provide them to the laboratories, which tasks providers understandably do not want to undertake for free.[20] How these issues will bear out long term remains to be seen.

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Supreme Court Hears Oral Arguments on 340B Cuts

[Excerpted from the article published in December 2021.]

On November 30, 2021, the U.S. Supreme Court heard oral arguments regarding the challenges arising from the cuts made by the Centers of Medicare & Medicaid Services (CMS) to the 340B Drug Pricing Program. The 340B Drug Pricing Program allows hospitals and clinics that treat low-income, medically underserved patients to purchase certain "specified covered outpatient drugs"[1] at discounted prices (applying a ceiling to what drug manufacturers may charge certain healthcare facilities) – 25% to 50% of what providers would typically pay – and then receive reimbursement pursuant to the rates set forth in the Outpatient Prospective Payment System (OPPS) at the same rate as all other providers.[2] 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.[3] However, many healthcare industry stakeholders assert that 340B participants are realizing substantial profits by purchasing deeply discounted cancer drugs, which are then reimbursed by Medicare at full cost – providing hospitals with up to 100% profit margins on these expensive drugs.[4]

CMS originally announced cuts to the reimbursement rates for 340B drugs in the 2018 OPPS rule, to address "recent trends of increasing drug prices, for which some of the cost burden falls to Medicare beneficiaries."[5] Prior to 2018, the reimbursement rate for these outpatient drugs was the drug's average sales price (ASP) *plus* 6%.[6] In the 2018 OPPS final rule, however, CMS finalized a reduction to this reimbursement rate, specific to 340B participants only, of ASP *minus* 22.5%, beginning in 2018.[7] CMS claimed in the final rule that it had authority to enact such a cut under federal law that allows for calculation and adjustment of the rates "as necessary."[8]

In 2017, three hospital associations, including the American Hospital Association (AHA), and several non-profit hospitals filed a lawsuit in the U.S. District Court for the District of Columbia to challenge the cuts and enjoin the implementation of the cuts, asserting that the U.S. Department of Health & Human Services (HHS), of which CMS is part, violated its authority by 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).[9] According to the plaintiffs, the 340B statute requires CMS to conduct a survey as to the hospitals' average drug acquisition costs prior to enacting reimbursement cuts.[10] In December 2017, the court dismissed that lawsuit on procedural grounds because the policy was not yet effective.[11] The hospital associations and hospitals re-filed the suit once the reimbursement cuts took effect, leading to the current challenge.[12] Plaintiffs argued that the reduction exceeded HHS's statutory authority and violated the Administrative Procedure Act (APA) and the Social Security Act.[13] On December 27, 2018, a the district court ruled in favor of the plaintiffs, finding that HHS's authority to

make "adjustments" does not equate to "fundamentally rework[ing] the statutory scheme."[14] HHS subsequently appealed the case and the appellate court reversed the lower court's decision, finding that HHS had the power to make the cuts.[15] The case was then appealed to the U.S. Supreme Court, which agreed to hear the dispute.

The key point of contention in the case is whether HHS acted within its authority in making cuts in the 2018 OPPS Final Rule that singled out 340B hospital participants.[16] The plaintiffs argue that HHS does not have the authority under the 340B statute to make cuts and therefore cannot single out 340B hospital participants.[17] On the other side, HHS argues that the cuts were necessary in order to reimburse hospitals for the acquisition costs of the drugs.[18] Justice Steven Breyer seemed to agree with the agency's position, stating that "the point seems to be to pay the hospitals what they actually pay for the drugs, which sometimes you can figure out and sometimes you can't…When it says adjust for purposes, they mean adjust so that you get closer to what hospitals are really paying for these drugs."[19] The plaintiffs responded to this line of reasoning by asserting that HHS should do a cost study prior to enacting rate changes for a specific group of hospitals, which the agency began doing in 2020.[20] Justice Elena Kagan questioned why HHS had not conducted cost studies prior to 2020, as she interpreted the 340B statute as requiring a cost study prior to changing rates.[21] Justice Brett Kavanaugh raised the concern of many healthcare industry stakeholders in seeking to ascertain from the plaintiffs whether 340B hospital participants are being overpaid as HHS asserts.[22]

The potential implications of the U.S. Supreme Court's decision in this case are likely to be impactful, although whether that impact is negative or positive is indeterminate. According to David J. Skorton, M.D., President and CEO of the Association of American Medical Colleges (one of the plaintiffs in the lawsuit):

> *"The current reimbursement rates reduce the 340B drug discounts granted to safety-net providers, many of which are teaching hospitals. These hospitals use the current savings to deliver critical health care services to low-income and vulnerable patients, which includes providing free or substantially discounted drugs to low-income patients, establishing neighborhood clinics, and improving access to specialized care previously unavailable in some areas. A reversal of the cuts will ensure that low-income, rural, and other underserved patients and communities are able to access the vital services they need."*[23]

On the other hand, proponents of the cuts have repeatedly argued that the payment reductions have saved money for Medicare beneficiaries, i.e., seniors and people with disabilities, through lowered out-of-pocket costs.[24] Some proponents have gone so far as to argue that reversing the cuts will cost these beneficiaries millions of dollars.[25]

A decision on this case is likely to be released by the Supreme Court sometime in the first half of 2022.

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U.S. Supreme Court Rules Against HHS in 340B Case

[Excerpted from the article published in June 2022.]

On June 15, 2022, the U.S. Supreme Court released its decision regarding the cuts made by the Department of Health and Human Services (HHS) to the 340B Drug Pricing Program, finding that HHS acted outside its statutory authority in changing reimbursement rates for one group of hospitals without first surveying them on their costs.

The 340B Drug Pricing Program allows hospitals and clinics that treat low-income, medically underserved patients to purchase certain "specified covered outpatient drugs"[1] at discounted prices (applying a ceiling to what drug manufacturers may charge certain healthcare facilities) – 25% to 50% of what providers would typically pay – and then receive reimbursement under the Outpatient Prospective Payment System (OPPS) at the same rate as all other providers.[2] 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.[3] However, many healthcare industry stakeholders assert that 340B participants are realizing substantial profits by purchasing deeply discounted drugs, which are then reimbursed by Medicare at full cost – providing hospitals with up to 100% profit margins on these expensive drugs.[4]

Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, HHS must follow a statutory formula (consisting of two options) in setting the annual reimbursement rate for 340B drugs. Beginning in 2006, HHS's reimbursement rate for each covered drug "shall be equal" to either:

"(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group…), as determined by the Secretary taking into account the hospital acquisition cost survey data…; or

(II) if hospital acquisition cost data are not available, the average price for the drug…as calculated and adjusted by the Secretary as necessary for purposes of this paragraph."[5] [Emphasis added.]

From 2006 to 2018, the reimbursement rate for these outpatient drugs was determined using Option 2: the drug's average sales price (ASP) *plus* 6%.[6] In the rulemaking for the 2018 OPPS, however, HHS instead finalized a reduction to this reimbursement rate, specific to 340B participants only, of ASP *minus* 22.5%, pursuant to the formula set forth in Option 1 (non-340B participants are still reimbursed ASP plus 6%). HHS finalized these cuts for 2018 (and continued them through 2019), to address "recent trends of increasing drug prices, for which some of the cost burden falls to Medicare beneficiaries."[7][8] HHS claimed in the final rule that it had authority to enact such a cut under federal law that allows for calculation and adjustment of the rates "as necessary."[9]

Subsequently, three hospital associations, including the American Hospital Association (AHA), and several non-profit hospitals filed a lawsuit in the U.S. District Court for the District of Columbia to challenge the cuts and enjoin their implementation, asserting that HHS, violated its authority by 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).[10] In December 2017, the court dismissed that lawsuit on procedural grounds because the policy was not yet effective.[11] The hospital associations and hospitals re-filed the suit once the reimbursement cuts took effect, leading to the current challenge.[12] Plaintiffs argued that the reduction exceeded HHS's statutory authority because the statute requires the agency to survey the hospitals' average drug acquisition costs *prior* to enacting reimbursement cuts, particularly if only one group of hospitals would be affected by the cuts.[13]

The district court ruled in favor of the plaintiffs, finding that HHS's authority to make "adjustments" does not equate to "fundamentally rework[ing] the statutory scheme."[14] HHS subsequently appealed the case and the appellate court reversed the lower court's decision, finding that HHS had the power to make the cuts.[15] The U.S. Supreme Court's unanimous opinion, authored by Justice Brett Kavanaugh, reversed the appellate court. The Court found that a reading of the statutory language makes clear that without surveying hospitals as to their drug acquisition costs, HHS may not change drug reimbursement rates for a subset of hospitals. The court noted that this "protects all hospitals by imposing an important procedural prerequisite—namely, a survey of hospitals' acquisition costs for prescription drugs—before HHS may target particular groups of hospitals for lower reimbursement rates."[16] As to HHS's assertion that the agency has the authority under Option 2 to adjust the average price, the Court stated that:

"[r]egardless of the scope of HHS's authority to 'adjust' the average price up or down under the statute, the statute does not grant HHS authority to vary the reimbursement rates by hospital group unless HHS has conducted the required survey of hospitals' acquisition costs…Otherwise stated, HHS's power to increase or decrease the price is distinct from its power to set different rates for different groups of hospitals"[17]

The potential implications of the U.S. Supreme Court's decision in this case are still unclear, but it may be difficult to "put the genie back in the bottle." HHS argued that allowing judicial review of the now-unlawful reimbursement rates is impractical because HHS is required to operate the program on a budget-neutral basis. As a result, the Court's decision may require HHS to repay some amounts to the 340B participants, necessitating offsets elsewhere in the OPPS to account for those repayments. However, the Court stated in its opinion that "[a]t this stage, we need not address potential remedies," and remanded the case back to the lower court. A University of Pennsylvania law professor has stated that the implications "will be really quite limited both from a practical perspective and from a legal perspective."[18] But from where that money will come to repay the 340B drug claims for 2018 and 2019 is an "open issue"

according to a health lawyer with Foley Hoag, and attempting to redistribute the money "could penalize more hospitals than are benefited…[as t]here are way more hospitals that got the extra money than benefit from 340B."[19] The 2023 OPPS proposed rule is expected to be released in July 2022 and is anticipated to address how the 340B money will be reapportioned and the reimbursement rates for drug costs going forward. Stay tuned for a future Health Capital Topics article examining the 2023 OPPS proposed rule once it is released.

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1 These are "a subset of 'separately payable drugs,' which are not bundled with other Medicare Part B outpatient services and are therefore reimbursed on a drug-by-drug basis." "Memorandum Opinion: Denying Defendants' Motion to Dismiss; Granting Plaintiffs' Motion for a permanent Injunction; Denying as Moot Plaintiffs' Motion for a Preliminary Injunction" in "The American Hospital Association, et al., v. Azar, et al." Civil Action No. 18-2084 (RC) (D.C. Cir. Dec. 27, 2018), p. 4 (citing "Payment of benefits" 42 U.S.C. § 1395l(t)(14)(A)).

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Coordinated Actions Indicate Growing Scrutiny of Telemedicine

[Excerpted from the article published in July 2022.]

On July 20, 2022, the Office of Inspector General (OIG) of the U.S. Department of Health & Human Services (HHS) released a Special Fraud Alert on telemedicine. On the same day, the U.S. Department of Justice (DOJ) announced a "nationwide coordinated law enforcement action" against 36 defendants, and the Centers for Medicare & Medicaid Services (CMS) Center for Program Integrity announced administrative actions against 52 providers, related to alleged telemedicine arrangements.[1] These coordinated actions indicate a growing scrutiny of telemedicine arrangements by federal government regulators.

With the rapid shift in the utilization of telehealth during the COVID-19 pandemic, the number of OIG investigations and enforcement actions related to Medicare payments for telehealth services have similarly grown. Fraudulent telemedicine arrangements may implicate numerous federal fraud and abuse laws, including the Anti-Kickback Statute, which prohibits any person from "*knowingly and willfully*" soliciting or receiving, or offering or paying, 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] Additionally, a violation of the Anti-Kickback Statute is sufficient to state a claim under the False Claims Act, which prohibits any person from knowingly submitting false claims to the government.[3]

Since 1988, the OIG has periodically published special fraud alerts to alert and provide general guidance to healthcare industry stakeholders regarding "specific trends of health care fraud and certain practices of an industry-wide character."[4] In this most recent Special Fraud Alert, the OIG noted a common theme among most of the telehealth arrangements they have investigated: telemedicine companies arranging with practitioners "to order or prescribe medically unnecessary items and services for individuals [i.e., patients]…who are solicited and recruited by Telemedicine Companies."[5] This is compounded by the limited communication the practitioners have with the patient – typically not at all, or only by phone.[6] The practitioners are then paid "per review, audit, consult, or assessment of medical charts," i.e., via a methodology that contemplates the volume or value of referrals.[7]

Specifically, the OIG identified seven "suspect characteristics" in arrangements between healthcare practitioners and companies providing telehealth, telemedicine, or telemarking services, which, if present, "could suggest an arrangement that presents a heightened risk of fraud and abuse":

(1) "The purported patients for whom the Practitioner orders or prescribes items or services were identified or recruited by the Telemedicine Company, telemarketing company, sales agent, recruiter, call center,

health fair, and/or through internet, television, or social media advertising for free or low out-of-pocket cost items or services";

(2) "The Practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed";

(3) "The Telemedicine Company compensates the Practitioner based on the volume of items or services ordered or prescribed, which may be characterized to the Practitioner as compensation based on the number of purported medical records that the Practitioner reviewed";

(4) "The Telemedicine Company only furnishes items and services to Federal health care program beneficiaries and does not accept insurance from any other payor";

(5) "The Telemedicine Company claims to only furnish items and services to individuals who are not Federal health care program beneficiaries but may in fact bill Federal health care programs";

(6) "The Telemedicine Company only furnishes one product or a single class of products (e.g., durable medical equipment, genetic testing, diabetic supplies, or various prescription creams), potentially restricting a Practitioner's treating options to a predetermined course of treatment";

(7) "The Telemedicine Company does not expect Practitioners (or another Practitioner) to follow up with purported patients nor does it provide Practitioners with the information required to follow up with purported patients (e.g., the Telemedicine Company does not require Practitioners to discuss genetic testing results with each purported patient)."[8]

This list, which "is illustrative, not exhaustive," was developed based on the OIG's and DOJ's experience in telehealth investigations and enforcement activities. The OIG also clarifies that not all of these characteristics need be present for an arrangement to be considered high-risk. Nevertheless, this alert "is not intended to discourage legitimate telehealth arrangements," as the OIG has previously noted that "[f]or most, telehealth expansion is viewed positively, offering opportunities to increase access to services, decrease burdens for both patients and providers, and enable better care, including enhanced mental health care."[9]

On the same day that the Special Fraud Alert was released, the DOJ announced a "nationwide coordinated law enforcement action," wherein 36 defendants (one of which was a telemedicine company executive) were criminally charged for approximately $1.2 billion in alleged fraud between telemedicine companies and genetic testing laboratories and durable medical equipment (DME) manufacturers.[10] Specifically, the enforcement action involved alleged kickbacks to induce medically unnecessary orders and prescriptions.[11] In addition, the CMS Center for Program Integrity "took administrative actions against 52 providers involved in similar schemes."[12]

Coordinated Actions Indicate Growing Scrutiny of Telemedicine

The regulatory scrutiny of telehealth services and arrangements is at "an all-time high."[13] With this Special Fraud Alert and latest enforcement action, the OIG appears to be sending a clear message – providers need to ensure that telemedicine arrangements are justified and have appropriate guardrails. Any payments under these arrangements should also be consistent with Fair Market Value and not fluctuate with the volume and value of referrals.

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IV. COMPETITION TOPICS

Literature Review Debunks Claims Against Physician-Owned Hospitals

[Excerpted from the article published in September 2021.]

Approximately 250 hospitals across the U.S. are completely or partially physician owned.[1] These physician-owned hospitals (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, suggesting 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.[3] However, a recent literature review rebuts the assumptions that led to these policy restrictions.

A systemic review of 30 years of healthcare services research was released on September 7, 2021, through the Mercatus Center,[4] wherein the authors sought to answer the questions of comparative cost and quality in POHs, and found that "focused factory" POHs – particularly those focusing on cardiac and orthopedic care – offered higher quality and lower or equivalent cost services, with general surgical POHs demonstrating higher quality in limited studies.[5] Additionally, "physician-owned community hospitals (or general acute care POHs) had similar cost and quality to their non-profit and for-profit competitors, suggesting a lack of harms."[6]

In their review of 21 studies between 1990 and January 2020, the authors classified those articles according to whether the POHs studied were:

(1) Physician-owned cardiac specialty hospitals;
(2) Physician-owned orthopedic specialty surgical hospitals;
(3) Physician-owned general surgical hospitals; or,
(4) Physician-owned general acute care hospitals.[7]

As regards quality of care data, the measures were divided into the following four domains to facilitate comparison:

(1) Facility characteristics;
(2) Pre-procedure capabilities;
(3) Care episode characteristics; and
(4) Care delivery outcomes or complications.[8]

In analyzing the studies related to physician-owned cardiac specialty hospitals, the literature review found that any difference in cost of care between cardiac specialty POHs and non-POHs was not statistically significant.[9] However, numerous studies examining various facets of quality related to certain cardiac

conditions found POHs to be better on measures such as length of stay (LOS), inpatient mortality, inpatient plus 30-day mortality, and readmissions.[10]

More robust results were found in a review of the studies related to physician-owned orthopedic specialty surgical hospitals. Multiple studies demonstrated decreased costs for orthopedic procedures at POHs, although "low quality" studies from the Medicare Payment Advisory Committee (MedPAC) that were less recent than the aforementioned research found higher costs for care delivered in orthopedic specialty surgical POHs.[11] However, the authors noted that both the 2005 and the 2006 MedPAC studies reviewed only one year of claims data and did not analyze data by Medicare Severity-Diagnosis Related Group (MS-DRG).[12] As regards quality, the literature review found that orthopedic specialty surgical POHs achieved higher quality metrics "across a multitude of categories," such as overall hospital ratings, doctor-nurse communication, and staff responsiveness, as well as on more specific clinical characteristics, such as lower rates of LOS, various complications, inpatient mortality, inpatient plus 30-day mortality, readmission, risk-adjusted complication scores, and surgical interventions on initial consultation (i.e., the PHOs are more willing to try other, nonsurgical interventions first).[13]

In reviewing the literature related to physician-owned general surgical hospitals, the researchers found that those POHs had slightly higher costs, but the difference was not statistically significant.[14] While there was a relative dearth of quality data specific to general surgical POHs, it was generally in favor of POHs – one study in particular found POHs to have statistically significant lower inpatient mortality rates and lower inpatient plus 30-day mortality rates.[15]

Literature examining physician-owned general acute care hospitals found that compared to patients at general acute care hospitals, "patients at POHs were younger…and more likely to be male…, but they were also more likely to be African American…or use Medicaid," and had higher mean predicted morbidity, refuting long-held beliefs that POHs "cherry pick" healthier and more profitable patients.[16] Nevertheless, risk-adjusted costs at general acute care POHs were found to be slightly lower than those at general acute care hospitals and the quality data for both types of hospitals were similar.[17]

In summarizing their literature review, the researchers noted that their "review did not identify a service market where the quality data disfavored POHs," while the differences in cost of care was more mixed.[18] Specifically however, "[a]lthough some policy experts have expressed historical concerns of favorable patient selection ("cherry picking") in POHs, our systemic review found no consistent evidence to support this assertion."[19] In fact, the authors assert that "in the absence of evidence that POHs provide services of lower quality or higher cost, Medicare's ban on new POH participation and expansion of pre-existing POHs lacks justification."[20] Instead, the researchers argue, repealing the ban would actually have potential positive effects on the healthcare delivery system, such as allowing for "new joint ventures and

clinical operating models" and "promot[ing] flexibility and competition among hospital ownership models."[21]

Considering the more recent research finding hospital consolidation results in higher costs and lower quality, and the subsequent push to increase competition in the U.S. healthcare industry,[22] this latest research as to the effectiveness of POHs may provide a strong argument to regulators that increasing competition through the addition of more POHs in the marketplace may provide a much-needed jolt to the U.S. healthcare delivery system.

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Healthcare Industry Hit with the Great Resignation & Retirement

[Excerpted from the article published in October 2021.]

The COVID-19 pandemic has served as a catalyst for two current healthcare workforce trends: the Great Retirement and the Great Resignation. While the Great Resignation among physicians and other clinicians has been well reported, a potential onslaught of retirements by senior executives may further impact hospitals and health systems at an already precarious time. This Health Capital Topics article will discuss some of the key challenges and issues surrounding healthcare's Great Retirement and Great Resignation.

Hospital chief executive officers (CEOs) have a significant role in ensuring the stability of the organizations that they run. Despite their significance, the average tenure of a hospital CEO is just over 5.5 years, with a median of only 4.5 years.[1] There are a number of reasons why high level executives might leave their organizations, including:

(1) Increase in mergers and acquisitions in the healthcare marketplace;

(2) A growing number of alternative opportunities that offer career growth;

(3) Tensions between organizational boards and their healthcare affiliated staff; and,

(4) Exposures of financial and quality-control issues.[2]

The onset of the COVID-19 pandemic caused a new slew of issues for senior executives, as they had to move quickly to decide how to meet the demands of the pandemic and attempt to educate their local communities on the virus. This time in the spotlight has not been without controversy, due to the unfortunate political tinge of the virus, which has sowed discord across the U.S. Perhaps due to the tumultuous state of the overall healthcare industry, many hospital CEOs ostensibly stayed in their positions, or hospital boards decided not to make a leadership change, until the worst of the pandemic subsided, resulting in a hospital CEO turnover rate of 16% in 2020, the lowest since 2011.[3] As the pandemic draws to a close, a high turnover rate might be expected once again as a number of large healthcare systems have already announced their CEOs' plans to retire in the next several months:

(1) Jim Hinton, CEO of Baylor Scott & White, the largest nonprofit health system in Texas, will retire at the end of 2021;[4]

(2) Stephen Klasko, MD, CEO of Jefferson Health, an 18-hospital system in Philadelphia, will retire at the end of 2021;[5]

(3) Penny Wheeler, MD, CEO of Allina Health, an 11-hospital and 90+-clinic system located throughout Minnesota and western Wisconsin, will retire at the end of 2021;[6]

(4) Marna Borgstrom, CEO of Yale New Haven Health, Connecticut's largest healthcare system, will retire in March 2022;[7] and,

(5) Lloyd Dean, CEO of CommonSpirit Health, a 140-hospital system, will retire in summer 2022.[8]

The number of hospital executives leaving their positions indicates a larger current trend in the healthcare industry – the considerable number of hospital workers willing to walk away from the profession.

Even before the COVID-19 pandemic, morale and optimism about the future practice of medicine was low, with 46% of physicians planning to change career paths.[9] The pandemic's unique challenges and frustrations seems to have accelerated this change, with physicians quitting at historic rates over the past 17 months.[10] Chief among the reasons for resignation among physicians is burnout, which has become so pervasive in recent years that a 2019 report published by the Harvard T.H. Chan School of Public Health, the Harvard Global Health Institute, the Massachusetts Medical Society, and the Massachusetts Health and Hospital Association (MHA) deemed the condition a public health crisis.[11] Burnout manifests as emotional exhaustion, depersonalization (cynicism), and a sense of inefficacy, and can develop into depression, substance abuse, and family dysfunction.[12] Nearly half of all physicians experience burnout in some form, negatively impacting physician productivity.[13] Every one-point increase in burnout (on a seven-point scale) was found to be associated with a 30-40% increase in the likelihood that physicians will reduce their work hours in the next two years, which equates to losing all of the graduates from seven medical schools every year.[14]

The cause for burnout is rooted in deep-seated challenges facing the nation's providers. One challenge is the excessive number of working hours demanded of physicians. Nearly 60% of physicians work 71 or more hours in a week and 50% work between 61 and 70 hours each week.[15] This excessive number of working hours leads in part to a lack of time for other sectors of life. For example, nearly 40% of female physicians scale back their medical practice, or leave the profession altogether, early in their careers, citing family as their primary reason.[16] Another challenge is the administrative burdens being placed on physicians' shoulders. In countless surveys and studies, physicians of all specialties consistently cite the time and energy they must devote to filling out forms and other administrative tasks near or at the top of their list of grievances.[17] Physicians also cite frustrating computer interfaces and issues caused by the electronic health records (EHRs), which tend to crowd out physicians' face-to-face engagement with patients and increase the already long working hours.[18]

The COVID-19 pandemic has exacerbated these aforementioned challenges and presented additional unique issues, not just for physicians, but for all healthcare workers. A survey of 20,947 healthcare workers across 42 healthcare organizations found that 61% of those surveyed felt high fear of exposing themselves or their families to COVID-19, while 38% experienced anxiety or depression.[19] Another 43% suffered from work overload and 49% had

burnout.[20] Approximately 90% reported that they had been getting less than the recommended eight hours of sleep each night, and one in three admitted to sleeping four hours or less.[21] Work performance is suffering as a result – one in three healthcare workers feel that they have been making more mistakes at work.[22] Nearly half have considered retiring, quitting their jobs, or changing their careers altogether, while the same number say that their mental health has deteriorated.[23] Losing physicians and other healthcare workers may result in a lack of accessibility in medical care for patients and comes at a steep cost to employers – one estimate of the lost revenue per full-time-equivalent physician is $990,000, with the cost of recruiting and replacing a physician ranging from $500,000 to $1,000,000.[24]

According to a 2021 Association of American Medical Colleges (AAMC) report, the U.S. could see an estimated shortage of 37,800 to 124,000 physicians by 2034.[25] As this report does not "expressly model the impact of COVID-19,"[26] the Great Retirement and Great Resignation will likely exacerbate this critical shortage as more and more physicians, and other healthcare workers, seek to scale back their work hours or leave medicine altogether. This trend, coupled with the increased number of retiring CEOs could put some hospitals in dire straits. At the same time however, a historic number of female applicants are entering clinical professions and the number of medical schools applicants has increased dramatically.[27] Such increases in new entrants to the medical profession, as well as continued advancements in healthcare technology, will likely be needed to stymie worsening workforce shortages and may have the added benefit of paving the way for new innovation to achieve a truly value-based healthcare system.

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Study: Vertical Integration Not Financially Beneficial for Physicians

[Excerpted from the article published in December 2021.]

A study released in the December 2021 issue of Health Affairs examined the correlation between hospital/health system ownership of physician practices and physician compensation. While a number of studies have analyzed the "rapidly growing trend" of vertical integration from the hospital/health system perspective, this is the first study to evaluate vertical integration from the physician practice perspective.[1] The researchers found that those physicians whose practices were acquired by a hospital or health system received slightly less compensation under hospital ownership, with some differences among specialties; further, hospital-owned physician practices were "associated with larger reductions in physician income in more competitive hospital markets and in nonprofit hospitals."[2] This *Health Capital Topics* article will discuss the study's findings and potential implications.

Vertical integration may be defined as "[t]he combination in one firm of two or more stages of production normally operated by separate firms."[3] Firms engage in vertical integration transactions in pursuit of certain benefits typically associated with this form of organization, including:

(1) The development of economies of scale,[4] i.e., the ability of large firms to produce large quantities of a good at a reduced cost per unit;[5]

(2) The development of economies of scope,[6] i.e., the ability of large firms to produce a variety of goods more cheaply than producing those goods separately;[7] and,

(3) Vertically integrated firms with centralized management structures can, if strategically constructed and implemented, create superior production efficiencies relative to more fragmented business structures and markets.[8]

In the U.S. healthcare industry, vertical integration describes the "integration of providers at different points along the continuum of care, such as a hospital partnering with a skilled nursing facility (SNF) or a physician group,"[9] which organizational model can provide additional benefits to healthcare delivery organizations, as well as, to the communities they serve. The latest iteration in the push toward value-based reimbursement (VBR), which commenced in 2010 with the passage of the Patient Protection and Affordable Care Act (ACA), has driven the pursuit of closer relationships between hospitals and physicians through strategies such as vertical integration. In fact, from 2010 to 2018, hospital/health system ownership of physician practices increased 89.2%, from 24.1% of physician practices owned by a hospital/health system in 2010 to 45.6% by 2018.[10] While research has found that hospitals profit from vertical integration (an approximately 19% increase in revenue), "little is known about the degree to which the income of physicians whose practices have been acquired has been affected."[11]

In analyzing physician compensation and physician practice ownership, the Health Affairs researchers examined data for 41,648 physicians (48.3% of whom were in independent practices and 51.7% of whom were in hospital-acquired practices), during the study period of 2014 through 2018.[12] Physician compensation data was obtained from the Career Navigator Survey conducted by Doximity, "an online social network for physicians…that includes more than 70 percent of US physicians."[13] This data was then compared to information on practice ownership data during the period of 2010 to 2018 from the SK&A Office-Based Physicians Database administered by IQVIA, "a commercial database of health care providers, which provides a nearly complete sampling frame of US office based physicians," i.e., over 95% of office-based physicians.[14] This compensation and ownership data was then matched up at the physician level and analyzed from a myriad of angles. First, the researchers examined the association between vertical integration and physician compensation among overarching physician specialty types – primary care, nonsurgical specialists, and surgical specialists.[15] Second, the researchers analyzed whether this association varied by the tax status of the hospital – for-profit or non-profit. Third, the association was examined by the competitiveness of the market in which the hospital operated (at the county level) – concentrated or competitive.[16]

While physicians overall generally saw a small reduction in compensation of 0.8% post-integration (an absolute difference of -$2,987), the change in physician compensation post-integration varied depending on the specialty of the physician.[17] Nonsurgical specialists experienced a *decrease* of approximately 2.4% (an absolute difference of -$9,652) post-integration, while primary care physicians saw an *increase* of approximately 1.2% (an absolute difference of $3,179) and surgical specialists saw an increase of 2.1%, in compensation (an absolute difference of 10,741), post-integration.[18]

The association between physician income and vertical integration also varied depending on the marketplace in which the hospital operated. Physician income did not significantly change post-integration in highly concentrated markets, but it did decrease approximately 2.2% in competitive (i.e., not highly concentrated) markets.[19] Further, physicians acquired by a non-profit hospital saw a 1.9% reduction in their annual compensation; in contrast, physicians acquired by a for-profit hospital saw no statistically significant change in their income.[20] The researchers theorized that the variances between these two attributes (competitive marketplace and tax status) may be due to "differential bargaining power between physicians and hospitals in less concentrated hospital markets and with for-profit hospitals."[21]

The researchers noted that while physicians may not experience the same level of financial benefit from vertical integration as hospitals (or any financial benefit at all), there may be other, non-financial benefits associated with integration that were not captured by the study. For example, physicians may be willing to sacrifice some part of their income for a steady paycheck and consistent schedule; this "risk protection" may be more favorable than the

variable income and scheduling that results from practice ownership.[22] Additionally, physicians may appreciate hospitals taking on the administrative services (e.g., billing) and regulatory responsibilities (e.g., compliance), as well as interactions with insurance companies, that are required to operate a physician practice. As office-based physicians have experienced tightening reimbursement over the last few years, at the same time that they are being required to heavily invest in capital-intensive infrastructure such as healthcare information technology (e.g., electronic health records) that aggregates the requisite data and information required to report the metrics to the federal government (or commercial insurers), it is understandable that they may be willing to sacrifice some degree of autonomy and income for the relative stability of hospital ownership. In essence, physicians may prefer to make less money in return for being able to focus solely on treating patients.

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Study: Most Physician Compensation Plans Still Productivity-Based

[Excerpted from the article published in February 2022.]

A study conducted by the RAND Corporation and published in the January 2022 issue of the Journal of the American Medical Association (JAMA) seeking to determine whether health systems primarily incentivize volume or value in their physician compensation models found that almost all physicians are still compensated through a volume-based model that rewards productivity over the value of care provided.

The most recent iteration of healthcare reform, formalized in the 2010 *Patient Protection and Affordable Care Act* (ACA), signaled the shift to both *value-based care* (VBC), i.e., the goal of improving a patient's outcomes and the quality of care, and *value-based reimbursement* (VBR), how health systems and payors financially incentivize physicians to practice VBC over volume-based care.[1] Volume-based care has been, and still is, the default method of care and payment model in the U.S. because it incentivizes healthcare providers to treat more patients in order to achieve higher revenue.[2] The problem with volume-based care is that it largely disregards a patient's health outcomes and the quality of care received. As a result, volume-based care and volume-based payment models are increasingly under scrutiny and the Centers for Medicare & Medicaid Services (CMS) is leading the charge with their goal of shifting all Medicare beneficiaries to be treated by a provider in a VBC model by 2030.[3]

In the article's introduction, the RAND researchers noted that since the ACA's passage, physician hires and the size of health systems have increased.[4] They also noted that the majority of physician payment models were still based on volume-based care in 2019 (the end date of the study's survey).[5] This result, nine years after the ACA was passed, led RAND researchers to investigate how physicians are compensated and why VBR has been slow to be embraced.[6]

In determining why VBR has been slow to be incorporated, RAND researchers collected data, conducted interviews, and ran surveys from November 2017 through July 2019.[7] The researchers collected information from 31 physician organizations (POs) among 22 non-profit health systems across four states (California, Minnesota, Washington, and Wisconsin).[8] These 31 POs were comprised of 27 medical groups and 4 independent practice associations; all but one had compensation plans for both primary care providers (PCPs) and specialists.[9]

The two-year study indicated that VBC practices were the easiest and quickest way for physicians to increase their compensation.[10] 26 of the 31 primary care PO compensation models incentivized the volume of services in their base compensation, as did 28 of the 30 specialist PO compensation models.[11] Further, of the 26 primary care POs that cited volume as a compensation model component, it comprised, on average, just over 68% of the PCPs' total compensation; for specialist POs, that component was nearly 74% on average.[12]

Beyond volume-based compensation methods, capitation and salary were the next most common forms of physician payment, leaving VBR models at the bottom.[13] However, many physicians on capitation and salary payment models still receive benefits from increased volume.[14] Of the 31 primary care POs, 26 POs (nearly 84%) did include some form of incentives based on quality and cost effectiveness, although they accounted for (on average) just 9% of a physician's overall compensation and benefits.[15] Further, compensation plans for specialists within the POs studied relied more heavily on the volume of patients seen compared to the primary care providers.[16] Within the "quality" and "cost effectiveness" incentives studied by RAND were various subcategories; the most prominently incentivized subcategories included clinical quality and patient safety/patient experience/satisfaction.[17] However, these subcategories only added up to half of the total compensation incentives from VBC practices.[18]

The study highlights the issues with U.S. healthcare system's payment hierarchy, which includes payors at the top imposing payment policies onto health systems, which, in turn, pass those incentives down to the POs.[19] The problem, according to RAND, is that health systems often pass down the incentives, but not the larger payment model, to the POs.[20] The study noted the challenge of "translat[ing] risk-bearing payment arrangements and many measures of quality, utilization, or value to the individual physician level for payment purposes owing to limitations in panel sizes and reliability concerns with measuring individual physician performance."[21] In response, many health systems and physician practices position themselves "as a buffer between payers' incentives and physicians…[which] also likely contributes to the dominance of volume-based compensation and modesty of quality and cost performance incentives."[22] This leads to the current challenge facing the U.S. healthcare delivery system – how to incentivize VBC.

These study results are in direct contradiction to the longstanding narrative that the U.S. healthcare delivery system is shifting away from volume-based reimbursement and toward VBR. Over a decade after the passage of the ACA, the limited incentives for physicians to incorporate more VBC measures into their care routines is unsettling. Despite the low percentage of a physician's compensation that these incentives comprise, they are higher than before the ACA's passage.[23] It is difficult to change decades-old payment models, especially when considering that POs and health systems have undergone tremendous growth the last decade. This strong growth makes it all the more critical for health systems to incentivize patient volume to keep pace with competitors for market share, revenue, and physician retention. It is worth considering, however, that incentivizing physicians to incorporate VBC measures is not the only way health systems can affect patients' care experience. Other ways to improve the quality, safety, and outcomes of care include nonfinancial incentives, leadership incentives, and improving referrals and ordering support.[24]

The shift to VBR is certainly occurring, albeit much slower than expected. Nevertheless, many health systems and physicians are active in pursuing this shift. In response to RAND's study, Evident Health in California noted that physicians' minds are being changed, but there is still a long way to go.[25] Additionally, a physician and researcher at RAND noted that current physician compensation models are designed for volume, not value and emphasized the need to re-think payment models across health systems.[26] This comes at a time when many experts are pointing to evidence suggesting that more can be done at an organizational level to pass down value-based incentives (but not risk) to physicians, rather than keeping them.[27] Of course, that alone will not be enough to ensure a smooth transition to VBR.

As noted above, physician buy-in is crucial to the movement because many will not want to assume more risk if they are not appropriately compensated for it. Beyond physician buy-in is health system buy-in. While many systems are forced by payors, through VBR models, to incorporate VBC practices, health systems will need to know for certain that they can maintain revenue levels under a VBR model. The shift to value-based care is underway, but is by no means secure.

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2021 M&A in Review: Indications for 2022

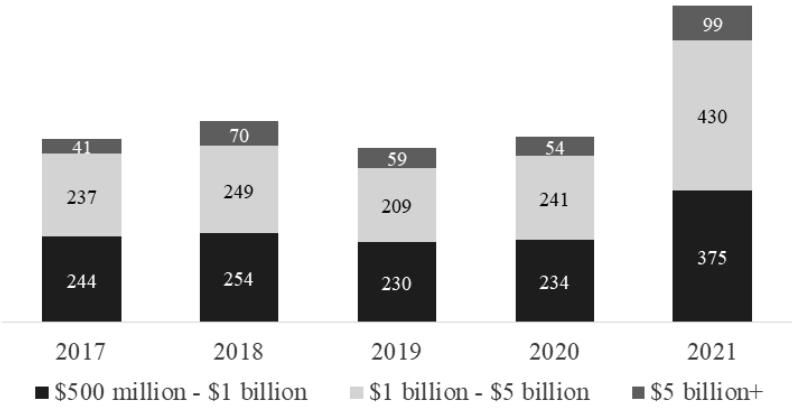
[Excerpted from the article published in February 2022.]

After an understandable slowdown in 2020, due to the onset of the COVID-19 pandemic,[1] merger & acquisition (M&A) activity in the healthcare industry accelerated in 2021, and the industry is expected to continue the high number of deals and high deal volume in 2022. This Health Capital Topics article will review the U.S. healthcare industry's M&A activity in 2021, and discuss what these trends may mean for 2022.

2021 M&A Activity

As set forth in the below exhibit, the overall number of healthcare deals were up significantly in 2021 (56% for the 12 months ending November 15, 2021) compared to 2020.[2]

Healthcare M&A Deals, 2017-November 15, 2021[3]



Deal value also increased 46%, with the healthcare sector-wide mean enterprise value to earnings before interest, taxes, income, depreciation, and amortization (EBITDA) multiple reaching 15.2x in 2021.[4] Overall deal value increases were driven by increases in managed care EBITDA multiples (up 2.9 to 16.6x) and in senior care (up 2.1 to 14.0x).[5] EBITDA multiples also decreased in the acute care, ambulatory care-rehab-dental, and lab-imaging-pharmacy subsectors, between 0.5 and 1.0x.[6] Despite the increases in these sectors, multiples were down in four of the seven subsectors tracked by global consulting firm PwC, although the multiples in many of sectors were still quite high; for example, home health/hospice subsector EBITDA multiples decreased 5.0, to 21.0x (a higher multiple than either the managed care or long-term care subsectors).[7]

2021 also saw significant growth in the number of healthcare megadeals (defined as deals valued at $5 billion or greater).[8] Several of those megadeals occurred in the contract research and manufacturing space, which was unsurprising based on the increase in products spurred by the COVID-19

pandemic (e.g., vaccinations, testing).[9] Some of the other notable megadeals included:

(1) Humana's acquisition of the remainder of Kindred at Home. Humana previously had a 40% stake and purchased the other 60% in 2021; and,[10]

(2) Two deals involving Walgreens Boots Alliance: a divestiture of Alliance HealthCare Services, a "comprehensive provider of outpatient radiology and oncology solutions for hospitals, health systems and physician groups,"[11] and an increased stake in VillageMD, a primary care business.[12]

Regarding publicly-traded companies, there were eight pure health services initial public offerings (IPOs) in 2021, an increase from 2020 (which saw only two IPOs), as well as previous years, which had no health services IPOs.[13] Additionally, 2021 continued 2020's trend of more and more deals backed by special purpose acquisition companies (SPACs).[14]

Across the healthcare sector, the most popular subsector in 2021 was long-term care.[15] There was also high growth in deals among physician practices, with over 400 deals in 2021 compared to 200-250 deals per year previously,[16] as well as in the managed care and rehabilitation subsectors.[17] Notably, the only subsector to decrease in deal volume in 2021 was hospitals and health systems,[18] with only 49 announced transactions; however, the size of these transactions increased from 2020 levels.[19] This is not altogether surprising as hospitals and health systems were largely distracted in 2021 by the ongoing COVID-19 pandemic and associated issues such as labor shortages and cost increases.[20] Consequently, it is also not surprising that nearly one-third of these transactions involved a rural or urban/rural seller (i.e., those hospitals and health systems that have been most acutely affected by the pandemic).[21]

Some of the major 2021 deals involving hospitals, health systems, and physicians included:

(1) Oak Street Health's $130 million acquisition of RubiconMD, a specialist network covering specialties such as cardiology, nephrology, and pulmonology;[22]

(2) Tenet Healthcare's $1.1 billion acquisition of SurgCenter Development's ambulatory business;[23]

(3) Steward Health Care's $1.1 billion acquisition of five hospitals and associated physician practices in South Florida from Tenant Healthcare; [24]

(4) The merger of Jefferson Health and Einstein Healthcare (which was finalized after the Federal Trade Commission [FTC] failed attempt to block the deal), resulting in a 18-hospital system in the Philadelphia area;[25] and,

(5) The merger of LifePoint Health and Kindred Healthcare. Among other moves, the merged parties broke off a new company called

ScionHealth, which will be comprised of 79 hospitals in 25 states, including 61 of Kindred's long-term acute care hospitals (LTACHs) and 18 of LifePoint's community hospitals.[26]

2021 Value Drivers

The M&A trends observed in 2021 indicated a number of value drivers, which may be useful in predicting the healthcare M&A landscape for 2022. First, as is often the case in healthcare, regulatory oversight may serve to slow down or outright prevent some deals. Overall deal timeframes have been expanding, due to the backlog of regulatory reviews by federal and state regulatory agencies.[27] Further, it is expected that the federal government may contest a greater number of mergers going forward, as a result of President Joe Biden's July 2021 executive order related to increasing competition across industries, including healthcare.[28] One section of that executive order encouraged the Department of Justice (DOJ) and the FTC to increase focus on antitrust issues related to hospital consolidation.[29] Similarly, the relatively new price transparency regulations established by the Centers for Medicare & Medicaid Services (CMS) may serve to shake up the competitive landscape with payors and providers, as reimbursement information that was previously private is now publicly available.[30]

Second, as noted above the COVID-19 pandemic continues to wreak havoc on the U.S. healthcare delivery system. One of the corollaries of the pandemic has been labor and supply chain shortages. These issues, which have had a significant, negative impact on healthcare in particular, may drive investment up and down the supply chain as providers seek to ensure continuity of services.[31] Additionally, the ongoing pandemic makes it harder to anticipate the future. Uncertainty as to when the public health emergency will end lends to uncertainty as to when the myriad regulatory relaxations and waivers that have been in place for nearly two years will also end.[32] Further, federal funds that have provided economic relief over the past nearly two years will likely dry up in 2022, potentially motivating some sellers who have been able to continue operations as a result of government funding.[33]

Third, the economic downturn likely contributed to the increase in the number of deals in 2021, and is expected to continue in 2022.[34] It has been previously established that deals tend to surge after an economic downturn.[35] Especially in an industry such as healthcare, which has historically been seen as largely "recession proof,"[36] an overall economic downturn will motivate both buyers (who may see opportunities to grow and/or invest) and sellers (who may see a need to sell or otherwise divest).[37]

Fourth, the continuing emergence of non-traditional healthcare providers such as Best Buy, Amazon, and Wal-Mart, may serve to shake up the healthcare sector.[38] These non-traditional healthcare players have made numerous large, strategic moves over the past several years to make a place for themselves in healthcare, and do not appear to be slowing down. Many of these companies first developed their own entities to address their and their employees' own healthcare needs, but then expanded their offerings to other companies and

individuals in hopes of being an agent of change in the wider U.S. healthcare system. With wide brand name recognition, these retail giants are poised to make a large impact in the healthcare sector.

What does this mean for 2022?

The trends and value drivers discussed above help set the scene for what could be a very eventful 2022. Overall, most industry analysts expect to see more deals in 2022, due to a continuance of the 2021 value drivers, as well as a continuation of high multiples.[39] Specifically, behavioral health is poised for a big year, given the well-documented access issues in that subsector; further, behavioral health has been an increasing target for startups looking to enter the market and shake up the status quo.[40] The home care subsector also anticipates more deals, due to increased Medicare payments in 2022.[41] Alternatively, in other subsectors, such as physician services, potential Medicare cuts may drive consolidation and PE roll-ups.[42]

PwC anticipates that 2022 M&A activity could be even bigger than 2021.[43] Per PwC's U.S. Pharmaceutical & Life Sciences Consulting Solutions Leader, it is anticipated that there will be a continuance of "[b]iotech and smaller medical device deals" in the first half of 2022, and larger deals in the back half of the year, "driven by a need for scale and an expected settling of the regulatory landscape."[44] Further, Rich Bayman, senior vice president and managing director with H2C Securities, Inc., expects "to see more merger-of-equals-type scenarios."[45] With the ongoing COVID-19 pandemic, whether these predictions will ultimately pan out remains to be seen.

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Declining Popularity and Uncertain Outlook for SPACs

[Excerpted from the article published in March 2022.]

In 2020, special purpose acquisition companies (SPACs) began tremendous growth and looked to be a new mainstream avenue of investing. Two years later, the growth of SPACs across all industries, including healthcare, has plateaued and appears to be dropping in some industries. This Heath Capital Topics article will examine how SPACs grew to their 2021 height in popularity and their future in a post-COVID world.

SPACs are companies set up by investors that do not produce or sell their own products.[1] Instead, these companies, also termed "blank check companies," are set up solely to raise money through their initial public offering (IPO) and the future acquisition of other companies.[2] SPACs typically have a deadline of two years after the IPO to find an acquisition deal, and shareholders vote to approve these deals.[3] They differ from traditional *initial public offerings* (IPOs), which sell shares of stock to generate capital and transfer the ownership of that company to the stockholders, or public ownership. In other words, while transitional IPOs must make their pitch to a myriad of potential investors, SPAC-related transactions must only convince one company – the SPAC.

The number of SPACs has grown exponentially over the past decade, with the establishment of 35 times more SPACs in 2020 than in 2010.[4] The most recent surge in popularity can be seen by contrasting the number and value of deals between the end of 2020 and the beginning of 2021. In the third quarter of 2020, there were 119 SPAC-related deals, with a value of $40 billion;[5] in the first quarter of 2021, there were 437 deals involving SPACs, with an estimated value of $129.6 billion – a 244% increase in value.[6] The growth and strong performance of SPACs has been largely attributed to the market uncertainty resulting from the COVID-19 public health emergency (PHE), creating challenges for companies to raise capital the traditional way and consequently leading them to SPACs.[7] Given their strong performance and growth, the outlook for SPACs was high through the latter half of 2021 and into 2022. However, as of the first quarter of 2022, the popularity of SPACs has plateaued. Thus far, there have been just 25 SPAC-related deals, with an estimated value of only $4.1 billion – down from the 437 deals worth nearly $130 billion reported around this time in 2021.[8]

The rise in SPACs has been attributed to the sense of security they provide by having all the necessary capital raised beforehand, the high uptick in market valuations for companies who join a SPAC, and the increase in reputable names joining SPACs.[9] However, the subsequent decline in SPAC popularity over the last year has highlighted growing concerns regarding a lack of transparency and less rigorous vetting processes for companies involved.[10] SPACs are not required to divulge as much information about their investments as traditional IPOs.[11] This is evidenced by some SPACs rapidly dropping in value after going public. One such example is Cano Health, which was valued at $4.4 billion when it went public in 2021, but is now worth less than half that.[12] Another

firm, SOC Telemed, has so severely underperformed that it recently announced it is reverting back to a private company.[13] In fact, roughly only half of all SPACs (across all industries) are value-creating, suggesting they are a risky investment.[14] Additionally, because of their reduced transparency and less rigorous vetting process, they struggle to curb fraud and other suspicious business activities.[15]

The stabilization of the financial markets post-COVID and the growing concerns mentioned above have limited the future prospects of SPACs. Since October 2021, only 20% of SPACs are trading at more than $10 a share, and over 80% of SPACs are trading at less than their expected value.[16] Further, research shows that SPACs are tightly bound to the technology industry, demonstrating an inability to conduct transactions with mature, non-technology businesses.[17] Another important factor in the decline of SPAC interest is the number of broken deals (i.e. agreed-upon deals that do not ultimately close), which has risen dramatically since the end of 2021 after remaining low in 2020.[18] Consequently, the number of SPAC deals, as well as the average value of these deals, is declining rapidly – in February 2022, the overwhelming majority of deals (9 of 10) were valued at less than $1 billion, a reversal from the last 24 months.[19]

Unlike some other industries, the rise of SPACs in recent years has significantly aided growth in the healthcare and biotechnology industries, allowing start-ups and emerging companies to go public quicker.[20] These industries have also been aided by the COVID-19 PHE and the shift to telehealth by demonstrating the need for new services and products.[21] Despite the growing concerns regarding SPACs and their popularity plateau in 2022, the healthcare industry seems to be defying the overall trends; as of March 2022, 52 SPACs are looking to make healthcare acquisitions contrasting all other sectors, which saw 20 cancelled deals in January alone.[22] While the overall number of healthcare SPAC deals may not reach 2021 numbers and value, it is expected that SPACs will likely continue playing a role in the industry, although the types of healthcare deals that are sponsored by SPACs may shrink.

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FTC Scrutiny Results in Several Scrapped Hospital Deals

[Excerpted from the article published in June 2022.]

A series of Federal Trade Commission (FTC) challenges to hospital mergers and acquisitions in 2022 indicates heightened regulatory scrutiny of hospital deals. Perhaps emboldened by the July 2021 executive order that focused attention on antitrust enforcement of hospital consolidation,[1] the agency has voted to challenge a number of transactions, which has lead hospitals to call off the deals rather than challenge the government. This Health Capital Topics article reviews three of the largest transactions called off this year, two of which were announced in June.

HCA's Cancelled Acquisition of Five Steward Hospitals

On June 16, 2022, Nashville-based HCA Healthcare announced that it was abandoning its proposed acquisition of five Utah hospitals from Dallas-based Steward Health Care System due to opposition from federal regulators.[2] Steward operates five hospitals in Salt Lake City while HCA operates eight hospitals, making it the second-largest system in the area.[3] The FTC voted unanimously to file suit to block the acquisition on June 2, 2022, alleging that the transaction "would eliminate the second [HCA] and fourth [Steward] largest healthcare systems in the Wasatch Front region, where approximately 80 percent of Utah's residents live… [and r]educe the number of healthcare systems offering inpatient general acute care hospital services," thereby decreasing competition and increasing costs.[4] The agency argued that this is especially important because HCA and Steward "compete for inclusion in insurer networks, and for health care quality, service lines, and nurse and physician recruitment."[5] However, if this deal were to close, the market concentration levels would increase significantly, as Steward would be eliminated as a low-cost competitor, enabling "HCA to command even higher reimbursement rates," which higher rates would likely be passed on by insurers to employers and beneficiaries through "increased premiums, deductibles, co-pays, and other out-of-pocket expenses."[6]

In a response to HCA and Steward's announcement, the FTC stated that this deal "should never have been proposed in the first place" and should be "a lesson learned to hospital systems all over the country."[7]

RWJBarnabas Health's Abandoned Acquisition of St. Peter's Healthcare System

The same week that HCA scrapped its acquisition plans, West Orange, New Jersey-based RWJBarnabas Health announced its decision to abandon its acquisition of St. Peter's Healthcare System in New Brunswick, NJ.[8] RWJBarnabas, a non-profit corporation, is one of the largest healthcare systems in New Jersey, operating 12 general acute care hospitals, numerous ambulatory surgery centers (ASCs), a pediatric rehabilitation hospital, and a freestanding behavioral health center.[9] St. Peter's University Hospital, also a non-profit system, is the only other hospital in New Brunswick, less than one mile from

RWJBarnabas.[10] As a result, the systems "are direct competitors and both systems routinely identify the other as the most significant competitor when assessing competition and strategizing on providing general acute care services in Middlesex County."[11]

The parties originally announced their plans in September 2020,[12] 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, this 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.[13] The FTC alleged that "There is overwhelming evidence that this acquisition would be bad for patients, because the parties would no longer have to compete to provide the lowest prices and the best quality and service."[14]

In announcing that RWJBarnabas would not move forward with the acquisition, CEO Barry H. Ostrowsky stated that the system is "disappointed in the termination of the proposed transaction, which we believe would have transformed quality, increased access and decreased the overall cost of care for the people of this State through the creation of a premier academic medical center… Despite the loss of this opportunity, RWJBarnabas Health remains resolute in its commitment to serve the people of New Jersey..."[15] Responding to the RWJBarnabas announcement, the FTC's Bureau of Competition Director stated, "I am glad that rival hospital systems RWJ and Saint Peter's have terminated an anticompetitive merger that would have harmed patients in Middlesex County… the transaction was presumptively unlawful and would have resulted in higher prices and lower quality of care for New Jersey residents."[16]

Lifespan and Care New England Health System's Scrapped Merger Plans

Earlier in the year, Lifespan and Care New England Healthcare System (CNE) walked away from their plans to merge, as a result of federal and state opposition. Non-profits Lifespan and CNE are the two largest providers in Rhode Island.[17] Together, the systems would have controlled at least 70% of the general inpatient care, outpatient surgery, and inpatient behavioral healthcare in the state; even expanding the market to include surrounding Massachusetts towns, the entities would control 60% of the inpatient market and 50% of the inpatient behavioral market.[18] In issuing a decision denying the proposed merger, the Rhode Island Attorney General stated that "[i]f this extraordinary and unprecedented level of control and consolidation were allowed to go forward, nearly all Rhode Islanders would see their healthcare costs go up for healthcare that is lower in quality and harder to access, and Rhode Island's healthcare workers would be harmed."[19] Further, in its joint suit with the Rhode Island Attorney General blocking the merger, the FTC argued that "the merger would increase the combined firm's ability to raise hospital rates, and individuals would likely face higher premiums, co-pays, and deductibles. Similarly, if…consummated, the combined healthcare system will

have reduced incentives to invest in vital non-price dimensions of competition, such as quality of care, access to services, and technology."[20]

Conclusion

This heightened antitrust scrutiny may result in a cooling period for hospital transactional activity. According to one antitrust attorney, "These (outcomes) have emboldened the FTC…Parties who were contemplating affiliations have to take into account the risk of an FTC challenge more than they had in the past. There is a deterrent effect that they are trying to cause."[21] The FTC's more aggressive stance seems to have had such an effect, with the hospital subsector seeing a decline in merger & acquisition activity over the past year.[22] As to how health systems will ultimately respond to these regulatory pressures, it is anticipated that more clinical affiliations and other informal partnerships will be pursued in lieu of full acquisitions.[23]

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FTC Discourages Certificates of Public Advantage Laws

[Excerpted from the article published in September 2022.]

On August 15, 2022, the Federal Trade Commission (FTC) published a policy paper and fact sheet regarding the use of Certificates of Public Advantage laws (COPAs) by states in regulating healthcare mergers. Specifically, the FTC asserts that COPAs can negatively impact healthcare costs, quality of care, and hospital staff wages.[1] This Health Capital Topics article will discuss the policy paper and how this publication appears to fit in with the FTC's recent moves to increase competition in healthcare.

Description of COPAs

The FTC defines COPAs as "regulatory regimes adopted by state governments intended to displace competition among healthcare providers, and immunize mergers and collaborations from antitrust scrutiny."[2] States will often use COPAs to permit certain hospital mergers to occur despite antitrust concerns, assuming that their regulatory oversight will mitigate any anticompetitive effects while allowing the hospital to attain certain efficiencies.[3]

COPAs were signed into law beginning in the 1990s. While numerous states have COPA legislation on the books, nine of those states have approved hospital mergers pursuant to a COPA.[4] Other states (including those who have previously put COPAs into use) have repealed COPA legislation; in fact, "[a]lmost all of the COPAs established prior to 2015 have expired or were repealed."[5] However, an unfortunate byproduct of those legislative repeals, according to the FTC, is that the "state regulatory oversight of the hospital systems that were allowed to merge under COPAs" was also eliminated.[6]

Description of FTC Policy Paper

The FTC operates as "an independent, bipartisan agency with a dual mission of promoting competition and protecting consumers."[7] Part of its work involves (along with the Department of Justice) challenging mergers and acquisitions, across all industries, that are "likely to substantially lessen competition and harm consumers."[8]

FTC began a "COPA Assessment Project" in 2017 to "assess the impact of COPAs on prices, quality, access, and innovation for health care services."[9] As part of that project, the agency held a public workshop wherein staff sought public comment on a number of issues, including:

(1) The effects of COPAs in terms of price, cost, and quality of healthcare services; access to healthcare services; and innovations in healthcare delivery models, as well the measurement of these effects;

(2) The amount of time, as well as the commitment of resources and expertise, required to implement and monitor the effectiveness of COPAs;

(3) The long-term viability of COPAs and likelihood that states will oversee COPAs in perpetuity;

(4) The impact to healthcare markets following the expiration or repeal of COPAs, when the state is no longer monitoring the behavior of the healthcare providers;

(5) The public reaction to COPAs, and whether that is incorporated into state oversight; and

(6) Whether healthcare services competition is more or less effective than regulation in lowering prices, costs, and expenditures; improving quality and access; promoting efficient resource allocation; and fostering innovation in delivery models.[10]

Further, as part of the Assessment Project, the FTC conducted a number of case studies on both recently-approved COPAs and the effect of rescinded COPAs. Summaries of some of these studies were included in the policy paper that the FTC published on August 15th, which paper appears to be the culmination of the agency's 5-year assessment project. In general, the agency found that COPAs "are often unsuccessful in mitigating merger-related price and quality harms" and when COPAs are rescinded, "the risk of price and quality harms increases significantly because of the absence either of the preexisting competition or regulation."[11] More specifically, the FTC listed five "reasons to be skeptical" of COPAs:

(1) "COPAs exacerbate the widespread problem of hospital consolidation," as studies have identified several harms that can arise from hospital consolidation;

(2) "COPAs can reduce hospital employee wage growth," when fewer hospitals compete for workers;

(3) "COPA monitoring and compliance are difficult," as effective oversight requires the state to have significant expertise and resources;

(4) "COPAs are susceptible to regulatory evasion," as COPA regulation is not sufficiently comprehensive to address all ways in which hospitals exercise market power; and

(5) "COPAs are only temporary," because they are eventually repealed, revoked, or terminated.[12]

The policy paper also addressed the "flawed" arguments that hospitals typically make in favor of COPAs. First, the FTC cited research findings that hospital mergers often do not result in cost savings and efficiencies, in contrast to hospital claims.[13] Second, the agency dismissed assertions that hospitals must merge to ensure financial sustainability and achieve healthcare reform objectives, stating that:

> "[i]n each of the last four hospital mergers the FTC investigated that received a COPA, and in our experience more broadly, hospitals seeking COPAs have had adequate financial resources to continue operating independently and to maintain quality and access to healthcare services…Indeed, if a hospital is truly failing financially and the proposed merger is the only way for it to remain viable, the FTC is unlikely to

> challenge such a merger and the hospital does not need COPA protection against antitrust enforcement."[14]

Third, hospitals argue that proposed mergers would "create jobs and ensure local access to healthcare facilities and services"; in contrast, the FTC's experience has been that hospitals tend to consolidate facilities and jobs, and eliminate services, in order to achieve post-transaction cost savings.[15] Fourth, although hospitals assert that a merger would result in a larger combined patient base, enabling them to improve population health efforts and facilitate value-based payment models, the FTC cites empirical research finding the opposite, and adds that value-based payment models are already occurring and, in some cases, are being mandated by the Centers for Medicare & Medicaid Services (CMS).[16] Fifth, in response to hospital claims that mergers eliminate unnecessary and duplicative costs, the FTC points to research findings that "[m]any hospital mergers do not result in significant cost savings," and in fact, other studies have found that hospital competition leads to improved health outcomes.[17]

In sum, the FTC recommends that states repeal existing COPA laws, so long as an active COPA is not in place.[18] The FTC cites extensive evidence indicating that "[i]n the long run, hospital mergers shielded with COPAs often lead to higher prices and reduced quality from unconstrained provider market power,"[19] in its appeal to state lawmakers to "avoid using COPAs to shield otherwise anticompetitive hospital mergers."[20]

Part of Bigger FTC Strategy?

The FTC has made a number of different 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; [21] the FTC is currently reworking its merger guidelines, which are anticipated to result in stricter oversight;[22] and emboldened FTC scrutiny of hospital mergers has resulted in a number of scrapped hospital deals over the past year.[23] It seems that the FTC's COPA policy paper is yet another indication of the administration's focus on enhancing competition in the healthcare industry.

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V. TECHNOLOGY TOPICS

Additional $20 Million Directed to Rural Telehealth Expansion

[Excerpted from the article published in September 2021.]

Amazon, the largest e-commerce company in the world,[1] has made large, It has been well documented that the COVID-19 pandemic resulted in unprecedented increases in telemedicine utilization across the U.S.[2] However, rural providers and patients, as evidenced by their lower rates of telemedicine usage during this time, have not been able to take advantage of the opportunities provided by telemedicine to the same extent as urban providers.[3] On August 18, 2021, the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (HHS) announced the latest attempt to ameliorate this issue – the distribution of nearly $20 million to 36 recipients for the purpose of strengthening telehealth services in rural and underserved communities and expanding innovation and quality.[4]

The $20 million will be distributed as follows:

(1) Approximately $4.28 million will be allocated to nine healthcare organizations and used to build "tele-mentoring" programs and networks, which will help specialists at academic medical centers train and support primary care providers in rural and underserved areas that are treating patients with conditions such as long COVID and substance use disorders;

(2) Approximately $4.55 million will be allocated to 12 regional and two national Telehealth Resource Centers (TRCs), which "provide information, assistance, and education on telehealth to organizations and individuals who are actively providing or want to provide telehealth services to patients."

(3) Approximately $3.85 million will be allocated to expanding primary, acute, and behavioral telehealth services in 11 states by way of "updat[ing] technology in rural health clinics, train[ing] doctors and nurses how to conduct telehealth appointments and teach[ing] patients how to take advantage of virtual appointments when they cannot see a doctor in person;" and,

(4) $6.5 million will be granted to the University of Mississippi Medical Center and the Medical University of South Carolina to improve healthcare in the rural and underserved areas of their states that have high rates of both chronic disease and poverty. Toward that end, these universities will establish Telehealth Centers of Excellence that will "serve as telehealth incubators to pilot new telehealth services, track outcomes, and publish telehealth research." The universities will also "establish an evidence base for telehealth programs and a framework for future telehealth programs."[5]

This announcement is just the latest installment in efforts to expand telehealth to rural areas since the start of the COVID-19 pandemic. Over the past 18 months, a number of federal spending bills have included money directed to

rural providers generally, and rural telehealth programs specifically. The Coronavirus Aid, Relief, and Economic Security (CARES) Act, signed into law in March 2020, appropriated nearly $500 million for various endeavors related to rural telehealth expansion. Approximately $165 million was distributed by HRSA to rural hospitals and TRCs to "provide technical assistance on telehealth to help rural and underserved areas combat COVID-19."[6] Additionally, the Federal Communications Commission (FCC) received $200 million for the purpose of expanding telemedicine services and infrastructure and $100 million to finance a three-year Connected Care Pilot program, which will subsidize internet connectivity for healthcare providers.[7]

The more recent American Rescue Plan, signed into law in March 2021, also included funds for rural telehealth expansion. Approximately $500 million was allocated to the U.S. Department of Agriculture to create the Emergency Rural Health Care Grant Program.[8] This program "will provide at least $350 million to help rural hospitals and local communities increase access to…telehealth," among other items.[9] Another $52 million was allocated to HHS to create "rural health networks," which will focus in part on "expanding the workforce to support virtual and telehealth systems."[10] Additionally, approximately $14.2 million was allocated to HRSA to expand Pediatric Mental Health Care Access projects, which will provide (among other things) teleconsultations by pediatric mental health teams to pediatric primary care providers in the diagnosis, treatment, and referral of pediatric patients with mental health conditions and substance use disorders.[11]

In addition to the allocation of financial resources, federal agencies are working to expand rural telehealth knowledge, access, and coverage. For example, the National Institutes of Health will be holding public workshops in October 2021 to "identify ways to improve rural health through telehealth-guided provider-to-provider communication."[12] Additionally, the Centers for Medicare & Medicaid Services (CMS) is proposing to expand access to telehealth mental health services for rural and underserved Americans by expanding coverage under the 2022 Medicare Physician Fee Schedule (MPFS).[13] If finalized, CMS will allow patients to access telehealth mental services from their home, rather than traveling to a rural health clinic or federally-qualified health center to access the telehealth platform.

HHS hopes that this latest $20 million investment will help increase access for the approximately 15% of Americans who live in rural areas and are some of the oldest and sickest in the U.S.[14] Rural patients, who have the greatest need for telehealth services, still struggle to access telemedicine due to limited broadband availability. On the supply side, the up-front costs of the hardware, software, and human resources needed to offer telehealth services may also be a steep barrier for providers, and particularly for those in rural areas. Whether these funding initiatives will serve as a panacea for rural healthcare access, especially given the uncertainty of expanded coverage and reimbursement post-COVID-19,[15] remains to be seen.

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The End of Amazon Care: A Setback in Amazon's Healthcare Experiment?

[Excerpted from the article published in September 2022.]

On August 24, 2022, Amazon announced its plans to shut down Amazon Care at the end of 2022.[1] The e-commerce giant determined that Amazon Care, a medical care service it uses internally and sells to employer health plans, was not the "right long-term solution for [Amazon's] enterprise customers" because it is not a "complete enough offering for the large enterprise customers [Amazon has] been targeting."[2] This Health Capital Topics article will discuss the history of Amazon Care and what this move may mean for Amazon's larger healthcare efforts.

Amazon rolled out Amazon Care in 2019 as a pilot employee benefit for their own employees.[3] The service is a combination of virtual and in-person care, offering home health services, telehealth appointments, and prescription delivery.[4] 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.[5] The program expanded quickly, from servicing only their Seattle area employees and dependents to non-Amazon employers across the U.S. (including large companies such as Hilton, TrueBlue, and Silicon Labs) by 2021.[6]

The August 24th announcement comes as a shock, as Amazon 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.[7] The company was also working to add behavioral health support to Amazon Care through a partnership with Ginger, a mental health company.[8] Further, in July 2022, Amazon announced an expansion of its primary care services through a $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."[9] Amazon Care executives have stated that the issues that led to the decision to end Amazon Care preceded, and are separate from, the company's decision to purchase One Medical.[10] Nevertheless, some health tech investors theorize that there would have likely been some overlap between One Medical and Amazon Care "that may have been awkward to navigate," had they co-existed.[11]

As one tech industry pundit noted, "Amazon is known for sticking to a long-term vision while experimenting with different approaches to achieve its goals."[12] True to form, Amazon Care is not the only healthcare initiative that Amazon has abandoned. The Haven joint venture, formed between Amazon, Berkshire Hathaway, and JPMorgan Chase, disbanded in January 2021, three years after its formation.[13] The goal of Haven was to tackle high and increasing costs for employee healthcare.[14] While the joint venture did not live up to some expectations, it may have informed its three partners on how to better create healthcare systems for their respective employees.[15]

While the end of Amazon Care is not anticipated to impact Amazon's other healthcare projects, insights from these ventures will likely be important for Amazon as it continues its attempts to disrupt the healthcare industry. In fact, it appears that Amazon may already have its next big healthcare move in sight, as the company has been reported to be one of the bidders (along with CVS and UnitedHealth Group) for Signify Health, an in-home health assessments provider, which deal is anticipated to surpass $8 billion.[16] Perhaps the closing of the Amazon Care door is a necessary step to opening another, larger door into primary care.

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Telehealth's Post-Pandemic Outlook

[Excerpted from the article published in St. Louis Metropolitan Medicine.]

Introduction

Telemedicine has rapidly advanced over the past couple of decades. These virtual services have the potential to allow greater access to, and quality of, care, while also resulting in significant cost savings. However, the technology also has numerous challenges, such as infrastructure gaps, capital requirements, and knowledge barriers among patients. The utilization of this technology significantly accelerated since the COVID-19 pandemic struck the U.S. in March 2020 due to a number of regulatory relaxations and changes. The popularity of this service line over the past year has spurred conversation regarding telehealth's place in the healthcare industry at the conclusion of the COVID-19 public health emergency (PHE).

Review of Telehealth Expansions & Relaxations

In response to the COVID-19 pandemic, and in an effort to help medical practices whose revenue was decimated as a result of canceled in-person office visits, provide backup to hospital providers who were overwhelmed by the virus, and provide patients with an alternative to in-person medical treatment (without the risk of infecting themselves or others), federal and state governments enacted an array of regulatory waivers, relaxations, and expansions related to telehealth. Some of those actions include:

(1) The $8.3 billion Coronavirus Preparedness and Response Supplemental Appropriations Act gave authority to the Secretary of Health and Human Services (HHS) to lift some telehealth delivery restrictions, such as the "originating site" requirements for telehealth services.[1]

(2) The $2 trillion Coronavirus Aid, Relief and Economic Security (CARES) Act included a number of additional provisions related to telehealth services such as:

   (a) Allocating $200 million to the Federal Communications Commission (FCC) for telehealth development support;

   (b) Waiving the requirement that a physician must have treated a patient within the last three years to receive payment for telehealth;

   (c) Allowing hospice care to be recertified via telehealth; and,

   (d) Expanding eligibility for home dialysis patients to receive telehealth.[2]

(3) Centers of Medicare & Medicaid Services (CMS) Guidance – CMS issued new rules and waived other rules, effective through the end of the PHE, that:

   (a) Allows beneficiaries to receive care wherever they were located, including in their home;

   (b) Allows physicians to treat patients (both new and established) outside of the state in which they are licensed;

   (c) Expands the types of providers that can conduct telemedicine visits to include physical therapists, occupational therapists, and speech language pathologists;

   (d) Expands telemedicine reimbursement coverage to 135 new services, including emergency department visits;

   (e) Establishes a pay parity rule for telemedicine visits, so they are reimbursed at the same rate as in-person visits; and,

   (f) Extends coverage to over 80 additional services, including emergency department visits, initial visits, discharges from nursing facilities, and home visits.[3]

(4) Drug Enforcement Agency (DEA) Guidance – Allows physicians to prescribe controlled substances via telemedicine, without an in-person examination.[4]

(5) State Waivers – 41 states enacted waivers for out-of-state physicians, preexisting relationships, and audio-only requirements.[5]

(6) August 3, 2020 Executive Order – Allows some of the 135 telehealth services that were originally waived on a temporary basis to be permanently delivered via telemedicine technology going forward.[6]

(7) The 2021 Medicare Physician Fee Schedule (MPFS) final rule – Added numerous telemedicine procedure codes, either permanently or temporarily, to those currently covered by Medicare.[7]

Post-Pandemic Interest in Telehealth

Over the past year, a multitude of studies have been conducted related to the utilization, efficiency, and quality of telehealth. Analyses suggest that telehealth could be further expanded in the coming years, with anywhere from $106 billion up to $250 billion of current U.S. healthcare spending that could be "virtualized" (up from $29 billion in 2020).[8] This is in part due to the popularity that telehealth has achieved among patients, providers, and payors, although to differing degrees. The interest of each of these stakeholders in continuing the level of telehealth services currently in place, as well as the federal government's appetite for extending, or even expanding, the coverage of and payment for telehealth, will significantly drive the future outlook for these services.

Patient Interest

While patients were relatively apathetic toward telehealth prior to the COVID-19, exposure to the technology has largely changed their minds. Approximately 61% of patients have accessed telehealth services as of March 2021 (compared to only 11% in 2019);[9] importantly, 74% of those who utilized telehealth reported high satisfaction.[10] Going forward, nearly 88% of survey respondents want to continue using telehealth for non-urgent consultations post-pandemic.[11]

Despite these assertions, the number of telehealth visits dropped precipitously in the latter part of 2020 as patients felt comfortable enough to return to in-office visits.[12] In particular, telehealth usage among privately-insured individuals fell approximately 18.6% and 15% in January and February 2021, respectively.[13] Further, future reforms will still likely rescind the current waiver allowing telehealth visits via FaceTime, Zoom, and other non-HIPAA-compliant platforms, which may make virtual care less convenient for patients, further deteriorating their asserted interest.[14]

Provider Interest

Similar to patients, providers' interest in telehealth has also increased, with a study reporting that 54% of providers view telehealth more favorably, and 64% are more comfortable using it, than before COVID-19.[15] However, the extra work required of non-physician providers to serve patients via telehealth, and the impending requirement that telehealth services be performed on a HIPAA-compliant platform, may erode that desire to continue providing telehealth services. A recent analysis of nursing activities performed for Type 2 diabetes and hypertension patients found that nurses performed approximately twice as many activities with telehealth patients compared to in-person patients.[16] This additional work could result in additional nurse burnout, accelerating staffing shortages.[17] Further, as any future reforms will still require the use of HIPAA-compliant platforms,[18] requiring providers to come up with the capital necessary to purchase a telehealth-specific platform may serve as an unscalable barrier, especially for smaller practices.

These required resources to operate telehealth services going forward may be moderated by recent research indicating that practices utilizing telehealth may secure more downstream (i.e., follow-up) care. An analysis of privately-insured patients between 2016 and 2019 found that those who used telehealth for upper respiratory infections were more likely to attend an in-person visit within seven days (10%) than those who sought in-person care (5.9%).[19] Researchers did not quantify the value of the follow-up care, but they did note that the telehealth cohort had fewer emergency department visits (0.5% versus 0.6%) and more subsequent office, urgent care, and telemedicine visits.

Payor Interest

Private Payors

Prior to the COVID-19 pandemic, most private payors offered some level of telehealth coverage. Due to the federal government's outsized presence in the healthcare marketplace, most private payors tend to follow Medicare's lead on

reimbursement, so when Medicare expanded telehealth beginning in March 2020, most private payors did the same. However, private payors have largely already ended their temporary telehealth expansion policies.[20]

Additionally, while private insurers remain interested in telehealth, their alignment focus has largely been with telemedicine companies, and not providers. Therefore, private reimbursement for telehealth services may not be a windfall for practices, as payors may direct patients to their own platform that utilizes health plan-employed providers.[21]

Public Payors

CMS in particular has indicated its interest in maintaining some of the telehealth expansions and relaxations it put in place during the PHE. For example, the 2021 MPFS permanently added over 60 services to the Medicare telehealth list.[22] Additionally, CMS announced in December 2020 that it was commissioning a study of the telehealth flexibilities it has provided during the COVID-19 pandemic, which "will explore new opportunities for services where telehealth and virtual care supervision, and remote monitoring can be used to more efficiently bring care to patients and to enhance program integrity," [23] indicating the agency's belief that telehealth will endure past the end of the pandemic.[24]

However, as CMS has pointed out, "Medicare does not have the statutory authority to pay for telehealth to beneficiaries outside of rural areas or, with certain exceptions, allow beneficiaries to receive telehealth in their home."[25] Therefore, congressional intervention may be required for more fundamental changes to telehealth coverage.

Congressional Interest

Congress has also indicated some willingness to expand telehealth coverage over the past year in a slew of proposed (largely bipartisan) legislation. To date, the Alliance for Connected Care has identified 19 telehealth-related bills,[26] the most notable of which are summarized below:

(1) *Telehealth Modernization Act* (Senate Bill) – Would allow: rural health clinics and federally qualified health centers to serve as the distant site; a beneficiary's home to serve as the originating site for all services (other than for only certain services); and all types of practitioners to furnish telehealth services.[27]

(2) *Protecting Access to Post-COVID-19 Telehealth Act* (House Bill) – Would eliminate most geographic and originating site restrictions on Medicare coverage and include the patient's home as an eligible distant site;[28] and,

(3) *The Expanded Telehealth Access Act* (House Bill) – Would permanently expand Medicare-covered telehealth services for physical therapists, occupational therapists, audiologists, and speak and language pathologists.[29]

Despite this activity, lawmakers have expressed concerns related to telehealth expansion, including whether it may lead to overutilization of healthcare services, result in healthcare fraud and abuse, or intensify current disparities in healthcare.[30] Some industry commentators believe that specific areas of telehealth, where physical examinations are not needed (such as behavioral health and chronic care management), may be an easier sell.[31]

Conclusion

Telehealth technology has undoubtedly been one of the few beneficiaries of the COVID-19 pandemic. The significant number of actions taken over the past year to relax regulatory and reimbursement restrictions has resulted in a windfall of demand for telehealth providers, and may be unfeasible to reverse at the conclusion of the pandemic, as patients and providers become more comfortable with the new technology; as has been seen time and again in healthcare, once industry stakeholders get used to a new benefit or technology, it is extremely difficult to take it away.

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VI. About
Health Capital Consultants

FIRM PROFILE

HCC HEALTH CAPITAL CONSULTANTS

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

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

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

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

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  - Compensation for professional clinical services, including physician administrative services, executive administrative services, board positions, and other healthcare related services;
  - Tangible and intangible assets, including covenants not to compete, rights to first refusal, and intellectual property;
- Commercial Reasonableness opinions;
- Accountable Care Organization (ACO) value metrics, capital formation, and development and integration;
- Financial feasibility analyses, including the development of forecasts, budgets and income distribution plans;
- Healthcare provider related merger and acquisition services, including integration, affiliation, acquisition and divestiture;
- Certificate of Need (CON) and related regulatory consulting;
- Litigation support and expert witness services; and,
- Industry research services.

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

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

Mr. Zigrang is the co-author of "*The Adviser's Guide to Healthcare – 2nd Edition*" [AICPA - 2015], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Guide to Valuing Physician Compensation and Healthcare Service Arrangements* (BVR/AHLA); *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *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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Jessica L. Bailey-Wheaton, Esq., is Senior Vice President & General Counsel of HCC, where she focuses on project management and consulting services related to the impact of both federal and state regulations on healthcare exempt organization transactions, and research services necessary to support certified opinions of value related to the Fair Market Value and Commercial Reasonableness of transactions related to healthcare enterprises, assets, and services. She has presented before associations such as the American Bar Association and NACVA.

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

Janvi R. Shah, MBA, MSF, is Senior Financial Analyst of HCC where she prepares, reviews and analyzes forecasted and pro forma financial statements to determine the most probable future net economic benefit related to healthcare enterprises, assets, and services and applies utilization demand and reimbursement trends to project professional medical revenue streams and ancillary services and technical component revenue streams. In addition she performs financial and operational benchmarking using public company comparables and/or normative industry benchmark survey data. Mrs. Shah holds a M.S. in Finance from Washington University Saint Louis.

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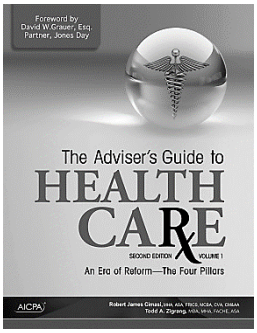

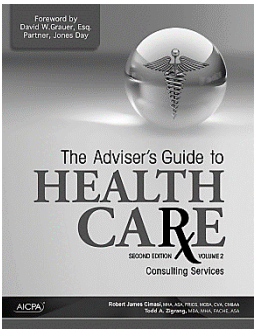

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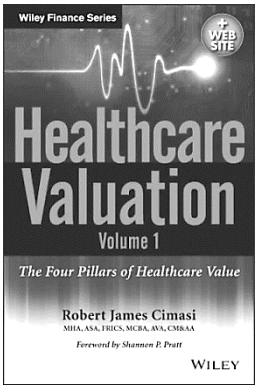

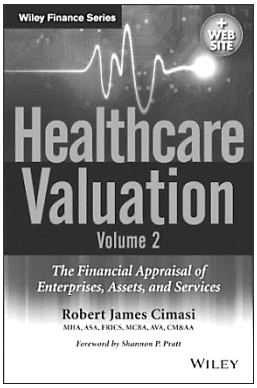

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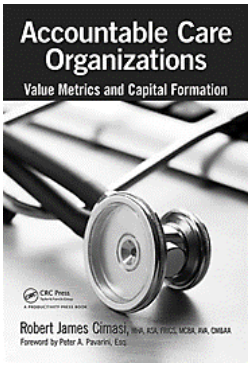

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