2024

written by the professionals of

Providing Solutions in an Era of Healthcare Reform

314-994-7641
1807 Park 270 Drive, Suite 110, St. Louis, MO 63146

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 another year of service, the entire team at **Health Capital Consultants** dedicates this 13th edition of Health Capital Topics to the many clients nationwide whom we have had the privilege to serve; to their attorneys, accountants, consultants, and vendors with whom HCC has worked to serve the needs of the projects we undertake on their behalf; and, to our professional colleagues nationwide, who both inform and inspire us toward excellence.

Preface

Health Capital Topics is a monthly e-journal, which has been published by **Health Capital Consultants** since 2007, featuring timely topics related to the regulatory, reimbursement, competition, and technology aspects of the U.S. healthcare delivery environment. It is sent monthly to over 20,000 healthcare executives, physicians, attorneys, accountants, and other professionals in the healthcare industry. Past issues of the Health Capital Topics e-journal, as well as special alert issues, may be found at www.healthcapital.com.

Acknowledgements

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

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

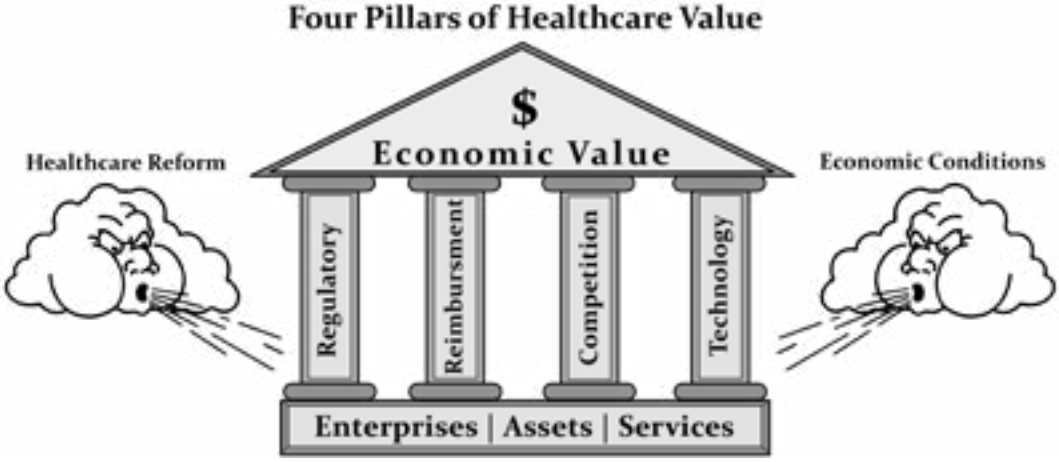
Janvi R. Shah, MBA, MSF, CVA, Senior Financial Analyst, has excelled in representing HCC throughout numerous healthcare client engagements, assisted with research, writing, review, and comments.

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

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

Introduction

In 2024, we at **Health Capital Consultants** (HCC) have witnessed, and our clients have experienced, industry changes in each of the Four Pillars i.e., regulatory, reimbursement, competition, and technology. See figure below.



U.S. healthcare providers are facing a growing financial strain due to ongoing reimbursement cuts across a wide range of medical specialties. While these measures are often framed as necessary for controlling healthcare costs, they do not take into account heightened inflation or the rising costs encountered by providers, leading to significant operational challenges. In 2024, the healthcare regulatory environment experienced numerous high-profile court decisions and an historical $2.68 Billion received in False Claims Act settlements and judgments. Competition in healthcare continues to be highly scrutinized, with federal and state governments taking steps to more closely regulate private equity's role in healthcare transactions. Despite increased governmental efforts, both traditional and non-traditional healthcare organizations continue to align, albeit more creatively. Technology became even more of a mainstay of healthcare delivery, with many providers fully integrating telehealth services into their care models, allowing patients to access a wide range of services, from routine check-ups to mental health counseling, and seamlessly submit data via wearables and other devices. This book is a selection of some of the changes mentioned above that have impacted how our clients operate and our considerations when performing valuations of healthcare enterprises, assets, and services.

At HCC, we strongly believe that in developing an understanding of the forces and stakeholders that have the potential to drive healthcare markets, especially during a time of such uncertainty, it is useful to examine what value may be attributable to healthcare enterprises, assets, and services as they relate to the Four Pillars of the healthcare industry, i.e., regulatory, reimbursement, competition, and technology.

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

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,

Valuation Topics

Reimbursement Topics

Regulatory Topics

Competition Topics

Technology Topics

About HCC

Valuation Topics

Valuation of Accountable Care Organizations: Introduction

[Excerpted from the article published in June 2023.]

As the U.S. healthcare system continues to shift its reimbursement scheme from traditional fee-for-service (FFS) payment to value-based alternative payment models, one value-based alternative payment model that has gained popularity since its establishment by the Patient Protection and Affordable Care Act (ACA) is the accountable care organization (ACO).[1] In general, the ACO model holds groups of healthcare providers responsible for the quality and cost of healthcare delivery provided to an ACO's patient population.[2] ACOs are controlled by the provider members who work together to control costs, improve quality, and coordinate care, and those that achieve the spending and quality targets designated by payors receive a share of the savings.[3] Most ACOs adhere to one of three primary structures: (1) hospital-led; (2) physician-led; and (3) jointly-led.[4] ACOs vary significantly in the services delivered to patients and the types of providers included in an ACO group, as well as in their range of capabilities, which may include care management, advanced analytics, and shared interdisciplinary decision making.[5]

On average, ACOs are associated with improved patient satisfaction and other patient-reported measures.[6] Many of the gains related to ACOs are concentrated in high-need, high-cost populations.[7] However, there is significant variance in ACO performance, with some ACOs achieving savings and others spending far more after formation.[8]

Most ACOs participate in government programs offered by the Centers for Medicare and Medicaid Services (CMS).[9] Currently, there are two CMS-run ACO models: (1) the Medicare Shared Savings Program (MSSP) and (2) the Realizing Equity, Access, and Community Health (REACH) Model.[10] As of 2023, 456 ACOs participated in the MSSP and 132 ACOs participated in the REACH Model.[11] There are multiple MSSP participation options (tracks), split into *Basic* and *Enhanced* Tracks.[12] The *Basic Track* is further divided into five track levels: A, B, C, D, and E.[13] Financial risks associated with the different tracks are set forth below.

Comparison of MSSP Tracks[14]

Characteristic	Basic Track Level A	Basic Track Level B	Basic Track Level C	Basic Track Level D	Basic Track Level E	Enhanced Track
Shared Savings Cap	10% of benchmark	10% of benchmark	10% of benchmark	10% of benchmark	10% of benchmark	20% of benchmark
Shared Losses Cap	Not Applicable	Not Applicable	Lesser of 2% of total Medicare Parts A & B FFS Revenue or 1% of benchmark	Lesser of 4% of total Medicare Parts A & B FFS Revenue or 2% of benchmark	Lesser of 8% of total Medicare Parts A & B FFS Revenue or 4% of benchmark	15% of benchmark
Type of APM	MIPS	MIPS	MIPS	MIPS	Advanced	Advanced
Risk-Sharing Agreement	1st dollar savings up to 40% with no loss sharing	1st dollar savings up to 40% with no loss sharing	1st dollar savings up to 50% with 1st dollar losses at 30%	1st dollar savings up to 50% 1st dollar losses at 30%	1st dollar savings up to 50% 1st dollar losses at 30%	1st dollar savings up to 75% 1st dollar losses at 40-75%

CMS's determination of which ACO track applies to a participating ACO depends on the experience of ACO and whether the ACO is Low Revenue or High Revenue.[15] High Revenue ACOs are ACOs with total Medicare FFS revenue of at least 35% of the total Medicare FFS expenditures for the ACO's assigned beneficiaries.[16] Low Revenue ACOs are any ACOs below this 35% threshold.[17] This distinction in ACO revenue is important because High Revenue ACOs will be required to assume downside financial risk, as CMS assumes that High Revenue ACOs can control spending more efficiently, and thus can assume more financial risk.[18]

Further, as an ACO moves across the MSSP track levels and takes on more risk, there are a number of waivers and beneficiary incentives available. For example, the skilled nursing facility (SNF) three-day waiver eliminates the requirement for a three-day inpatient hospital stay prior to extended-care services provided to Medicare beneficiaries.[19] The rule waiver allows for ACO participant hospitals to partner with SNFs to reduce inpatient costs. Additionally, the Beneficiary Incentive Program allows ACOs accepting downside financial risk to directly provide incentive payments up to $20 to Medicare beneficiaries to ensure beneficiaries have access to primary care resources.[20]

It is important to note that Advanced APM status is only available to the MSSP ACOs assuming downside risk.[21] Providers who participate in an Advanced APM through the Quality Payment Program (QPP), which was established by the *Medicare Access and CHIP Reauthorization Act* (MACRA), do not have to participate in the QPP's alternative program, the *Merit-based Incentive Payment System* (MIPS), which also has certain quality reporting requirements and resulting payment adjustments.[22] Most importantly, participation in the Advanced APM program provides for an additional 5% incentive bonus for ACO providers.[23]

In 2022, CMS announced their redesign of the Global and Professional Direct Contracting (GPDC) Model to advance the agency's priorities, e.g., advancing health equity.[24] The GPDC Model was renamed ACO Realizing Equity, Access, and Community Health (REACH).[25] The REACH Model focuses on changes in three important areas: (1) advancing health equity to ensure the benefits of ACOs reach underserved communities; (2) promoting governance and leadership by providers; and (3) vetting participants to protect beneficiaries of the program, greater overall transparency, and monitoring.[26] The first performance year of this model began January 1, 2023.[27]

The model serves Standard ACOs, High Needs Population ACOs, and New Entrant ACOs.[28] There are two voluntary risk options available, where providers receive ACO compensation because they accepted claims reductions from Medicare.[29] The first risk option, the Professional Option, is lower risk, with 50% savings/losses and a risk-adjusted monthly payment, called the Primary Care Capitation Payment (PCCP), for the primary care services provided by ACO participants.[30] The second option is a higher risk-sharing agreement, with 100% savings/losses, with two forms of payment: the PCCP or a Total Care Capitation Payment (TCCP), a risk-adjusted monthly payment for all services, including specialty care.[31]

Comparison of ACO REACH Tracks[32]

Characteristic	REACH Professional	REACH Global
Shared Savings Cap	Cap (Savings/Losses): 50%, 35% 15%, 5%	Cap (Savings/Losses): 100%, 50%, 25%, 10%
Shared Losses Cap		
Type of APM	Advanced	Advanced
Risk-Sharing Agreement	1st dollar savings and losses at 50%	1st dollar savings and losses at 100%

Early estimates, which projected a rapid growth in the number of ACOs, missed the mark significantly. Initial estimates projected that ACOs would cover over 70 million people by 2020;[33] however, as of 2019, ACOs only covered 44 million lives.[34] Moreover, growth has slowed in recent years, driven by decreases in ACO contracts.[35] Reductions in ACO contracts are primarily driven by providers' reluctance to participate in ACO arrangements that involve downside risk.[36] Many small- to medium-sized ACOs no longer see the value in participating in ACO contracts with Medicare,[37] and primary care focused ACOs are moving to the other models offered by Medicare, such as the Primary Care First Model.[38] However, many physician-led ACOs have remained in Medicare's ACO programs despite increased downside risk, and more physician-led ACOs have chosen to take on downside risk compared to hospital-led ACOs.[39] The trend may reflect the fact that physician-led ACOs significantly outperform hospital-led ACOs, making downside risk less of a concern.[40] The second installment of this five-part series will cover the supply and demand driving the competitive environment of ACOs.

Valuation of Accountable Care Organizations: Competition

[Excerpted from the article published in July 2023.]

As of the first quarter of 2022, 1,010 accountable care organizations (ACOs), comprising 1,760 private and public ACO contracts that covered 32 million beneficiaries, operated across the U.S.[41] The majority of these ACOs were physician-led (41%), rather than hospital-led (26%) or jointly-led (27%) ACOs.[42] While the number of ACOs have steadily increased over the past several years, ACO growth has slowed, and even slightly decreased, in the past couple of years;[43] this may be explained by shifts in federal government programs that are pushing all ACOs to take on downside risk at a faster pace.

Arguably the greatest resource of ACOs is primary care physicians (PCPs), who play a large role in these organizations as the so-called quarterbacks of coordinated patient care. Therefore, the supply of ACOs is partly driven by the supply of PCPs. Between 2017 and 2021, the supply of PCPs[44] generally increased, both overall and as a function of people per physician.[45] Despite primary care continuing to be one of the most popular medical specialties, the number of PCPs is expected to decrease in coming years, with more PCPs moving toward retirement.[46] Predictions from the Association of American Medical Colleges (AAMC) expect a shortage of over 14,000 to 49,000 PCPs by 2030.[47] In addition to workforce attrition, another critical factor in the supply of available physicians is the generation of new entrants into the physician workforce, which is currently not sufficient to make up for the retirement trends.[48] However, the ACO model does not solely require physicians for patient treatment; on the contrary, the participation of advanced practice clinicians (APCs) such as nurse practitioners is instrumental, and many Medicare beneficiaries already use nurse practitioners and physician assistants as their primary care providers.[49] Therefore, ACOs' use of non-physician providers may put the industry at a competitive advantage as PCP shortages become more acute.

ACO participants can vary greatly depending on the ACO. In addition to PCPs, most ACOs include hospitals, specialists, and post-acute providers; some also include pharmacies.[50] ACOs generally do not focus on one specialty because the organization is responsible for *all* beneficiary expenditures, leading many ACOs to integrate a variety of parties.[51] Physician-led ACOs are typically large specialty provider groups and a hospital, while hospitals employ the physicians in hospital-led ACOs.[52] In some ACOs, private insurers play a significant role, although payors are not in charge of medical care.[53]

Due to the variety of participants in a given ACO, the demand for ACO services correlates to the healthcare service industry overall. The variation in services offered allows ACOs to shift services to other less-costly areas of the ACO. For example, an ACO may find emergency room physicians to be relatively costly and move services to skilled nursing facilities (SNFs) or shift patients away from PCPs or specialists by utilizing telehealth. Consequently, ACOs are uniquely positioned to rewrite the traditional rules of supply and demand in healthcare services because the conventional analysis of physician demand cannot be utilized.

Overall, the demand for healthcare services is expected to rise, due in large part to the aging American population.[54] Medicare beneficiaries are projected to become the most significant core users of healthcare services in the U.S. by 2030.[55] While not all Americans may have insurance, many Americans will have increased spending power due to being employed.[56] Demand drivers for ACOs in particular include the U.S. healthcare delivery system's shift from *volume*-based to *value*-based reimbursement (VBR), which, as discussed in the previous installment in this series, requires providers to work together to reduce cost and increase quality. However, generating savings necessarily depends on the reimbursement paid to the ACO, which will be discussed in the next installment.

Valuation of Accountable Care Organizations: Reimbursement

[Excerpted from the article published in August 2023.]

The U.S. healthcare payment and delivery system is increasingly moving to a value- and quality-based system. Accountable care organizations (ACOs) are at the forefront of delivering high-quality and cost-effective care to millions of Medicare beneficiaries and privately insured patients, incentivized by substantial shared savings for those who increase quality while containing costs. This third installment of a five-part series on the valuation of ACOs will discuss the reimbursement environment in which ACOs participate.

The U.S. government is the largest payor of medical costs through Medicare and Medicaid and has a strong influence on reimbursement to hospitals. In 2021, Medicare and Medicaid accounted for an estimated $900.8 billion and $734.0 billion in healthcare spending, respectively.[57] 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.[58]

ACOs generally have the dual goal of achieving certain quality thresholds and containing costs, sufficient to attain reimbursement in the form of shared savings. Medicare Shared Savings Program (MSSP) ACO providers continue to receive fee-for-service (FFS) rates from Medicare under their respective fee schedules.[59] Unlike other FFS providers, MSSP participating providers also have the opportunity to earn shared savings and/or share the losses with Medicare.[60] If, at the end of a performance year (PY), the ACO's assigned beneficiary spending is *less* than the target, the ACO shares those savings (the difference between the target spending and the actual spending) with Medicare, up to a predetermined percentage.[61] In two-sided risk agreements, if the ACO's assigned beneficiary spending is *more* than the target, the ACO shares the losses with Medicare, up to a predetermined percentage.[62] Determining the target spending for an ACO during the PY (the "*benchmark*") is computed using the total Medicare Part A and Medicare Part B spending for the assigned beneficiaries for that period.[63] The baseline is calculated using the three years of data prior to the ACO's contract.[64] Spending is averaged over the three years prior to the contract's commencement, then blended with average regional expenditures for the beneficiaries who would have been eligible for assignment to the ACO.[65] The baseline also accounts for inflation by trending spending forward.[66] An ACO's actual spending for the year is compared to that baseline to calculate savings or losses for the year.[67] Savings and losses (if applicable) are shared with the ACO at the defined rate according to the track in which the ACO participates,[68] up to 75% in the MSSP.[69]

Quality is also factored into the calculation of shared savings and losses.[70] Higher quality gains by an ACO allows for larger shares of the savings and smaller shares of any losses.[71] The process of determining an ACO's performance in MSSP, for example, begins with a consideration of the health status of the ACO's population.[72] The MSSP utilizes risk scores of assigned beneficiaries to assess the risk,[73] which scores are limited to 3% increases between the baseline year and the PY.[74] Next, quality is measured based on four domains: (1) patient experience; (2) readmissions; and, (3) clinical care for at-risk population.[75] In order to share in savings, ACOs must meet the minimum level of attainment.[76] With the two-sided models of risk, the shared loss rate will be lower where quality scores (benchmark compared to performance of the ACO) are higher.[77]

In 2021, MSSP ACOs realized net savings of $1.66 billion, marking a fifth consecutive year where the program generated high-quality performance results and overall savings.[78] 58% of the ACOs earned payments for their performance; the ACOs that realized higher net savings tended to be low-revenue, serving rural areas, and principally comprised of physicians.[79] ACOs comprised of fewer primary care physicians saw $149 per capita in savings, whereas ACOs comprised of 75% or more primary care physicians saw $281 per capita.[80] Overall, close to 99% of ACOs met the quality standards needed to share savings.[81]

Going forward, ACOs will have to overcome a number of challenges in order to remain viable in the U.S. healthcare delivery system's ongoing paradigm shift, including the design and implementation of new care delivery, which is the

most-reported challenge for ACOs.[82] Other common challenges facing ACOs include aligning physician compensation with value-based contracts, mixed quality of payor data, and lack of data analytic capabilities.[83] Notably, ACOs in downside risk arrangements (two-sided contracts) are more likely to have concerns regarding the quality of health plan data.[84] The quality of data provided from a health plan can determine the success of an ACO, especially if the ACO does not have advanced data analytics capabilities.

The current state of regulatory enforcement for ACOs will be addressed in the next installment of this five-part series.

Valuation of Accountable Care Organizations: Regulatory

[Excerpted from the article published in September 2023.]

Because of the federal government's preference for, and reliance on the success of, accountable care organizations (ACOs), some ACOs assume their legal status shields the organization from legal scrutiny on all issues. However, since the 2010 advent of ACOs, the law has adapted uniquely to these organizations. This fourth installment of a five-part series on the valuation of ACOs will discuss this unique regulatory environment in which ACOs operate.

MSSP ACO Eligibility

Qualification for ACO contract participation with MSSP, the most popular ACO program, requires:

(1) General eligibility requirements;
(2) Being an eligible provider and supplier;
(3) Meeting minimum participation levels required of primary care providers;
(4) Reporting on qualities and costs;
(5) Care coordination capabilities; and,
(6) The governance structure of the ACO vests decision-making control in ACO participants.[85]

Additionally, ACOs must meet certain governance and leadership structure requirements:

(1) "*The ACO's governing body has made and duly authorized a bona fide determination… that the arrangement is reasonably related to the purposes of the Shared Savings Program*;
(2) "*Both the arrangement and its authorization by the governing body are documented*;" and,
(3) "*The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by*" HHS.[86]

ACOs must have at least 5,000 assigned beneficiaries for the lower levels of MSSP participation.[87] An ACO's clinical management must be managed by a board-certified physician that is a senior-level medical director.[88]

ACOs are required to maintain documentation for 10 years on:

(1) "*A description of the arrangement, including all parties to the arrangement*;"
(2) "*[The] date of the arrangement*;"
(3) "*The purpose of the arrangement*;"
(4) "*The items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods)*;" and,
(5) "*The financial or economic terms of the arrangement*."[89]

Finally, ACOs require extensive quality measures and patient satisfaction reporting.[90]

Antitrust Law

The formation of ACOs has often been criticized for facilitating the increased consolidation of market power in healthcare. Legal implications can arise from anticompetitive behavior on the part of ACOs, as antitrust laws still apply to ACOs and the Department of Health and Human Services (HHS) is not authorized to waive the applicability of antitrust laws to ACO formation and operation.[91] The lack of authorization leaves ACOs in a precarious position because ACO actions can be interpreted as anticompetitive. However, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) had originally allowed for certain exceptions to be made for ACOs participating in MSSP.[92] The goal of this FTC/DOJ policy was to prevent ACOs from enhancing or entrenching market power.[93] Further, the FTC and DOJ wanted to encourage the development of a competitive ACO marketplace.[94] However, the DOJ announced the withdrawal of this statement on February 6, 2023, classifying it as outdated and not reflecting the realities of the current market.[95] The withdrawal was seen as consistent with the Biden Administration's priorities on being more aggressive with the enforcement of antitrust issues.[96] The withdrawal of this FTC/DOJ policy signals a potential increase in the scrutiny of ACO antitrust actions, among other networks of organizations and providers.[97]

Federal Fraud & Abuse Laws

Additionally, healthcare provider organizations face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. Fraud and abuse laws, specifically those related to the federal *Anti-Kickback Statute* (AKS) and physician self-referral laws (the *Stark Law*), may have the greatest impact on the operations of healthcare providers.

The AKS and Stark Law are generally concerned with the same issue – the financial motivation behind patient referrals. However, while the AKS is broadly applied to payments between providers or suppliers in the healthcare industry and relates to any item or service that may 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.[98] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[99]

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,[100] even if only one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[101] Notably, a person need not have *actual knowledge* of the AKS or *specific intent* to commit a violation of the AKS for the government to prove a kickback violation,[102] only an awareness that the conduct in question is "*generally unlawful*."[103] Further, a violation of the AKS is sufficient to state a claim under the *False Claims Act* (FCA).[104]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[105] In response, AKS *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.[106] Failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[107] It should be noted that, in order for a payment to meet the requirements of many AKS *safe harbors*, the compensation must not exceed the range of *fair market value* and must be *commercially reasonable*.

Of note, in a December 2020 final rule, the HHS Office of Inspector General (OIG) released several revisions to the AKS, many of which are similar to those revisions to the Stark Law proposed by CMS, as discussed below.[108] 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).[109]

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).[110] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[111] Under the Stark Law, DHS include, but are not limited to, the following:

(1) Inpatient and outpatient hospital services;
(2) Radiology and certain other imaging services;
(3) Radiation therapy services and supplies;
(4) Certain therapy services, such as physical therapy;
(5) Durable medical equipment; and,
(6) Outpatient prescription drugs.[112]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities also have an ownership interest in the entity that provides DHS.[113] 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.[114] 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.[115] Similar to the AKS safe harbors, without these exceptions, the Stark Law may prohibit legitimate business arrangements.

As noted above, in December 2020, CMS released a number of revisions to the Stark Law in a final rule, including new permanent exceptions for value-based arrangements.[116] These new exceptions protect the following arrangements:

(1) Full Financial Risk Arrangements: Includes capitated payments and predetermined rates or a global budget;
(2) Value-Based Arrangements with Meaningful Downside Financial Risk: Where a physician pays no less than 25% of the value of the remuneration the physician receives when he or she does not meet pre-determined benchmarks; and,
(3) Value-Based Arrangements: Applies regardless of risk level to encourage physicians to enter value-based arrangements, even if they only assume upside risk.[117]

ACO Fraud & Abuse Waivers

ACO formation may have a variety of legal risks. To encourage participation in MSSP, CMS and the OIG have created *waivers* to shield participating ACOs from legal risks related to fraud and abuse.[118] There are five waivers available:

(1) The *Pre-Participation Waiver* allows ACO participants to fund ACO development for the overall benefit of the ACO participants;[119]
(2) The *Participation Waiver*, applies broadly to ACO-related arrangements and is similar to the *Pre-Participation Waiver* in that it protects ACO activities required to sustain the business, such as investment and operating agreements.[120]
(3) The *Shared Savings Waiver* protects arrangements related to, and allows for the distribution and use of, shared savings payments earned from the MSSP.[121]
(4) The *Compliance with Stark Law Waiver* allows the ACO to pursue arrangements that may otherwise implicate the AKS;[122] and
(5) The *Patient Incentive Waiver* offers protection from fraud and abuse laws when an ACO, ACO participant, or ACO provider provides medically-related incentives to MSSP beneficiaries, e.g., free or below-fair market value items and services that advance the goals of preventative care, adherence to medications/treatment, or management of chronic diseases/conditions.[123]

Importantly, the waivers must be reasonably related to the MSSP to shield an ACO from fraud and abuse implications.[124] Arrangements that are unrelated to the MSSP (even if they have similar underlying purposes) are not shielded from fraud and abuse law by ACO waivers.[125]

Conclusion

ACOs face many obstacles within the regulatory environment that can prohibit their formation, growth, and development. Understanding fraud and abuse laws, among other statutes and regulations, are integral to the success of an ACO. Another factor integral to the success of an ACO is their health information technology infrastructure. Consequently, the final installment in this series will discuss the technological environment in which ACOs operate.

Valuation of Accountable Care Organizations: Technology

[Excerpted from the article published in October 2023.]

Over the past two decades, there has been a rapid adoption of technological innovations in the U.S., which has fundamentally changed the healthcare delivery system. Health information technology infrastructure is integral to the success of ACOs, as well as data analytics. Large organizations may be able to utilize their relatively substantial resources, whether technological or financial, to lower expenditures using telehealth and advanced data analytics. This final installment of a five-part series on the valuation of ACOs will discuss the rapidly-changing technological environment in which ACOs operate.

Health Information Technology (HIT)

Research indicates that implementation of health information technology (HIT) may lead to improved efficiency and quality management.[126] HIT includes a variety of software applications, such as billing software, staffing models, and electronic health record (EHR).[127] Technologies such as EHR systems have resulted in cost savings, greater patient care, and ease of workflow.[128] Accountable care organizations (ACOs) in particular may benefit from the utilization of EHR, as they have been shown to increase efficiencies and cost savings.[129] Further, EHRs are linked to clinical improvements,[130] which could financially benefit the operations of both ACOs and ACO participants.

Care coordination for ACOs makes EHR technology vital to success. A hallmark to a successful ACO is care coordination between providers, often achieved by leveraging EHR capabilities.[131] However, ACOs have seen interoperability issues among all the EHR software utilized within an ACO.[132] Interoperability issues are significant problems in achieving success for ACOs because care coordination and interoperability are fundamentally intertwined.[133] ACOs that utilize one EHR system across all ACO participants have real-time updates on patient data and optimized abilities to coordinate care.[134] The optimized abilities contrast with ACOs that use multiple EHR systems, which may inhibit care coordination across all providers.

Difficulties also arise between EHR incompatibilities to meet reporting requirements. However, there is potential for interoperability issues to be addressed by the *Trusted Exchange Framework and Common Agreement* (TEFCA).[135] The agreement seeks to support the development of a nationwide exchange of electronic health information to be utilized by the numerous health information networks.[136] Finally, patient engagement requires ACOs to maintain strong EHR capabilities.[137] EHR capabilities allow for patient engagement through the use of "patient portals."[138] The portal enables patients to view their medical records online, communicate with their provider, and request prescription refills.[139] ACOs leveraging patient portals can significantly increase patient engagement.

Artificial Intelligence

In the coming years, AI will likely be critical to the success of quality improvement, risk adjustment, and population health management, all key tenets of value-based care.[140] With the rapid growth in the amount and accessibility of clinical data, AI will likely be utilized to analyze this data to reduce inefficiencies and costs while contributing to better patient outcomes.[141] Providers are often time-constrained due to manually entering EHRs, increasing chances of burnout.[142] Leveraging AI can streamline workflow, close gaps in care, and allow for risk adjustment and the elimination of delays in reimbursement.[143]

Data Analytics

Health data analytics involves extracting insights from sets of patient data from various sources, but primarily EHRs.[144] The need for data analytics for ACOs is spurred by the use of data analytics technology for population health management (PHM).[145] PHM is a practical approach to improving healthcare delivery and outcomes for a group of patients while simultaneously lowering costs to the provider.[146] Using EHR data in analytics is a subset of data analytics called clinical data analytics.[147] Clinical data analytics follows the Healthcare Analytics Adoption Model, which classifies a group of analytical capabilities and the sequencing for adopting them.[148]

There are eight progressive levels to the Healthcare Analytics Adoption Model as follows:

(1) Level 0: Fragmented Point Solutions
(2) Level 1: Enterprise Data Warehouse
(3) Level 2: Standardized Vocabulary and Patient Registries
(4) Level 3: Automated Internal Reporting
(5) Level 4: Automated External Reporting
(6) Level 5: Waste and Care Variability Reduction
(7) Level 6: PHM and Suggestive Analytics
(8) Level 7: Clinical Risk Intervention and Predictive Analytics
(9) Level 8: Personalized Medicine and Prescriptive Analytics[149]

ACOs utilize data analytics to manage patient populations, manage financial risk, and monitor performance.[150] ACOs use a variety of data sources, including claims data from the Centers for Medicare & Medicaid Services (CMS), pharmacy data, disease registry data, patient-reported data, administrative data, and financial data, to achieve savings.[151] Data analytics has proven useful for managing care transitions, identifying gaps in care, and supporting post-discharge programs.[152] Robust data analytics programs used by ACOs allow for improved care coordination, hospital admissions, screening and vaccinations, and chronic disease management.[153] ACOs often use data analytics to identify high-risk or high-cost beneficiaries.[154] ACOs that employ data analytics tools engage their patients more, which creates a better provider-patient relationship and directly correlates to more personalized care plans and better patient adherence to provider recommendations.[155] Successful ACOs have maximized the potential of their HIT solutions. However, not all ACOs are utilizing tools such as PHM and personalized medicine.

Further, ACOs should not expect success in silos. For many data analytics tools to be successful, the ACO must also coordinate with other parties, such as schools, public health agencies, and local organizations, to manage personal behaviors in a measured way.[156] Finally, a fully successful data analytics program has access to data outside the organization or network, such as other providers that the ACO's assigned patients may visit.[157] Data analytics is an incredibly useful tool for ACOs; however, they must coordinate with other parties in order to fully realize the benefits of data analytics.

Telehealth

Telehealth delivers health-related services via telecommunications technology.[158] Telehealth services can supplement or replace face-to-face encounters with physicians. Large industry players connect physicians with patients that could be thousands of miles away and help address patients' minor medical concerns.[159] 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 the patient and the provider of the services versus face-to-face encounters.[160] As more studies validate the efficacy of telehealth services, more insurance providers are offering coverage of telehealth services.[161]

Telehealth capabilities greatly expanded for ACOs when CMS launched *Pathways to Success* in 2018 for ACOs that participate in the Medicare Shared Savings Program (MSSP).[162] ACOs that accept financial risk in the *Basic Track* and *Enhanced Track* of MSSP can receive payment from Medicare for telehealth services furnished to beneficiaries, regardless of geographic limitations.[163] The change also allows the patient's home to be the originating site, which significantly expands patient access to telehealth.[164] Telehealth will undoubtedly change how care is delivered to ACO patients and will likely lead to new opportunities to reduce expenditures from inpatient care.

Conclusion

Going forward, ACOs will have to overcome a number of challenges, in order to remain viable in the latest paradigm shift in the U.S. healthcare delivery system, including the design and implementation of new care delivery, which is the most-reported challenge for ACOs.[165] Other common challenges facing ACOs include aligning physician compensation with value-based contracts, mixed quality of payor data, and lack of data analytic capabilities.[166] Notably, ACOs in downside risk arrangements (two-sided contracts) are more likely to have concerns regarding the quality of health plan data.[167] The quality of data provided from a health plan can determine the success of an ACO, especially if the ACO does not have advanced data analytics capabilities. Ultimately, the utilization of technology in value-based reimbursement structures such as ACOs could promote one of the central goals of healthcare reform, i.e., increased efficiency in healthcare and high quality care.

1 "Moving Forward with Accountable Care Organizations: Some Answers, More Questions" By Carrie H. Colla, JAMA Internal Medicine, Vol. 177, No. 4, April 2017, p. 527.

2 "Accountable Care Organizations — The Risk of Failure and the Risks of Success" By Lawrence P. Casalino, The New England Journal of Medicine, Vol. 371, Issue 18, October 2014, p. 1750; "Moving Forward with Accountable Care Organizations: Some Answers, More Questions" By Carrie H. Colla, JAMA Internal Medicine, Vol. 177, No. 4, April 2017, p. 527.

3 "Shared Savings Program" Centers for Medicare & Medicaid Services, 2023, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram (Accessed 6/7/23).

4 "A taxonomy of accountable care organizations for policy and practice" By Stephen M. Shortell, et al., Health Services Research, Vol. 49, Issue 6, December 2014, p. 1883-1895; "Assessing Differences between Early and Later Adopters of Accountable Care Organizations Using Taxonomic Analysis" By Frances M. Wu, Stephen M. Shortell, Valerie A. Lewis, Carrie H. Colla, and Elliott S. Fisher, Health Services Research, Vol. 51, Issue 6, p. 2318-2329.

5 "First National Survey Of ACOs Finds That Physicians Are Playing Strong Leadership And Ownership Roles" By Carrie H. Colla, Valerie A. Lewis, Stephen M. Shortell, and Elliott S. Fisher, Health Affairs, Vol. 33, No. 6, June 2014, p. 967-970.

6 "Changes in Patients' Experiences in Medicare Accountable Care Organizations" By J. Michael McWilliams, Bruce E. Landon, Michael E. Chernew, and Alan M. Zaslavsky, The New England Journal of Medicine, Vol. 371, Issue 18, October 2014, p. 1715.

7 "Association Between Medicare Accountable Care Organization Implementation and Spending Among Clinically Vulnerable Beneficiaries" By Carrie H. Colla, Valerie A. Lewis, Lee-Sien Kao, et al, JAMA Internal Medicine, Vol. 176, Issue 8, August 2016, p. 1168; "Changes in Patients' Experiences in Medicare Accountable Care Organizations" By J. Michael McWilliams, Bruce E. Landon, Michael E. Chernew, and Alan M. Zaslavsky, The New England Journal of Medicine, Vol. 371, Issue 18, October 2014, p. 1715.

8 "Association of Pioneer Accountable Care Organizations vs Traditional Medicare Fee for Service With Spending, Utilization, and Patient Experience" By David J. Nyweide, Woolton Lee, Timothy T. Cuerdon, et al, JAMA, Vol. 313, Issue 21, June 2015, p. 2152-2161; "Association Between Medicare Accountable Care Organization Implementation and Spending Among Clinically Vulnerable Beneficiaries" By Carrie H. Colla, Valerie A. Lewis, Lee-Sien Kao, et al, JAMA Internal Medicine, Vol. 176, Issue 8, August 2016, p. 1167-1175.

9 "Moving Forward with Accountable Care Organizations: Some Answers, More Questions" By Carrie H. Colla, JAMA Internal Medicine, Vol. 177, No. 4, April 2017, p. 527.

10 "ACO Comparison Chart" National Association of Accountable Care Organizations, 2023, https://www.naacos.com/assets/docs/pdf/2023/ACO-Comparison-Chart2023.pdf (Accessed 6/7/23).

11 "Shared Savings Program" Centers for Medicare & Medicaid Services, 2023, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/about (Accessed 6/7/23); "ACO REACH" Centers for Medicare and Medicaid Services, May 26, 2023, https://innovation.cms.gov/innovation-models/aco-reach (Accessed 6/9/23).

12 Centers for Medicare & Medicaid Services, 2023.

13 *Ibid.*

14 National Association of Accountable Care Organizations, 2023.

15 Centers for Medicare & Medicaid Services, 2023.

16 "NAACOS Assessment of High-Low Revenue Designations" National Association of ACOs, 2020, https://www.naacos.com/naacos-assessment-of-high-low-revenue-designations (Accessed 6/9/23).

17 *Ibid.*

18 *Ibid.*

19 "Skilled Nursing Facility 3-Day Rule Waiver: Guidance" Centers for Medicare & Medicaid Services, May 2022, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SNF-Waiver-Guidance.pdf (Accessed 6/9/23), p. 1.

20 "Beneficiary Incentive Program" Centers for Medicare & Medicaid Services, May 2021, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/BIP-guidance.pdf (Accessed 6/9/23).

21 "Advanced Alternative Payment Models (APMs)" Quality Payment Program, Centers for Medicare & Medicaid Services, 2023, https://qpp.cms.gov/apms/advanced-apms (Accessed 6/9/23).

22 *Ibid.*

23 *Ibid.*

24 "Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health (REACH) Model" Centers for Medicare and Medicaid Services, February 24, 2022, https://www.cms.gov/newsroom/fact-sheets/accountable-care-organization-aco-realizing-equity-access-and-community-health-reach-model (Accessed 6/9/23).

25 "Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health (REACH) Model" Centers for Medicare and Medicaid Services, February 24, 2022, https://www.cms.gov/newsroom/fact-sheets/accountable-care-organization-aco-realizing-equity-access-and-community-health-reach-model (Accessed 6/9/23).

26 Centers for Medicare and Medicaid Services, May 26, 2023.

27 *Ibid.*

28 *Ibid.*

29 *Ibid.*

30 *Ibid.*

31 *Ibid.*

32 National Association of Accountable Care Organizations, 2023.

33 "Growth And Dispersion Of Accountable Care Organizations In 2015" By David Muhlestein, Health Affairs, March 31, 2015, https://www.healthaffairs.org/do/10.1377/hblog20150331.045829/full/ (Accessed 6/9/23).

34 "Spread of ACOs And Value-Based Payment Models In 2019: Gauging the Impact of Pathways to Success" By David Muhlestein, et al., Health Affairs, October 21, 2019, https://www.healthaffairs.org/do/10.1377/hblog20191020.962600/full/ (Accessed 6/9/23).

35 *Ibid.*

36 *Ibid.*

37 *Ibid.*

38 "Primary Care First Model Options" Centers for Medicare & Medicaid Services, 2020, https://innovation.cms.gov/initiatives/primary-care-first-model-options/ (Accessed 6/9/23); "Spread of ACOs And Value-Based Payment Models In 2019: Gauging the Impact of Pathways to Success" By David Muhlestein, et al., Health Affairs, October 21, 2019, https://www.healthaffairs.org/do/10.1377/hblog20191020.962600/full/ (Accessed 6/9/23).

39 Muhlestein, et al., Health Affairs, October 21, 2019.

40 "Medicare Spending after 3 Years of the Medicare Shared Savings Program" By J. Michael McWilliams, Laura A. Hatfield, Bruce E. Landon, Pasha Hamed, and Michael E. Chernew, The New England Journal of Medicine, Vol. 379, Issue 12, September 2018, p. 1139; "The 2018 Annual ACO Survey: Examining the Risk Contracting Landscape" By Robert Mechanic, et al., Health Affairs, April 23, 2019, https://www.healthaffairs.org/content/forefront/2018-annual-aco-survey-examining-risk-contracting-landscape (Accessed 6/22/23).

41 "Growth Of Value-Based Care And Accountable Care Organizations In 2022" By David Muhlestein et. al., Health Affairs, December 2, 2022, https://www.healthaffairs.org/content/forefront/growth-value-based-care-and-accountable-care-organizations-2022 (Accessed 6/14/23).

42 *Ibid.*

43 *Ibid.*

44 Comprised of: Family Medicine/General Practice, Internal Medicine, Internal Medicine/Pediatrics, and Pediatrics.

45 "Number of People per Active Physician by Specialty, 2017" Association of American Medical Colleges, https://www.aamc.org/data-reports/workforce/data/number-people-active-physician-specialty-2017 (Accessed 7/20/23); "Number of People per Active Physician by Specialty, 2021" Association of American Medical Colleges, https://www.aamc.org/data-reports/workforce/data/number-people-active-physician-specialty-2021 (Accessed 7/20/23).

46 "The Complexities of Physician Supply and Demand: Projections from 2019 to 2034" Submitted by IHS Markit Limited, for the Association of American Medical Colleges, June 2021, https://www.aamc.org/media/54681/download (Accessed 6/8/23).

47 "What specialties do doctors choose?" By Lindsay Kalter, Association of American Medical Colleges, November 2, 2018, https://www.aamc.org/news/what-specialties-do-doctors-choose (Accessed 7/20/23).

48 "The Complexities of Physician Supply and Demand: Projections from 2019 to 2034" Submitted by IHS Markit Limited, for the Association of American Medical Colleges, June 2021, https://www.aamc.org/media/54681/download (Accessed 6/8/23).

49 "March 2019 Report to the Congress: Medicare Payment Policy: Chapter 4:

Physician and other health professional services" Medicare Payment Advisory Commission, March 2019, p. 107.

50 "Accountable Care Organizations, Explained" By Jenny Gold, Kaiser Health News, Kaiser Family Foundation, September 14, 2015, https://khn.org/news/aco-accountable-care-organization-faq/ (Accessed 6/8/23).

51 *Ibid.*

52 *Ibid.*

53 *Ibid.*

54 "Healthcare Industry Forecast: High Demand Due to Aging, Economy" AMN Healthcare, 2017, https://web.archive.org/web/20230320230757/https://www.amnhealthcare.com/amn-insights/news/healthcare-industry-forecast/(Accessed 6/8/23).

55 *Ibid.*

56 *Ibid.*

57 "NHE Fact Sheet" Centers for Medicare & Medicaid Services, December 14, 2022, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet (Accessed 5/26/23).

58 "Medicare's Role in Determining Prices Throughout the Health Care System: Mercatus Working Paper" By Roger Feldman et al., Mercatus Center, George Mason University, October 2015, https://www.mercatus.org/research/working-papers/medicares-role-determining-prices-throughout-health-care-system (Accessed 5/26/23), p. 3-5; "Physician Panel Prescribes the Fees Paid by Medicare" By Anna Wilde Mathews and Tom McGinty, The Wall Street Journal, October 26, 2010, https://www.wsj.com/articles/SB10001424052748704657304575540440173772102 (Accessed 5/26/23)

59 "Accountable Care Organization Payment Systems" Medicare Payment Advisory Commission, October 2022, https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_ACOs_FINAL_SEC.pdf (Accessed 6/8/23).

60 *Ibid.*

61 *Ibid.*

62 *Ibid.*

63 *Ibid.*

64 *Ibid.*

65 *Ibid.*

66 *Ibid.*

67 *Ibid.*

68 *Ibid.*

69 *Ibid.*

70 *Ibid.*

71 *Ibid.*

72 *Ibid.*

73 *Ibid.*

74 *Ibid.*

75 *Ibid.*

76 *Ibid.*

77 *Ibid.*

78 "Medicare Shared Savings Program Saves Medicare More Than $1.6 Billion in 2021 and Continues to Deliver High-quality Care" Centers for Medicare & Medicaid Services, Press Release, August 30, 2022, cms.gov/newsroom/press-releases/medicare-shared-savings-program-saves-medicare-more-16-billion-2021-and-continues-deliver-high (Accessed 6/9/23).

79 *Ibid.*

80 *Ibid.*

81 *Ibid.*

82 "The 2018 Annual ACO Survey: Examining the Risk Contracting Landscape" By Robert Mechanic, Jennifer Perloff, Teresa Litton, Kerstin Edwards, and David Muhlestein, Health Affairs, April 23, 2019, https://www.healthaffairs.org/do/10.1377/hblog20190422.181228/full/ (Accessed 2/11/20).

83 *Ibid.*

84 *Ibid.*

85 "Health Law: Cases, Materials and Problems" Furrow, Greaney, Johnson, Jost, Schwartz, Brown, Clark, Gatter, King, and Pendo, West Academic, 2018, p. 657.

86 "Medicare Program; Final Waivers in Connection with the MSSP" Federal Register Vol. 80, No. 209 (October 29, 2015), p. 66743.

87 "ACO Participant List and Participant Agreement: Guidance" Centers for Medicare & Medicaid Services, March 2023, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Participant-List-Agreement.pdf (Accessed 6/8/23), p. 3.

88 *Ibid*, p. 13.

89 Federal Register Vol. 80, No. 209 (October 29, 2015) p. 66743.

90 "ACO Comparison Chart" National Association of Accountable Care Organizations, 2023, https://www.naacos.com/assets/docs/pdf/2023/ACO-Comparison-Chart2023.pdf (Accessed 6/7/23).

91 "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" Federal Trade Commission and the Department of Justice, 2011, https://www.justice.gov/sites/default/files/atr/legacy/2011/10/20/276458.pdf (Accessed 6/13/23), p. 1-5.

92 *Ibid.*

93 *Ibid.*

94 *Ibid.*

95 "Antitrust: DOJ Scuttles ACO Guidance, Unsettles Ground under Provider Joint Contracting Models" By Kinai Patel, Alexis Bortniker, and Diane Hazel, Foley & Lardner LLP, March 17, 2023, https://www.foley.com/en/insights/publications/2023/03/antitrust-doj-aco-guidance-provider-joint (Accessed 6/9/23).

96 *Ibid.*

97 *Ibid.*

98 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 5/26/23).

99 *Ibid.*

100 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 USC § 1320a-7b(b)(1).

101 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf (Accessed 5/13/22), p. 4-5; "U.S. v. Greber" 760 F.2d 68, 69 (3d. Cir. 1985).

102 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 6402, 10606, 124 Stat. 119, 759, 1008 (March 23, 2010).

103 "Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview" By Jennifer A. Staman, Congressional Research Service, September 8, 2014, https://www.fas.org/sgp/crs/misc/RS22743.pdf (Accessed 5/13/22), p. 5.

104 "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" McDermott Will & Emery, April 12, 2010, p. 3; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 6402, 124 Stat. 119, 759 (March 23, 2010).

105 Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, p. 5.

106 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" Federal Register Vol. 64, No. 223 (November 19, 1999), p. 63518, 63520.

107 "Re: Malpractice Insurance Assistance" By Lewis Morris, Chief Counsel to the Inspector General, United States Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, https://oig.hhs.gov/fraud/docs/alertsandbulletins/malpracticeprogram.pdf (Accessed 5/13/22), p. 1.

108 "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements" Federal Register, December 2, 2020, Vol. 85, No. 232, p. 77814-77815.

109 *Ibid.*

110 "CRS Report for Congress: Medicare: Physician Self-Referral ("Stark I and II")" By Jennifer O'Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, available at: http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf (Accessed 5/13/22); "Limitation on certain physician referrals" 42 USC § 1395nn.

111 "Limitation on certain physician referrals" 42 USC § 1395nn(a)(1)(A).

112 "Limitation on Certain Physician Referrals" 42 USC § 1395nn(a)(1)(B); "Definitions" 42 CFR § 411.351 (2015). Note the distinction in 42 CFR § 411.351 regarding what services are included as DHS: "Except as otherwise noted in this subpart, the term 'designated health services' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)."

113 "Limitation on certain physician referrals" 42 USC § 1395nn (a)(2).

114 "Limitation on certain physician referrals" 42 USC § 1395nn (h)(1).
115 "Limitation on certain physician referrals" 42 USC § 1395nn.
116 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77492.
117 *Ibid*, p. 77510-77528.
118 "Taking advantage of Medicare ACO waivers" Advisory Board, March 17, 2023, https://www.advisory.com/daily-briefing/2013/07/12/law-review (Accessed 6/8/23).
119 *Ibid.*
120 Federal Register, Vol. 80, No. 209 (October 29 2015), p. 66733.
121 *Ibid*, p. 66728.
122 *Ibid.*
123 *Ibid*, p. 66728, 66739.
124 *Ibid*, p. 66730.
125 *Ibid.*
126 "Understanding the Costs and Benefits of Health Information Technology in Nursing Homes and Home Health Agencies: Case Study Findings" By Andrew Kramer MD, et al., U.S. Department of Health and Human Services, June 2009, http://aspe.hhs.gov/sites/default/files/pdf/75876/HITcsf.pdf (Accessed 6/8/23), p. iv-v.
127 *Ibid*, p. 1.
128 "The Impact of Technology on Healthcare" American Institute of Medical Sciences and Education, June 2, 2019, https://aimseducation.edu/blog/the-impact-of-technology-on-healthcare (Accessed 6/8/23).
129 "Medical Practice Efficiencies and Cost Savings" HealthIT, 2023, https://www.healthit.gov/providers-professionals/medical-practice-efficiencies-cost-savings (Accessed 6/8/23).
130 "Improved Diagnostics and Patient Outcomes" HealthIT, 2023, https://www.healthit.gov/providers-professionals/improved-diagnostics-patient-outcomes (Accessed 6/8/23).
131 "How EHRs Help Make Successful Accountable Care Organizations" By Sara Heath, EHR Intelligence, March 21, 2016, https://ehrintelligence.com/news/how-ehrs-help-make-successful-accountable-care-organizations (Accessed 6/8/23).
132 "Care Coordination Paramount as New ACO Models Roll Out" By Frank Irving, EHR Intelligence, January 13, 2016, https://ehrintelligence.com/news/care-coordination-paramount-as-new-aco-models-roll-out (Accessed 6/8/23).
133 *Ibid.*
134 "Using Health IT for Care Coordination: Insights From Six Medicare Accountable Care Organizations" Office of Inspector General, U.S. Department of Health and Human Services, https://oig.hhs.gov/oei/reports/oei-01-16-00180.pdf (Accessed 6/8/23).
135 "Trusted Exchange Framework and Common Agreement" HealthIT.gov, 2023, https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement (Accessed 6/8/23).
136 *Ibid.*
137 "How EHRs Help Make Successful Accountable Care Organizations" By Sara Heath, EHR Intelligence, March 21, 2016, https://ehrintelligence.com/news/how-ehrs-help-make-successful-accountable-care-organizations (Accessed 6/8/23).
138 *Ibid.*
139 *Ibid.*
140 "Top Three Reasons Why AI is Critical for Value-Based Care" By Jay Ackerman, Managed Healthcare Executive, June 27, 2023, https://www.managedhealthcareexecutive.com/view/top-three-reasons-why-ai-is-critical-for-value-based-care (Accessed 10/20/23).
141 *Ibid.*
142 *Ibid.*
143 *Ibid.*
144 "What is Health Data Analytics?" USF Health, Morsani College of Medicine, November 16, 2021, https://www.usfhealthonline.com/resources/key-concepts/health-data-analytics/ (Accessed 6/8/23).
145 *Ibid.*
146 *Ibid.*
147 *Ibid.*
148 *Ibid.*
149 *Ibid.*
150 "First Annual Report: Next Generation Accountable Care Organization (NGACO) Model Evaluation" By Kristina Hanson Lowell, NORC, The University of Chicago, August 27, 2018, https://innovation.cms.gov/Files/reports/nextgenaco-firstannrpt.pdf (Accessed 6/8/23), p. 50-53.
151 *Ibid.*
152 *Ibid.*
153 *Ibid.*
154 *Ibid*, p. 50-56.
155 *Ibid*, p. 50-56.
156 "What is Health Data Analytics?" USF Health, Morsani College of Medicine, November 16, 2021, https://www.usfhealthonline.com/resources/key-concepts/health-data-analytics/ (Accessed 6/8/23).
157 "First Annual Report: Next Generation Accountable Care Organization (NGACO) Model Evaluation" By Kristina Hanson Lowell, NORC, The University of Chicago, August 27, 2018, https://innovation.cms.gov/Files/reports/nextgenaco-firstannrpt.pdf (Accessed 6/8/23), p. 50-56.
158 "Industry Report OD5775: Telehealth Services in the US" By Marley Brocker, IBISWorld, September 2023, p. 5.
159 *Ibid.*
160 *Ibid*, p. 25.
161 *Ibid*, p. 18.
162 "Final Rule Creates Pathways to Success for the Medicare Shared Savings Program" Centers for Medicare & Medicaid Services, December 21, 2018, https://www.cms.gov/newsroom/fact-sheets/final-rule-creates-pathways-success-medicare-shared-savings-program (Accessed 6/8/23).
163 *Ibid.*
164 *Ibid.*
165 "The 2018 Annual ACO Survey: Examining the Risk Contracting Landscape" By Robert Mechanic, Jennifer Perloff, Teresa Litton, Kerstin Edwards, and David Muhlestein, Health Affairs, April 23, 2019, https://www.healthaffairs.org/do/10.1377/hblog20190422.181228/full/ (Accessed 10/13/23).
166 *Ibid.*
167 *Ibid.*

Valuation of MSOs: Introduction & Competition

[Excerpted from the article published in November 2023.]

Management service organizations (MSOs) can be defined as "a healthcare specific administrative and management engine that provides a host of administrative and management functions necessary to be successful in the ever changing healthcare environment."[1] MSOs are primarily utilized by non-physicians as a vehicle to legally owning an entity that provides administrative support to a medical practice's operations.[2] These entities carry out a variety of duties, including (but not limited to) those related to:

(1) Financial Management;
(2) Business Operations;
(3) Human Resources Management;
(4) Staff Education/Training;
(5) Coding, Billing, and Collections;
(6) Office Space Management;
(7) Provision of Electronic Health Records (EHRs) and Medical Equipment;
(8) Regulatory Compliance Oversight/Management;
(9) Contract Management; and,
(10) Risk Management.[3]

MSOs are typically formed to transfer the non-clinical business functions of a medical practice to a separate (although often friendly/related) business entity that may be owned by non-physicians.[4] Most states only allow medical practices to be owned by physicians, which can limit the number of investors in a medical practice, as well as the financial value of the practice.[5] MSOs are a way for non-physicians to receive revenue from a medical practice's operation.

MSOs can be formed as a general business corporation or a limited liability company, a decision that is typically guided by accounting and legal considerations.[6] MSO entities can be formed outside of the state or inside the state a medical practice operates in.[7] After the MSO is formed, the MSO will enter into a management services agreement (MSA) with one or more medical facilities or practices, which serves as the start of a business relationship.[8] The MSA will include details of all the services which the MSO will provide, as well as services that an MSO may not provide (e.g., clinical services).[9] While MSOs are not required to provide a minimum number of services, they commonly provide financial services, utilization and care management services, information systems support, administrative and actuarial services, network development services, and quality improvement and reporting.[10]

The formation of an MSO can benefit medical practices or health systems in multiple ways, including:

(1) Improved cost and quality;
(2) Increased efficiency due to centralization of management and administrative function; and
(3) Enticement to attract partnerships or expand.[11]

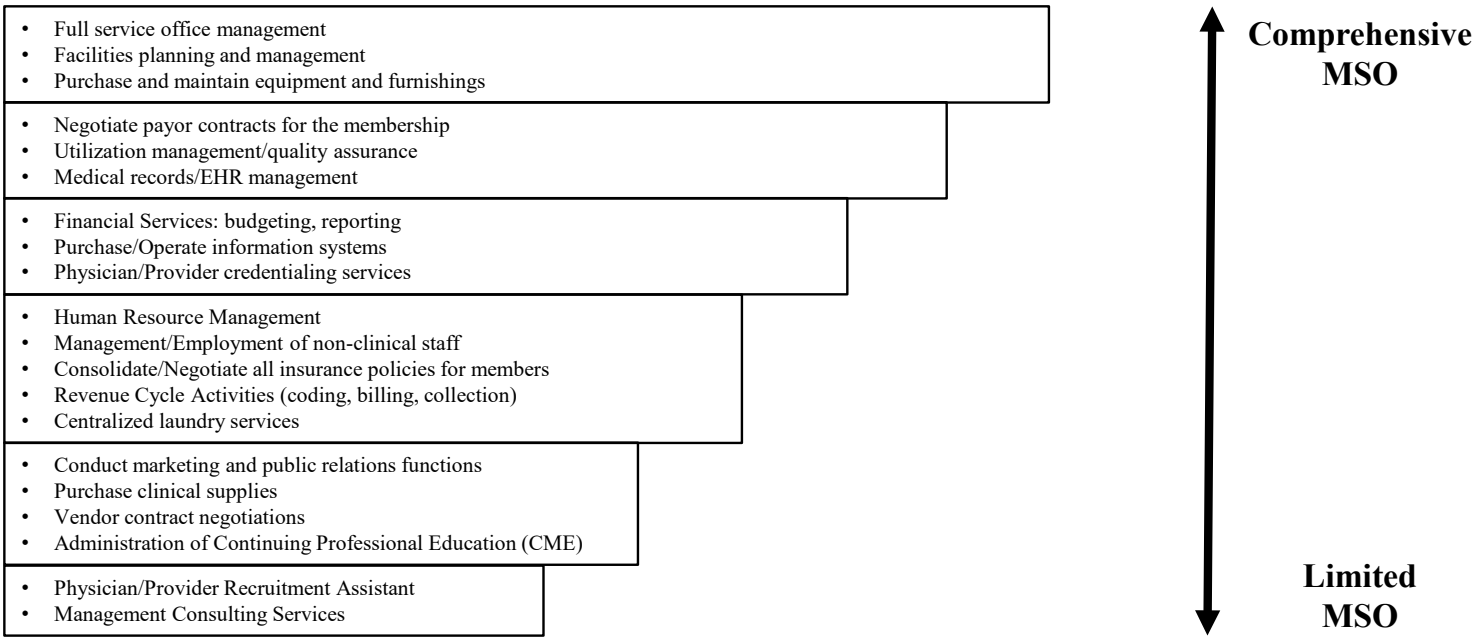
Joining an MSO will often provide access to the best pricing on services and supplies and allow practices to outsource as many non-clinical services as they wish. MSOs (particularly large ones) can obtain preferred pricing on healthcare insurance and medical supplies, and pass those benefits on to practices. Many MSOs also provide services for billing and/or discounted electronic health record (EHR) systems where members can all utilize the same platform.[12] These services provide cost efficiencies and increased purchasing power that can result in a competitive advantage for smaller medical practices.[13]

The rapid growth of managed care and the increased integration among providers in the mid-1990s led to the acceleration in the growth of MSOs; however, by the early 2000s, this trend reversed, effectively breaking up most of the MSOs in the healthcare industry.[14] The 2010 passage of the *Patient Protection and Affordable Care Act* (ACA) set off MSOs' modern popularity,[15] becoming ubiquitous in recent years among healthcare entities, due to pressures within the healthcare industry to reduce costs, implement new technologies, and comply with increasingly complex

regulations.[16] In particular, MSOs are becoming increasingly popular among healthcare entities seeking to better manage costs, implement new technologies, negotiate with payors, and comply with changing federal and state regulations.[17] The scope of services typically provided by an MSO may be characterized by two classifications, either: (1) a *comprehensive* MSO, or (2) a *limited* MSO. The various levels along the spectrum of MSO activities, ranging from comprehensive to limited, are set forth in the below exhibit.

The scope of MSO services may also reflect the specific needs and concerns of the healthcare entity contracting with the MSO. For example, as fraud and abuse scrutiny increases and the claims submission process for reimbursement becomes significantly more complex, MSOs may choose to focus their services on coding, billing, and other revenue cycle management tasks. Consequently, future installments in this three-part series on the valuation of MSOs will review the reimbursement and regulatory environments in which MSOs operate and the technological advancements being leveraged by MSOs.

Exhibit: Range of MSO Services



Valuation of MSOs: Reimbursement & Technology

[Excerpted from the article published in December 2023.]

As discussed in the first installment of this three-part series on the valuation of management service organizations (MSOs), technological innovation has allowed greater efficiency and automation within MSOs, which allow MSOs to provide more cost-effective services to medical practices, and potentially optimize their revenue. As a result, technology is expected to play a crucial role in the operations of MSOs and the overall delivery of healthcare services. This second installment discusses the impact of technological advancements on their operations, as well as how MSOs are reimbursed/compensated.

Research indicates that the implementation of technology may assist the management of complex patient records, payment invoices, and privacy requirements.[18] Technologies such as electronic health records (EHRs) have resulted in cost savings, improved quality, and better coordination of care.[19] Most EHR software systems are customizable and can

be designed for specific specialties, such as physical therapy, and increase the productivity of tasks such as appointment scheduling, medical billing, electronic prescribing, lab tests, document management, patient engagement, and telehealth services.[20]

MSOs may experience the indirect benefits of EHRs, as the technology has been shown to help deliver high-quality care and create measurable improvements within a practice.[21] EHRs allow a practice to provide accurate, up-to-date information that is easy to access at the point of care for more coordinated treatment.[22] EHRs allow providers to keep patient data private, but also utilize the platform to securely share patient information with other providers.[23] Along with clinical benefits, EHRs can provide numerous administrative benefits that can lead to increased convenience, efficiencies, and cost savings. EHRs can improve productivity and efficiency within a practice with thorough, uniform records on a patient that can reduce duplication, improve safety, promote coordinated care, and streamline billing and coding services.[24] Particularly, EHR systems may also serve as a platform for communication between providers and patients. With increased communication between provider and patient, cost savings can also be achieved, along with reduced hospitalization and readmissions.[25]

Research indicates that implementation of health information technology (HIT) may lead to improved efficiency and quality management.[26] HIT includes a variety of software applications, such as billing software, staffing models, and EHR.[27] Over the past decade, there has been a rapid adoption of technological innovations in the U.S., which has fundamentally changed the healthcare delivery system.[28] For example, as alluded to above, technologies such as EHRs have resulted in cost savings, improved quality, and better coordination of care.[29] However, HIT poses significant administrative and cost burdens to physician practices, which may prevent small-practice physicians from adopting this technology.[30]

Health data analytics involves extracting insights from sets of patient data from various sources, primarily EHRs.[31] The need for data analytics in MSOs is spurred by the use of data analytics technology for population health management (PHM).[32] PHM is a practical approach to improving healthcare delivery and outcomes for a group of patients while simultaneously lowering costs to the provider.[33] Using EHR data in analytics is a subset of data analytics called clinical data analytics.[34] MSOs that are positioned to adopt rapidly-advancing technology may be able to utilize data analytics to improve savings and the quality of care.

As noted above, MSOs that are well-positioned to harness technology to provide management services to medical practices may be able to optimize their revenue. MSOs are compensated by medical practices for the non-clinical services they provide, as dictated by their management services agreement (MSA).[35] Payments that are considered permissible to an MSO (e.g., do not violate fraud and abuse laws) can be for returns on expenses for items such as equipment, space, staff, loan payments, and intellectual property, as well as the payment of a management fee.[36] A management fee is typically structured as either a fixed fee or a percentage of collections (gross or net).[37] The fee's structure is dependent on federal and state law, as well as on the strategies and business plans of the involved parties.[38] Typically, the medical practice is responsible for paying the MSOs for rendered services provided by non-licensed professionals.[39] While U.S. federal healthcare programs do not directly pay MSOs, they remain the largest payor of medical costs, and have a strong influence on the reimbursement of physicians, which can in turn influence the management fees paid to MSOs, as some MSO fees are structured as a percent of the amounts reimbursed by payors.

However, as alluded to above, it is important to note that the management fee structure is regulated by healthcare fraud and abuse laws, which largely dictates how (and how much) a medical practice can pay an MSO for management services. The last installment in this three-part series will discuss the highly-regulated environment in which MSOs operate.

Valuation of MSOs: Regulatory

[Excerpted from the article published in January 2024.]

Management service organizations (MSOs) 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. The last installment in this three-part series on the valuation of MSOs discusses the regulatory environment in which these organizations operate

Federal Fraud and Abuse Laws

The AKS and Stark Law are generally concerned with the same issue – the financial motivation behind patient referrals. However, while the AKS is broadly applied to payments between providers or suppliers in the healthcare industry and relates to any item or service that may be paid for under any federal healthcare program, the Stark Law specifically addresses the referrals from physicians to entities with which the physician has a financial relationship for the provision of defined services that are paid for by the Medicare program.[40] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[41]

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,[42] even if only one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[43] Notably, a person need not have actual knowledge of the AKS or specific intent to commit a violation of the AKS for the government to prove a kickback violation,[44] only an awareness that the conduct in question is "generally unlawful."[45] Further, a violation of the AKS is sufficient to state a claim under the False Claims Act (FCA).[46]

Criminal violations of the AKS are punishable by up to ten years in prison, criminal fines up to $100,000, or both, and civil violations can result in administrative penalties, including exclusion from federal healthcare programs, and civil monetary penalties plus treble damages (or three times the illegal remuneration).[47] In addition to the civil monetary penalties paid under the AKS, if the AKS violation triggers liability under the FCA, defendants can incur additional civil monetary penalties of $13,508 to $27,018 per violation, plus treble damages.[48]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[49] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to HHS to protect certain business arrangements by means of promulgating several *safe harbors*.[50] 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.[51] Failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[52] It should be noted that, in order for a payment to meet the requirements of many AKS safe harbors, the compensation must not exceed the range of fair market value and must be commercially reasonable.

Of note, in a December 2020 final rule, the Department of Health & Human Services Office of Inspector General (HHS OIG) released several revisions to the AKS, many of which are similar to those revisions to the Stark Law proposed by the Centers for Medicare & Medicaid Services (CMS), as discussed below.[53] Among the more notable revisions are new safe harbors for value-based arrangements (the safe harbor requirements for which arrangements lessen as the participants take on more financial risk) and revisions to existing safe harbors, including to the safe harbor for Personal Services and Management Contracts and Outcomes-Based Payment Arrangements.[54] Among other things, this safe harbor requires that the "[t]he methodology for determining the compensation paid to the agent over the term of the

agreement 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…"[55] Notably, the OIG eliminated the requirement that *aggregate compensation* under these agreements be set in advance, instead requiring only that the *compensation methodology* be set in advance.[56]

The OIG regularly issues advisory opinions on the application of the AKS to certain business arrangements – either existing or proposed – on which a party has requested an opinion. An advisory opinion is the OIG's position on whether a certain business arrangement is in conflict with the AKS.[57] Over the years, a number of these advisory opinions have analyzed various management services arrangements. For example:

(1) A 1998 advisory opinion expressed concern regarding MSOs receiving payment from a physician group as a percentage of collections or revenue while performing marketing services.
(2) A 2006 advisory opinion reviewed payment to a dental marketing and management company.[58] While it ultimately found that the arrangement was in compliance with the AKS, the OIG noted that "Per patient, per unit-of-service, percentage, or similar variable compensation structures are particularly problematic under the statute, because they relate to the volume or value of business generated between parties."[59]
(3) A 2003 advisory opinion reviewed a proposed management fee, calculated on a per patient per day basis, to be paid to a company to develop inpatient rehab units in general acute care hospitals, to be in violation of the AKS.[60]

Stark Law

The Stark Law prohibits physicians from referring Medicare patients to entities with which the physicians or their family members have a financial relationship for the provision of designated health services (DHS).[61] Under the Stark Law, DHS include, but are not limited to, the following:

(1) Inpatient and outpatient hospital services;
(2) Radiology and certain other imaging services;
(3) Radiation therapy services and supplies;
(4) Certain therapy services, such as physical therapy;
(5) Durable medical equipment; and,
(6) Outpatient prescription drugs.[62]

If DHS is not included in the arrangement (which is not uncommon in management services arrangements, particularly those involving medical practices), the Stark Law would not apply.[63]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities also have an ownership interest in the entity that provides DHS.[64] 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.[65]

Civil penalties under the Stark Law include overpayment or refund obligations, a potential civil monetary penalty of $15,000 for each service, plus treble damages, and exclusion from Medicare and Medicaid programs.[66] Further, similar to the AKS, violation of the Stark Law can also trigger a violation of the FCA.[67]

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.[68] 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 Stark enforcement.[69]

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

(1) Revised definitions for Fair Market Value, General Market Value, and Commercial Reasonableness; and,
(2) New permanent exceptions for value-based arrangements.[70]

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

Corporate Practice of Medicine Provisions

Almost all states have provisions against the *corporate practice of medicine* (CPOM), a doctrine first developed by the American Medical Association (AMA).[71] Although the regulated content of CPOM provisions vary across states, these laws generally prohibit unlicensed individuals or corporations from engaging in the practice of medicine by employing licensed physicians.[72] CPOM laws were established with the intent of ensuring that licensed physicians could practice medicine without pressure from a lay person or being "*subject to commercialization or exploitation.*"[73] CPOM laws relate directly to MSOs because they dictate what type of relationship healthcare entities may have with physicians (i.e., employment versus independent contractor).[74] While there are significant variations in regulation between states, most states have adopted all or some of the following measures in the four key areas addressed by the doctrine:

(1) Prohibiting business entities from employing physicians to provide medical care;
(2) Requiring that licensed medical doctors own and operate facilities providing medical services;
(3) Not allowing professional fee splitting between licensed practitioners and non-licensed individuals or entities; and,
(4) Mandating that management service agreements (MSAs) adhere to fair market value standards.[75]

MSAs and MSOs have received increased regulatory scrutiny in recent years, in part because they allow outside (often non-healthcare) companies to manage medical practices or groups, including administration and operations.[76] In order to mitigate potential fraud and abuse issues, regulations require fees for these management services to be consistent with fair market value, and state laws and regulations create certain standards for decisions that must be made by a licensed physician and how much revenue that an MSO may receive from the practice.[77]

Conclusion

Considering the various competitive, reimbursement, technological, and regulatory trends discussed in this three-part series, MSOs may face some challenges in the coming years. As noted in the first installment, the scope of MSO services may also reflect the specific needs and concerns of the healthcare entity contracting with the MSO. For example, as fraud and abuse scrutiny increases and the claims submission process for reimbursement becomes significantly more complex, MSOs may choose to focus their services on coding, billing, and other revenue cycle management tasks. As noted in the second installment, MSOs that are positioned to adopt rapidly-advancing technology may be able to utilize technology to improve savings and the quality of care. As with most other healthcare organizations, MSOs will be required to efficiently provide services while maintaining compliance with regulations and remaining aware of government enforcement initiatives in order to survive.

1 "An Introduction to Building a Management Services Organization (MSO)" By Yomi Ajao and Stephanie King, Cope Health Solutions, 2020, https://copehealthsolutions.com/cblog/an-introduction-to-building-a-management-services-organization/ (Accessed 11/20/23).
2 "Management Services Organizations (MSOs)" Frier Levitt, https://www.frierlevitt.com/who-we-serve/healthcare/management-services-organizations/ (Accessed 11/20/23).
3 "Understanding Management Services Organizations (MSOs)" By Susanne Madden, Physicians Practice, April 27, 2016, https://www.physicianspractice.com/view/understanding-management-services-organizations-msos (Accessed 11/20/23).
4 Levitt (Accessed 11/20/23).
5 *Ibid.*
6 *Ibid.*
7 *Ibid.*
8 *Ibid.*
9 *Ibid.*
10 "An Introduction to Building a Management Services Organization (MSO)" By Yomi Ajao and Stephanie King, COPE Health Solutions, https://copehealthsolutions.com/cblog/an-introduction-to-building-a-management-services-organization/#:~:text=A%20management%20services%20organization%20(MSO)%20is%20a%20health%20care%20specific,the%20ever%20changing%20healthcare%20environment. (Accessed 11/20/23).
11 *Ibid.*
12 Madden, Physicians Practice, April 27, 2016.
13 "Management Services Organization (MSO)" Vanguard Health Solutions, https://www.vanguardhealthsolutions.com/management-services-organization (Accessed 11/27/23).
14 "Physician Practice Management Companies Stage A Comeback; Anatomic Pathology Groups Remain Skeptical" By Jon Stone, Dark Daily, February 26, 2016, https://www.darkdaily.com/2016/02/24/physician-practice-management-companies-stage-a-comeback-anatomic-pathology-groups-remain-skeptical-224/ (Accessed 11/20/23).
15 "MSOs: A Third Way For Physicians" By Jay Pruzanksy, American Healthcare Journal, September 4, 2019, available at: https://americanhealthcarejournal.com/2019/09/04/msos-a-third-way-for-physicians/ (Accessed 11/20/23).
16 Ajao and Stephanie King, Cope Health Solutions, 2020.
17 "Managed Services Organization" LBMC, https://www.lbmc.com/services/healthcare-consulting/mso/ (Accessed 11/27/23); Madden, Physicians Practice, April 27, 2016.
18 See "Medical Practice Efficiencies & Cost Savings" The Office of the National Coordinator for Health Information Technology (ONC), August 13, 2018, https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/medical-practice-efficiencies-cost-savings (Accessed 9/29/23).
19 *Ibid.*
20 "Patients' safety in the era of EMR/ EHR automation" By Bakheet Aldosari, October 5, 2017, https://doi.org/10.1016/j.imu.2017.10.001 (Accessed 9/29/23).
21 The Office of the National Coordinator for Health Information Technology (ONC), August 13, 2018.
22 "What are the advantages of electronic health records?" HealthIT.gov, March 8, 2022, https://www.healthit.gov/faq/what-are-advantages-electronic-health-records (Accessed 9/29/23).
23 *Ibid.*
24 *Ibid.*
25 *Ibid.*
26 "A Brief Primer to Health Information Technology" The Certification Commission for Health Information Technology (CCHIT), July 2, 2022, https://www.cchit.org/a-brief-primer-to-health-information-technology/ (Accessed 9/27/23).
27 "What Is Health Information Technology? Ultimate Guide" By Samikshan Sarkar, SelectHub, https://selecthub.com/medical-software/7-categories-healthcare-information-technology/ (Accessed 9/27/23).
28 "Office-Based Physician Electronic Health Record Adoption" The Office of the National Coordinator for Health Information Technology, https://www.healthit.gov/data/quickstats/office-based-physician-electronic-health-record-adoption (Accessed 9/27/23).
29 "The Impact of Technology on Healthcare" By Bianca Banova, American Institute of Medical Sciences and Education, June 2, 2019, https://aimseducation.edu/blog/the-impact-of-technology-on-healthcare (Accessed 9/27/23).
30 "EHRs: The Challenge of Making Electronic Data Usable and Interoperable" By Miriam Reisman, P&T, Vol. 42, No. 9 (September 2017), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5565131/pdf/ptj4209572.pdf (Accessed 9/27/23), p. 574; "Do Small Physician Practices Have a Future?" By David Squires and David Blumenthal, M.D., To The Point, The Commonwealth Fund, May 26, 2016, https://www.commonwealthfund.org/blog/2016/do-small-physician-practices-have-future (Accessed 9/27/23).
31 "What is Health Data Analytics?" USF Health, Morsani College of Medicine, November 16, 2021, https://www.usfhealthonline.com/resources/key-concepts/health-data-analytics/ (Accessed 12/18/23).
32 *Ibid.*
33 *Ibid.*
34 *Ibid.*
35 "MSO Field Guide: Part 1 (What is an MSO)" Byrd Adatto, August 29, 2022, https://byrdadatto.com/banter/mso-field-guide-part-1-what-is-an-mso/ (Accessed 12/18/23).
36 *Ibid.*).
37 *Ibid.*
38 *Ibid.*
39 "What Is An MSO And How Can It Help Your Medical Practice?" Carbon Law Group, June 6, 2022, / (Accessed 12/18/23).
40 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 1/9/24).
41 *Ibid.*
42 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 USC § 1320a-7b(b)(1).
43 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf (Accessed 1/9/24), p. 4-5; "U.S. v. Greber" 760 F.2d 68, 69 (3d. Cir. 1985).
44 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 6402, 10606, 124 Stat. 119, 759, 1008 (March 23, 2010).
45 "Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview" By Jennifer A. Staman, Congressional Research Service, September 8, 2014, https://www.fas.org/sgp/crs/misc/RS22743.pdf (Accessed 1/9/24), p. 5.
46 "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" McDermott Will & Emery, April 12, 2010, p. 3; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 6402, 124 Stat. 119, 759 (March 23, 2010).
47 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 USC § 1320a-7b(b)(1); "Civil Monetary Penalties" 42 USC § 1320a-7a(a).
48 "False claims" 31 USC § 3729(a)(1)(G); "Civil Monetary Penalties Inflation Adjustments for 2023" Federal Register, Vol. 88, No. 19 (January 30, 2023), p. 5777.
49 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf (Accessed 1/9/24), p. 5.
50 *Ibid.*
51 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" Federal Register Vol. 64, No. 223 (November 19, 1999), p. 63518, 63520.
52 "Re: Malpractice Insurance Assistance" By Lewis Morris, Chief Counsel to the Inspector General, United States Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, https://oig.hhs.gov/fraud/docs/alertsandbulletins/malpracticeprogram.pdf (Accessed 1/9/24), p. 1.
53 Federal Register, December 2, 2020, Vol. 85, No. 232, p. 77814-77815.
54 *Ibid.*
55 "Exceptions" 42 USC § 1001.952.
56 Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77839.
57 "Advisory Opinions" Office of Inspector General, Department of Health & Human Services, https://oig.hhs.gov/compliance/advisory-opinions/ (Accessed 1/9/24).
58 "Re: Advisory Opinion No. 98-4" Office of the Inspector General, Department of Health and Human Services, April 15, 1998, https://oig.hhs.gov/documents/advisory-opinions/379/AO-98-04.pdf (Accessed 1/9/24).
59 "Re: Advisory Opinion No. 6-17" Office of the Inspector General, Department of Health and Human Services, October 6, 2006, https://oig.hhs.gov/documents/advisory-opinions/520/AO-06-17.pdf (Accessed 1/9/24).

60 "Re: Advisory Opinion No. 03-8" Office of the Inspector General, Department of Health and Human Services, April 3, 2003, https://oig.hhs.gov/documents/advisory-opinions/465/AO-03-08.pdf (Accessed 1/9/24).

61 "CRS Report for Congress: Medicare: Physician Self-Referral ("Stark I and II")" By Jennifer O'Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, available at: http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf (Accessed 1/9/24); "Limitation on certain physician referrals" 42 USC § 1395nn.

62 "Limitation on Certain Physician Referrals" 42 USC § 1395nn(a)(1)(B); "Definitions" 42 CFR § 411.351 (2015). Note the distinction in 42 CFR § 411.351 regarding what services are included as DHS: "Except as otherwise noted in this subpart, the term 'designated health services' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)."

63 "Stark Exceptions" College of American Pathologists, https://documents.cap.org/documents/stark-law-exceptions.pdf (Accessed 1/9/24).

64 "Limitation on certain physician referrals" 42 USC § 1395nn (a)(2).

65 42 USC § 1395nn (h)(1).

66 42 USC § 1395nn (g).

67 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 1/9/24).

68 "Limitation on certain physician referrals" 42 USC § 1395nn.

69 Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 1/9/24).

70 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77492.

71 "Emergency Medicine Advocacy Handbook" EMRA, https://www.emra.org/books/advocacy-handbook/corporate-practice-of-medicine (Accessed 1/9/24); "Understanding the Corporate Practice of Medicine Doctrine and the Role of the Management Services Organization" Nelson-Hardiman, June 6, 2011, https://www.nelsonhardiman.com/hc-law-news/understanding-the-corporate-practice-of-medicine-doctrine-and-the-role-of-the-management-services-organization/ (Accessed 1/9/24).

72 "The Corporate Practice of Medicine" TMA Office of General Counsel, Texas Medical Association, September 2016, p. 1.

73 "People v. United Medical Service" 362 Ill. 442, 200 N.E. 157, 163 (1936), p. 6.

74 "Emergency Medicine Advocacy Handbook" EMRA, https://www.emra.org/books/advocacy-handbook/corporate-practice-of-medicine (Accessed 1/9/24).

75 "3 Steps to Navigate Through the Corporate Practice of Medicine" By Jennifer Brunkow, Becker's Hospital Review, March 26, 2012, https://www.beckershospitalreview.com/legal-regulatory-issues/3-steps-to-navigate-through-the-corporate-practice-of-medicine.html (Accessed 1/9/24).

76 "Understanding the Corporate Practice of Medicine Doctrine and the Role of the Management Services Organization" Nelson-Hardiman, June 6, 2011, https://www.nelsonhardiman.com/hc-law-news/understanding-the-corporate-practice-of-medicine-doctrine-and-the-role-of-the-management-services-organization/ (Accessed 1/9/24).

77 *Ibid.*

Valuation of Diagnostic Imaging: Introduction

[Excerpted from the article published in February 2024.]

Diagnostic imaging is "the process of making a visual representation of the interior of the body for medical intervention."[1] This process utilizes medical imaging techniques to "create pictures of a patient's internal anatomy and convert them to film" in order to detect, diagnose, and treat diseases and injuries.[2] Diagnostic imaging can be performed in a number of sites, including hospitals, physician offices, and freestanding independent diagnostic testing facilities (IDTFs), defined by the Centers for Medicare & Medicaid Services (CMS) as "a facility that is independent both of an attending or consulting physician's office and of a hospital."[3] Over 70% of imaging volume is performed in a hospital setting, while the remaining portion occurs in the outpatient setting.[4]

The various modalities that comprise diagnostic imaging may be utilized in a wide variety of medical applications, and include, but are not limited to:

(1) X-Ray;
(2) Magnetic resonance imaging (MRI);
(3) Computed tomography (CT);
(4) Mammography;
(5) Ultrasound; and
(6) Positron emission tomography (PET)

Each modality is discussed in turn below.

X-Ray

X-ray, or radiography, utilizes small doses of ionizing radiation to produce images of the body's internal structures.[5] In some x-ray exams, barium or iodine-based contrast may be used to improve the visibility of specific tissues, bones, blood vessels, or organs.[6] Soft tissues in the body, such as muscle or fat, allow the x-ray to pass through and appear gray on digital media or film.[7] Tumors and bones, which have a higher density compared to soft tissue, do not allow all of the x-rays to pass through, and thus appear white on the image.[8] When a break in the bone is present, the x-ray beam passes through the broken area, rendering the image as a dark line on the white bone.[9] To create a radiograph, patients are positioned so the body part being imaged is located between an x-ray detector and an x-ray source.[10] Technology used in x-rays is also utilized in other types of diagnostic procedures, including fluoroscopy, arteriograms, and CT scans.[11]

MRI

MRIs allow providers to noninvasively diagnose or monitor injuries or disorders of the brain, spinal cord, heart, abdominal organs, or joints.[12] Common MRI exams include functional MRIs (fMRIs), when a patient is asked to perform certain activities to map functional areas of the brain before surgery; breast scans; magnetic resonance angiographies (MRAs), which help visualize blood vessels; magnetic resonance venographies (MRVs), which help visualize organ blood vessels using a contrast dye; and cardiac MRIs.[13]

Unlike x-rays and CT scans, which use ionizing radiation technology in order to take images of the body, MRIs use a large magnet, radio waves, and a computer to create a cross-sectional image of the internal organ(s) and/or structure(s) in question.[14] An MRI may be more appropriate than a CT scan when organs or soft tissues are being studied, as an MRI scan is more capable of displaying the contrast between normal and abnormal soft tissues and can differentiate between fat, water, and muscle with more accuracy.[15] In order to highlight certain tissues and improve accuracy, a contrast dye, taken orally or intravenously, may be utilized in some patients, which may extend the length of treatment.[16]

CT

CT scans, also known as computerized axial tomography (CAT) scans, are often used to examine bones, muscles, fat, organs, or blood vessels, although they are capable of providing detailed images of any part of the body.[17] Unlike MRIs, CT scans use x-ray and computer technology to produce cross-sectional images, which are more appropriate for diagnosing cancer, pneumonia, abnormal chest x-rays, and brain bleeds.[18] CT scans go beyond the standard x-ray by providing additional detail related to internal organs and structures by emitting a series of narrow beams through the body in an arc-like formation.[19] These scans produce two-dimensional (2D) images of sections of the body, but can be combined to create a three-dimensional (3D) image.[20] Scans may take mere seconds to several minutes; however, if oral contrast is needed, it requires an additional 45 to 60 minutes to reach the digestive tract.[21]

Mammography

Mammograms are specifically utilized to conduct an x-ray examination of the breast in order to detect breast diseases.[22] In addition to conventional mammography, there are three additional advances, including digital mammography (rather than utilizing x-ray film), computer-aided detection (CAD), and digital breast tomosynthesis (DBT).[23] DBT, also known as 3D mammography, is an advanced form of imaging that creates a 3D image of the breast(s), combining multiple images from different angles.[24] Mammograms are often used as a screening tool to detect breast cancer, which can show changes in a breast up to two years before a patient or physician can feel them.[25] The U.S. Preventative Services Task Force recommends women between the ages of 50 and 74 receive mammograms biannually and states that the decision to undergo a mammogram is an individual one between the ages of 40 and 49.[26] Another common mammography use is for diagnostic purposes, to evaluate a patient with certain symptoms in or on the breast, e.g., lump, pain, skin dimpling, or nipple discharge, which takes longer to perform and utilizes a higher dose of radiation to obtain more views of the breast(s).[27]

Ultrasound

Ultrasounds utilize sound waves to produce pictures of the inside of the body.[28] Unlike other medical imaging tests, such as CT scans and x-rays, radiation is not utilized in ultrasounds.[29] Ultrasound imaging is used to examine unborn children in pregnant women, as well as to diagnose infection, swelling, and pain in internal organs.[30] No special preparation is required before an ultrasound scan is administered.[31] An image is produced by traveling through the blood in the chamber of the heart, for example, and if it hits a valve in the heart, it will bounce back or echo.[32] The denser objects will result in more of the ultrasound bouncing back, giving the ultrasound its features.[33] The three main types of ultrasound imaging utilized by providers are diagnostic ultrasounds, pregnancy ultrasounds, and ultrasounds used as guidance for procedures.

Ultrasounds that are performed during pregnancies are traditional ultrasounds, where a 2D image of the fetus is produced.[34] The 2D ultrasound produces flat-looking images and outlines, which allows providers to examine the structure and internal organs of the fetus.[35] 3D ultrasounds allow for the examination of certain facial features of the fetus, and other body parts such as the toes and fingers.[36] 4D ultrasounds are 3D ultrasounds taken in motion.[37]

PET

PET scans are imaging tests that help reveal the biochemical or metabolic function of the organs and tissues of the body.[38] PET scans utilize the injection of radioactive drugs called "tracers" to show both atypical and typical metabolic activity.[39] The most commonly utilized tracer is FDG (fluorodeoxyglucose), a simple sugar (glucose) that has been radiolabeled; FDG gives off energy in the body, which can be observed by the scanner.[40] PET scans will measure functions such as blood sugar metabolism, blood flow, and oxygen use.[41] Providers typically use PET scans to help diagnose cancer and assess cancer treatment; they can also use it to assess certain brain and heart issues.[42] PET scans will usually take about 15 to 20 minutes, but patients can expect to be in the PET imaging department approximately two to three hours.[43] PET scans are safe, and no side effects are associated with radioactive tracers, which only remain in the body for a short time.[44] The dose of radiation is very small, and approximate to a few years of natural radiation from the environment.[45]

Conclusion

In light of the current conditions of the diagnostic imaging industry, demand may be driven by: (1) the increased demand for services due to the aging Baby Boomer population, who will require more diagnostic imaging services; and (2) a patient and payor preference for diagnostic imaging conducted in freestanding centers (in contrast to the hospital or hospital outpatient department setting). The next installment of this five-part series will review the competitive environment of the diagnostic imaging industry.

Valuation of Diagnostic Imaging: Competition

[Excerpted from the article published in March 2024.]

Diagnostic imaging centers operate in a highly competitive environment with other providers of diagnostic imaging, such as hospitals and physician offices.[46] While hospitals may have some competitive advantages over freestanding imaging centers (e.g., location, wherein the patient is already admitted to the hospital and the reading radiologist is on-site), imaging centers have become more desirable by both patients, who find the freestanding locations to be more convenient, and payors, who find services at freestanding locations to be less expensive than those performed in the hospital or a hospital outpatient department (HOPD). This second installment in a five-part series on the valuation of diagnostic imaging centers will discuss the competitive environment in which these centers operate.

Supply of Diagnostic Imaging Facilities

The level of competition in the diagnostic imaging center industry is high.[47] As of 2022, there were over 9,769 diagnostic imaging centers in operation in the U.S., which number has declined by approximately 1.5% per year over the past five years.[48] Cost pressures have strained the environment in which diagnostic imaging centers operate, with inflation and steady patient volumes making it a challenge for centers to recoup profit, and consequently chilling the growth in the number of centers.[49] Nevertheless, competition is expected to remain high going forward, and the number of diagnostic imaging centers is anticipated to remain relatively stagnant over the next five years, increasing an annual rate of only 0.4%.[50] Due to factors such as imaging technology advancement and increased demand for diagnostic imaging services, imaging volumes have risen from over 115 million scans in 2012 to an estimated 120 million in 2019, with PET showing the most growth.[51]

The number of various types of modalities in the U.S. accredited by the American College of Radiology (ACR) is set forth below in Table 1.

Table 1: Number of ACR-Accredited Diagnostic Imaging Modalities[52]

2022 U.S. Population		334,279,739
Number	CT	7,123
	MRI	7,100
	Ultrasound	5,328
	Mammography	8,601
	PET	1,625
	Nuclear Medicine	3,104
Per 1 Million Population	CT	21.3
	MRI	21.2
	Ultrasound	15.9
	Mammography	25.7
	PET	4.9
	Nuclear Medicine	9.3

Demand for Diagnostic Imaging Services

The key drivers in the supply of diagnostic imaging facilities are largely attributable to an aging population, increases in chronic disease, the need for accessible and timely care, and advancements in technology.

One of the most important factors affecting demand for imaging procedures, and healthcare overall, is the aging Baby Boomer population. By 2030, all Baby Boomers will be age 65+, and by 2034, will outnumber children for the first time in U.S. history.[53] Approximately 20-30% of those age 65+ who fall suffer from moderate to severe injuries such as hip fractures or head trauma, potentially requiring the use of CT or MRI scans to diagnose the injury.[54] Additionally, with increases in chronic disease, medical imaging that can provide safe treatments and quick diagnosis is necessary now more than ever.[55] It is estimated that between 2020 and 2050, the number of individuals over the age of 50 with at least one chronic disease will increase nearly 100%, and those with multiple chronic diseases will increase over 91%.[56]

Technological advances, including those that have shrunk the size of medical imaging devices, have increased the accessibility of imaging, giving patients more location options than just hospital imaging departments.[57] Smaller and (thus portable) devices are more affordable, increasing accessibility for practitioners,[58] and allow scans to be done in other types of locations, helping to answer patient questions and provide early detection.[59]

Other advances in technology, such as artificial intelligence (AI), are also expected to drive growth in the diagnostic imaging market, as it could help guide practitioners around anatomy and change depth and contrast on an image automatically.[60] These features can lower the barrier to entry for providers who have never used medical imaging before, and allow them to use devices with accurate readings from the start.[61] While doctors are still required by the Food and Drug Administration (FDA) to provide the final reading on images, the FDA has already approved more than 400 AI algorithms that can scan for a variety of diseases with an 80-90% accuracy rate.[62]

Detailed imaging is required not only to diagnose cancer, but also to plan cancer treatment and determine if that treatment is successful.[63] As a result, imaging procedure growth is linked in part to the diagnosis of many diseases associated with later age, including cancer, so the incidence of cancer, for which a number of diagnostic imaging modalities are used to diagnose and treat, also drives demand for diagnostic imaging.[64] An estimated 1.9 million new cancer cases were diagnosed in 2022, and cancer incidence is expected to increase in the future.[65] As the U.S. population ages, the number of new cancer cases will also increase,[66] increasing the need for screening services, particularly CT scans, which are typically used for tumors and cancer monitoring.[67] Additionally, mammography

utilization may increase due to projected trends in breast cancer, as mammography demand rises with increases in cancer incidence and as the population ages (as age is one of the main risk factors for breast cancer).[68] Approximately 1 in 8 American women will develop breast cancer during her life, indicating that the need for mammography scans will continue, and potentially increase, in the future.[69]

Over the next few years, diagnostic imaging centers may benefit from: (1) increased demand for services due to the aging Baby Boomer population, who will require more diagnostic imaging services; and (2) a patient and payor preference for diagnostic imaging conducted in freestanding centers (in contrast to the hospital or HOPD setting). However, this growth in demand (i.e., the quantity of scans performed) may be tempered by decreasing Medicare reimbursement for diagnostic imaging. The next installment in this five-part series will review the reimbursement environment in which diagnostic imaging centers operate.

Valuation of Diagnostic Imaging: Reimbursement

[Excerpted from the article published in April 2024.]

The U.S. government is the largest payor of medical costs, through Medicare and Medicaid, and has a strong influence on physician reimbursement. In 2021, Medicare and Medicaid accounted for an estimated $900.8 billion and $734.0 billion in healthcare spending, respectively.[70] 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.[71]

Diagnostic imaging services are reimbursed by Medicare under the Medicare Physician Fee Schedule (MPFS). In order to make these payments, Medicare utilizes the Resource Based Relative Value Scale (RBRVS) system, which assigns relative value units (RVUs) to individual procedures based on the resources required to perform each procedure. Under this system, each procedure in the MPFS is assigned RVUs for three categories of resources:

(1) Physician work (wRVUs);
(2) Practice expense (PE RVUs); and
(3) Malpractice (MP RVUs) expense.

Each procedure's RVUs are then adjusted for local geographic differences using Geographic Practice Cost Indexes (GPCIs) for each RVU component. 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:[72]

Payment = [(wRVU x GPCI work) + (PE RVU x GPCI PE) + (MP RVU x MP GPCI)] x 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, while indirect expenses include administrative labor, office expenses, and all other expenses. MP RVUs correspond to the relative malpractice practice expenses for medical procedures, adjusted by specialty.[73]

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 components.[74] A locality's GPCI is determined by taking into consideration the median hourly earnings of workers in the area, office rents, medical equipment and supplies, and other miscellaneous expenses.[75] There are currently 112 GPCI payment localities.[76]

The conversion factor (CF) is a monetary amount that is multiplied by the RVU from a locality to determine the payment amount for a given service.[77] 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.[78]

The Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA) contains a predetermined schedule of updates to the CF. However, these annual updates are relatively small, and in fact the update is 0% for years 2020 through 2025.[79] In actuality, due in part to the COVID-19 pandemic, MPFS reimbursement decreased in each of the last four years (2021-2024) after seeing positive updates to reimbursement rates in each of the four years prior to that (2017-2020). It should be noted that, although the annual updates to the MPFS may be (at best) stagnant for at least the next couple years, MACRA includes several provisions related to financial rewards for providers who furnish efficient, high quality healthcare services.

MPFS reimbursement for diagnostic imaging services is split into a professional component (PC), representing the physician's efforts in interpreting a test, and a technical component (TC), representing "all non-physician work performed by an [Advanced Diagnostic Imaging] ADI supplier, including administrative and non-physician personnel time and use of the ADI equipment and facility."[80] Adding another layer of complexity, the reimbursement methodology changes depending on where the diagnostic imaging services are performed. For example, if the imaging services are performed in a physician practice, both the PC and the TC are billed using the MPFS.[81] However, if the imaging services are performed in a hospital, the PC is billed using the MPFS, while the TC is billed using the appropriate hospital prospective payment system, depending on whether the patient had been admitted.[82]

One source of payment reduction for imaging services is the equipment utilization rate. The Centers for Medicare & Medicaid Services (CMS) uses the utilization rate to calculate PE RVUs, reasoning that the more often a fixed piece of equipment is used, the lower the expense per use (and therefore, lower reimbursement for the use of that equipment). For most equipment, CMS assumes a utilization rate of 50% (i.e. the equipment is in use 50% of the time the provider is open for business).[83] However, for certain imaging equipment (including CT and MRI machines) that costs more than $1 million, CMS assumes a utilization rate of 90%.[84] With this higher utilization rate, imaging services receive less reimbursement per use of the equipment. Industry stakeholders have argued that 90% utilization is nearly unattainable, asserting that average utilization rates for imaging equipment are much closer to (and perhaps lower than) CMS's original assumption of 50%.[85]

Further, in an effort to control outsized diagnostic imaging costs in the early 2000s, the Deficit Reduction Act of 2005 (DRA) required MPFS reimbursement for the TC of diagnostic imaging services to be "capped" at what Medicare pays for those services under the Outpatient Prospective Payment System (OPPS).[86] The DRA also required Medicare to reduce reimbursement for certain repeated TC imaging services delivered by the same physician to the same patient on the same day, known as the Multiple Procedure Payment Reduction (MPPR).[87] Therefore, depending on the services provided, such imaging reimbursement policies may or may not have an impact on revenue.

Notably, Medicare reimbursement for diagnostic imaging procedures has generally decreased over the years. A 2022 study found that Medicare reimbursement for common diagnostic imaging studies, after adjusting for inflation, generally decreased between 2011 and 2021,[88] which trend has continued to present,[89] and is expected to continue going forward.[90] As alluded to above, the reimbursement environment is strongly driven by the complex regulatory environment, and a "[l]ack of compliance results in hefty fines and lower reimbursement rates."[91] Accordingly, the current state of the regulatory environment in which diagnostic imaging centers operate will be addressed in the next installment of this five-part series.

Valuation of Diagnostic Imaging: Regulatory

[Excerpted from the article published in May 2024.]

Outpatient enterprises, including imaging centers, are some of the most regulated healthcare entities in the U.S., with federal, state, and local regulators, laws, and agencies overseeing providers to ensure the safety of patients.[92] This regulatory environment constrains the market for all freestanding diagnostic imaging centers, represents a significant administrative burden, is a business risk factor, and also acts as a barrier to entry for new market entrants.

Federal Fraud and Abuse Laws

Healthcare organizations face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. Fraud and abuse laws, specifically those related to the federal Anti-Kickback Statute (AKS) and physician self-referral laws (the "Stark Law"), may have the greatest impact on the operations of healthcare organizations.

The AKS and Stark Law are generally concerned with the same issue – the financial motivation behind patient referrals. However, while the AKS is broadly applied to payments between providers or suppliers in the healthcare industry and relates to any item or service that may be paid for under any federal healthcare program, the Stark Law specifically addresses the referrals from physicians to entities with which the physician has a financial relationship for the provision of defined services that are paid for by the Medicare program.[93] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[94]

Anti-Kickback Statute

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,[95] even if only one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[96] Notably, a person need not have actual knowledge of the AKS or specific intent to commit a violation of the AKS for the government to prove a kickback violation,[97] only an awareness that the conduct in question is "generally unlawful."[98] Further, a violation of the AKS is sufficient to state a claim under the *False Claims Act* (FCA).[99]

Criminal violations of the AKS are punishable by up to ten years in prison, criminal fines up to $100,000, or both, and civil violations can result in administrative penalties, including exclusion from federal healthcare programs, and civil monetary penalties plus treble damages (or three times the illegal remuneration).[100] In addition to the civil monetary penalties paid under the AKS, if the AKS violation triggers liability under the FCA, defendants can incur additional civil monetary penalties of $13,508 to $27,018 per violation, plus treble damages.[101]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[102] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to HHS to protect certain business arrangements by means of promulgating several *safe harbors*.[103] 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.[104] Failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[105] 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.

Stark Law

The Stark Law prohibits physicians from referring Medicare patients to entities with which the physicians or their family members have a financial relationship for the provision of designated health services (DHS).[106] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[107] Under the Stark Law, DHS include, but are not limited to, the following:

(1) Radiology and certain other imaging services;
(2) Inpatient and outpatient hospital services;
(3) Radiation therapy services and supplies;
(4) Certain therapy services, such as physical therapy;
(5) Durable medical equipment; and,
(6) Outpatient prescription drugs.[108]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities also have an ownership interest in the entity that provides DHS.[109] 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.[110]

Civil penalties under the Stark Law include overpayment or refund obligations, a potential civil monetary penalty of $15,000 for each service, plus treble damages, and exclusion from Medicare and Medicaid programs.[111] Further, similar to the AKS, violation of the Stark Law can also trigger a violation of the FCA.[112]

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.[113] 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.[114]

Medicare Accreditation

Prior to receiving Medicare payment for the technical component services,[115] diagnostic imaging centers must become accredited by a CMS-approved organization as an Advanced Diagnostic Imaging (ADI) Supplier.[116] Certain regulatory requirements that must be met in order to become accredited include, but may not be limited to, the following areas:

(1) Staff qualifications;
(2) Equipment standards and safety;
(3) Safety of patients, family, and staff;
(4) Medical records; and,
(5) Patient privacy.[117]

CMS has approved the following four organizations to accredit ADI suppliers: (1) ACR; (2) Intersocietal Accreditation Commission (IAC); (3) RadSite; and, (4) The Joint Commission.[118] After receiving initial approval, ADI suppliers are then subject to triennial surveys.[119] In addition to these federal requirements, diagnostic imaging centers are also required to meet any and all state licensure requirements.

Diagnostic imaging centers face many obstacles within the regulatory environment that can prohibit their formation, growth, and development. Understanding fraud and abuse laws, among other statutes and regulations, are integral to the success of a diagnostic imaging center. Another factor integral to the success of a diagnostic imaging center is the usage of medical imaging devices. Consequently, the final installment in this series will discuss the technological environment in which diagnostic imaging centers operate.

Valuation of Diagnostic Imaging: Technology

[Excerpted from the article published in June 2024.]

Although medical imaging equipment is used to diagnose many conditions, a large capital investment may be required to obtain it. For example, a magnetic resonance imaging (MRI) machine can cost over $1 million for a refurbished model, and as high as $3 million for a new machine.[120] But beyond the considerable cost of the imaging equipment itself, some machines that employ radiation or powerful magnetic fields to generate diagnostic images have certain architectural requirements in order to be utilized safely. The rooms that house such equipment (referred to as "suites") are built to certain specifications so as to protect those outside the suite, i.e., in the scan room, control room, and/or computer equipment room.[121] Between the machine itself, installation costs, and the suite, a single MRI can ultimately cost between $3 million and $5 million.[122] This final installment of a five-part series on the valuation of diagnostic imaging centers will discuss the technological advancements impacting these enterprises.

Because of the significant level of capital investment, large, integrated healthcare organizations may have an advantage in the provision of diagnostic imaging services, because the initial fixed capital investment is spread over a greater number of patients. In response, smaller healthcare organizations, which may not be able to supply the necessary initial capital investment, often turn to leasing medical equipment in order to provide imaging services.[123]

MRI

MRIs are classified based on the strength of the magnetic field that they generate, which is measured in "*Teslas*" (abbreviated to "*T*").[124] Newer models of MRI machines, i.e., 3T MRIs, can provide efficiency and generate magnetic fields twice as strong as the fields generated by regular MRIs.[125] One of the benefits associated with this advancement is that 3T MRIs may be capable of generating higher quality images in a shorter amount of time, thus improving the ability to diagnose a patient's condition.[126] For example, 3T MRIs may be able to produce images faster than 1.5T MRIs, ultimately improving a provider's efficiency.[127] However, 3T MRIs are significantly more expensive than 1.5T MRIs.[128] In 2017, the Food and Drug Administration (FDA) cleared the first 7T MRI system for clinical use in the U.S., providing more than twice the magnetic field strength of a 3T scanner, resulting in ultrafine image resolution.[129] The continued advancements of MRI machines may indicate that the standard for MRI imaging will change; however, such changes will almost certainly increase the price. Consequently, the pros and cons of each technology must be weighed in order to determine which model is more suited for the organization, as the 3T and 7T MRIs may not be better than 1.5T or 3T MRIs for all purposes.

Other recent advances in MRI technology include: (1) updated software that shortens patient exam times; (2) scanners that allow patients to be positioned at a 90-degree angle, allowing clinicians to pinpoint areas of trouble for those injured in accidents or those with musculoskeletal disorders; (3) scanners that eliminate the narrow tunnels seen in traditional MRI machines, allowing patients with claustrophobia to still have images taken; and (4) scanners that include noise-reduction technology, which may reduce patient stress triggered by the loud sounds that emanate from typical MRIs.[130]

CT

Technological advancements in computed tomography (CT) scanners reflect the need for higher quality images with fewer "*artifacts*" (i.e., discrepancy between the reconstructed image and what is expected)[131] and dosages of radiation. CT scanner "*slices*," or the number of sections in which the CT machine divides the body to image,[132] have been increased in order to improve the quality of CT images.[133] Currently, the standard machinery for a CT is a 4-, 8-, 16-, 32-, 64-, or 128-slice CT; however, other, more advanced CT scanners have incorporated higher slices, including 256, 320, and even 640 slices.[134] The higher-slice systems are thought to lead to better diagnoses, as they have higher quality images, partly due to the decrease in artifacts, in which those using a standard 64-slice scanner may have to

discount when assessing CT images.[135] Some of the artifacts seen may be due to breathing and patient movement, affecting image quality.[136] Higher-slice systems are often faster and have a larger imaging area, which may be more realistic for patients that squirm or have faster heart rates, as they reduce the number of artifacts seen on the image due to movement.[137]

It is important to note that there are other components to high-end CT imaging than simply slice numbers that determine the quality of an image that should be taken into account. Previously, CT systems reconstructed images on filtered back projection, due to the short length of time required.[138] Now, all major vendors offer software for iterative image reconstruction, which revises the image to clean up artifacts and clarify pixels, allowing the image to run on significantly lower radiation dose scans.[139] Additionally, some CT scanners may incorporate detector technology that utilizes microelectronic circuits or dual-energy spectral imaging to reduce electronic noise and produce sharper images.[140] Wider detector systems have higher sensitivity, allowing iterative construction software to improve contrast and spatial resolutions.[141] The combination of the latest iterative construction and detector technology can reduce the effective radiation dose 20- to 30-fold, reducing exposure to radiation and increasing patient safety.[142]

As the number of slices increases, the cost of the system also typically increases. Although CT scanners have experienced significant advancements, many clinicians still conclude that the 64-slice scanning standard is adequate, as more clinical evidence for the diagnostic difference between the two would be needed to justify the tremendous cost difference for higher-slice systems.[143] When justifying the cost difference, technological advancements improving quality (decreasing artifacts) will need to be addressed in addition to patient volume. High-patient volume could influence the justification for a higher-slice system due to a higher-slice system's ability to scan patients more quickly.[144]

Mammography

Conventional 2D mammography has long been the standard for breast imaging, advancing from originally utilizing x-ray film to the introduction of digital mammography (which most organizations use today) that can be read on computers.[145] A digital mammography utilizes the same technology as film mammography, but incorporates solid-state detectors to convert the x-rays passing through the breast into electronic signals to a computer in order to translate the signals into images.[146] These digital mammography scans improve the ability to manipulate contrast in the image, use computer-aided detection for abnormalities, and often decreases the likelihood of re-takes as compared to 2D film mammography scans.[147]

As high density breasts can often mask cancer and put patients at an increased risk for non-detection, newer advancements are becoming more heavily utilized, overcoming the limitations of 2D mammography.[148] The FDA approved DBT/3D mammography technology in 2011,[149] which allows detection past the dense tissue to view the cancer underneath, because the images are taken at different angles to generate cross sections.[150] DBT uses a low-dose x-ray system to take these cross-sectional images to recreate 3D images of the breast, aiding in early detection and diagnosis of breast cancer.[151] Additionally, a 3D mammogram is relatively fast, producing up to 15 images in four seconds, and allows the breast to be viewed in one-millimeter slices, rather than at full thickness, from the top and side of the breast.[152] 3D mammography is often used in combination with digital 2D mammography, only adding a few additional minutes to the screening.[153] With the advancement of 3D mammography technology, more cancers have been detected and the number of false positives has been reduced. A JAMA Oncology study found that 3D mammography is more effective for breast cancer screening than conventional mammography.[154] In addition, the combination of 3D and 2D mammography has spotted more cancers and reduced the number of false positives than 2D alone.[155]

Mammography is also benefiting from the use of artificial intelligence (AI) technology, which can help clinicians detect issues or diagnose cancer, with AI storing, and learning from, vast amounts of data to catch abnormalities that a radiologist may miss.[156] Studies show that the better rates of cancer detection with AI are promising, but radiologists warn that further evaluation of AI usage in diagnosis may be necessary before drawing conclusions.[157]

Ultrasound

Similar to other diagnostic imaging modalities, ultrasound imaging quality has dramatically improved over the last fifteen years, creating pictures that are more defined and clear.[158] Real-time computer imaging has been able to increase the speed of processing, which also allows for better imaging.[159] This improved imaging quality has resulted in increased diagnosis accuracy.[160]

3D/4D volume transducers create 3D images in real time, allowing sonographers to examine patient anatomy.[161] As techniques for 3D/4D image acquisition start to become more common, sonographers may find themselves re-evaluating workflows in order to increase efficiency while providing accurate and diagnostically relevant results.[162] Additionally, newer ultrasound technology, such as liver imaging, has reduced the need for invasive tests.[163] With the utilization of contrast during an ultrasound, liver lesion diagnostic imaging has allowed for sonographers to diagnose the type of lesion without the need of a biopsy.[164]

Nuclear Medicine

Molecular imaging techniques such as SPECT and PET have been rapidly advancing, with these techniques allowing for the quantification and visualization of molecular processes within the human body.[165] As new imaging agents and radiotracers develop, imaging at the molecular level has become more sensitive and specific, allowing for accurate and earlier detection of diseases.[166] Hybrid imaging, which combines two or more modalities of imaging, has merged anatomical and functional information, which provides a comprehensive view of the processes of disease.[167]

Developments in alpha-emitting radionuclides have shown promising outcomes in the delivery of localized radiation to cancer cells, which in turn reduces the damage to healthy tissue that surrounds cancer cells.[168] Additionally, targeted radionuclide therapy utilizes radioactive substances to bind to specific receptors or cells within the body.[169] This allows radiation to be delivered directly to cells that are diseased, also minimizing the damage to healthy tissues.[170]

Both AI and radiomics have the potential to positively impact nuclear medicine utilization.[171] Radiomics – when a large amount of quantitative data from medical imagery is extracted and analyzed – can be paired with AI algorithms to process the data to extract information that can predict patient outcomes.[172] AI and radiomics have the potential to assist clinicians in interpreting images, planning treatment, and overall providing more individualized patient care.[173]

Conclusion

Going forward, diagnostic imaging centers will have to overcome a number of challenges in order to remain viable in the U.S. healthcare delivery system. Although diagnostic imaging centers operate in highly competitive environments, patients and payors find those services provided in freestanding centers to be more convenient and less expensive.[174] Notably, Medicare reimbursement for diagnostic imaging procedures has generally decreased over the years, due in part to a complex regulatory environment.[175] Diagnostic imaging centers are some of the most regulated entities in healthcare, with federal, state, and local regulators overseeing providers.[176] Nevertheless, diagnostic imaging technology may allow providers to streamline care and reduce costs through identifying clinical issues early on. Ultimately, this could promote some of the central goals of healthcare reform, i.e., high quality care and increased efficiency.

1 "Global Diagnostic Imaging Market" Mordor Intelligence, Sample Report, 2017.
2 *Ibid.*
3 "Independent Diagnostic Testing Facility (IDTF) Fact Sheet" Centers for Medicare & Medicaid Services, Medicare Learning Network, ICN909060, October 2022, available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ICN909060-IDTF-Fact-Sheet.pdf (Accessed 11/1/23), p. 1.
4 "Healthcare Utilisation: Diagnostic Exams" Organisation for Economic Co-Operation and Development, https://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT# (Accessed 11/3/23).
5 "X-ray (Radiography)" RadiologyInfo.org, https://www.radiologyinfo.org/en/x-ray (Accessed 11/1/23).
6 *Ibid.*
7 "X-Rays" Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/xrays (Accessed 11/1/23).
8 *Ibid.*
9 *Ibid.*
10 "X-rays" National Institute of Biomedical Imaging and Bioengineering, June 2022, https://www.nibib.nih.gov/science-education/science-topics/x-rays (Accessed 11/1/23).
11 "X-Rays" Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/xrays (Accessed 11/1/23).
12 "MRI (Magnetic Resonance Imaging): Uses" U.S. Food and Drug Administration, December 9, 2017, https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MRI/ucm482763.htm (Accessed 11/1/23); "Magnetic Resonance Imaging (MRI)" Johns Hopkins Medicine, https://www.hopkinsmedicine.org/healthlibrary/conditions/adult/radiology/Magnetic_Resonance_Imaging_22,MagneticResonanceImaging (Accessed 11/1/23).
13 "What Are the Different Types of MRI Examinations" Stanford Health Care, https://stanfordhealthcare.org/medical-tests/m/mri/types.html (Accessed 11/1/23).
14 "What is an MRI?" WebMD, https://www.webmd.com/a-to-z-guides/what-is-a-mri#1 (Accessed 11/1/23).
15 "Benefits and Risks" in "MRI (Magnetic Resonance Imaging)" U.S. Food & Drug Administration, December 9, 2017, https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MRI/ucm482765.htm (Accessed 11/1/23).
16 "Magnetic Resonance Imaging (MRI)" Johns Hopkins Medicine, https://www.hopkinsmedicine.org/healthlibrary/conditions/adult/radiology/Magnetic_Resonance_Imaging_22,MagneticResonanceImaging (Accessed 11/1/23).
17 "Computed Tomography (CT) Scan" Johns Hopkins Medicine, https://www.hopkinsmedicine.org/healthlibrary/conditions/adult/radiology/computed_tomography_ct_scan_22,computedtomographyscan (Accessed 11/1/23).
18 "What is a CT Scan?" WebMD, https://www.webmd.com/cancer/what-is-a-ct-scan#1 (Accessed 11/1/23); "CT scan or CAT scan: How does it work?" By Christian Nordqvist, Medical News Today, July 24, 2018, https://www.medicalnewstoday.com/articles/153201.php (Accessed 11/1/23).
19 "Computed Tomography (CT) Scan" Johns Hopkins Medicine, https://www.hopkinsmedicine.org/healthlibrary/conditions/adult/radiology/computed_tomography_ct_scan_22,computedtomographyscan (Accessed 11/1/23); "CT scan or CAT scan: How does it work?" By Christian Nordqvist, Medical News Today, July 24, 2018, https://www.medicalnewstoday.com/articles/153201.php (Accessed 11/1/23).
20 "CT scan or CAT scan: How does it work?" By Christian Nordqvist, Medical News Today, July 24, 2018, https://www.medicalnewstoday.com/articles/153201.php (Accessed 11/1/23).
21 "CT (CAT) Scan" St. Michael's, http://www.stmichaelshospital.com/programs/imaging/ctscan/faq.php (Accessed 11/1/23).
22 "Mammogram Procedure" Johns Hopkins Medicine, https://www.hopkinsmedicine.org/healthlibrary/test_procedures/gynecology/mammogram_92,P07781 (Accessed 11/1/23).
23 "Mammography" RadiologyInfo.org, https://www.radiologyinfo.org/en/info.cfm?pg=mammo (Accessed 11/1/23).
24 *Ibid.*
25 *Ibid.*
26 "Breast Cancer: Screening" U.S. Preventative Services Task Force, Final Recommendation Statement, January 11, 2016, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening (Accessed 11/3/23).
27 "Mammography" RadiologyInfo.org, https://www.radiologyinfo.org/en/info.cfm?pg=mammo (Accessed 11/1/23); "Mammograms" National Cancer Institute, https://www.cancer.gov/types/breast/mammograms-fact-sheet#q2 (Accessed 11/1/23).
28 "General Ultrasound" RadiologyInfo.org, https://www.radiologyinfo.org/en/info/genus (Accessed 11/1/23).
29 "Ultrasound" Cleveland Clinic, https://my.clevelandclinic.org/health/diagnostics/4995-ultrasound (Accessed 11/1/23).
30 RadiologyInfo.org, https://www.radiologyinfo.org/en/info/genus (Accessed 11/1/23).
31 "How do ultrasound scans work?" By Yvette Brazier, Medical News Today, June 23, 2017, https://www.medicalnewstoday.com/articles/245491 (Accessed 11/1/23).
32 *Ibid.*
33 *Ibid.*
34 Cleveland Clinic, https://my.clevelandclinic.org/health/diagnostics/4995-ultrasound (Accessed 11/1/23).
35 *Ibid.*
36 *Ibid.*
37 *Ibid.*
38 "Positron Emission Tomography Scan" Mayo Clinic, April 18, 2023, https://www.mayoclinic.org/tests-procedures/pet-scan/about/pac-20385078#:~:text=A%20positron%20emission%20tomography%20(PET)%20scan%20is%20an%20imaging%20test,typical%20and%20atypical%20metabolic%20activity. (Accessed 2/22/24).
39 *Ibid.*
40 "PET Scan" HealthDirect, February 2022, https://www.healthdirect.gov.au/pet-scan (Accessed 2/22/24).
41 "PET Scan" Cleveland Clinic, October 19, 2022, https://my.clevelandclinic.org/health/diagnostics/10123-pet-scan (Accessed 2/22/24).
42 *Ibid.*
43 HealthDirect, February 2022.
44 *Ibid.*
45 *Ibid.*
46 "Diagnostic Imaging Centers Industry in the US" By Marley Brocker, IBISWorld, February 2024, p. 12.
47 *Ibid*, p. 11.
48 *Ibid*, p. 8.
49 *Ibid.*
50 *Ibid.*
51 "Healthcare Utilisation: Diagnostic Exams" Organisation for Economic Co-Operation and Development, https://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT# (Accessed 11/3/23).
52 "Accredited Facility Search" American College of Radiology, https://www.acraccreditation.org/accredited-facility-search (Accessed 11/1/23); "Pop-Facts Demographic Snapshot: United States" Environics Analytics, 2022.
53 "Older People Projected to Outnumber Children for First Time in U.S. History" United States Census Bureau, March 13, 2018, Revised October 8, 2019, https://www.census.gov/newsroom/press-releases/2018/cb18-41-population-projections.html (Accessed 11/1/23).
54 "Falls" World Health Organization, April 26, 2021, https://www.who.int/news-room/fact-sheets/detail/falls (Accessed 11/1/23).
55 "The Drivers Of Medical Imaging Market Growth And Where Tech Leaders Fit In" By Ohad Arazi, Forbes, September 26, 2023, https://www.forbes.com/sites/forbestechcouncil/2023/09/26/the-drivers-of-medical-imaging-market-growth-and-where-tech-leaders-can-fit-in/?sh=65deac9c2988 (Accessed 3/13/24).
56 *Ibid.*
57 *Ibid.*
58 *Ibid.*
59 *Ibid.*
60 *Ibid.*
61 *Ibid.*
62 *Ibid.*
63 "Cancer Diagnostic Imaging" University of Rochester Medical Center, https://www.urmc.rochester.edu/encyclopedia/content.aspx?contenttypeid=85&contentid=p07178 (Accessed 11/1/23).
64 "Baby Boomers: The Radiological Outlook" By Cat Vasko, Radiology Business, April 23, 2014, https://www.radiologybusiness.com/topics/care-delivery/baby-boomers-radiological-outlook (Accessed 11/1/23); "Baby Boomers and Breast Cancer: When Can I Stop Getting Mammograms?" Center for Diagnostic Imaging, November 9, 2016, https://www.mycdi.com/viewpoints/baby_boomers_and_breast_cancer_when_can_i_stop_getting_mammograms_154 (Accessed 11/1/23).
65 "Cancer Facts & Figures: 2022" American Cancer Society, 2022, https://www.

cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2022/2022-cancer-facts-and-figures.pdf (Accessed 11/1/23), p.1.

66 "Age and Cancer Risk" National Cancer Institute, https://www.cancer.gov/about-cancer/causes-prevention/risk/age (Accessed 11/1/23).

67 "Age and Cancer Risk: A Potentially Modifiable Relationship" By Mary C. White, et al., American Journal of Preventative Medicine, Vol 46, No. 3 Suppl 1 (March 2014), p. 1; "CT Scan vs. MRI" Healthline, https://www.healthline.com/health/ct-scan-vs-mri (Accessed 11/1/23).

68 "Breast Cancer Risk Factors" Breastcancer.org, https://www.breastcancer.org/risk/factors (Accessed 11/1/23); "Tomosynthesis market healthy and only getting stronger" By Dave Pearson, Health Imaging, November 25, 2015, https://www.healthimaging.com/topics/breast-imaging/tomosynthesis-market-healthy-and-only-getting-stronger (Accessed 11/1/23).

69 "Get Tested for Breast Cancer" healthfinder.gov, https://healthfinder.gov/HealthTopics/Category/doctor-visits/screening-tests/get-tested-for breast-cancer (Accessed 11/1/23).

70 "NHE Fact Sheet" Centers for Medicare & Medicaid Services, December 28, 2022, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet (Accessed 10/30/23).

71 "Physician Panel Prescribes the Fees Paid by Medicare" By Anna Wilde Mathews and Tom McGinty, The Wall Street Journal, October 26, 2010, https://www.wsj.com/articles/SB10001424052748704657304575540440173772102 (Accessed 10/30/23).

72 "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule" Federal Register Vol. 80, No. 220 (November 16, 2015), p. 70890.

73 *Ibid*, p. 73208.

74 "Physician and Other Health Professional Payment System" Medicare Payment Advisory Commission, Payment Basics, October 2023, https://www.medpac.gov/wp-content/uploads/2022/10/MedPAC_Payment_Basics_23_Physician_FINAL_SEC.pdf (Accessed 3/28/24).

75 "Physician Reimbursement Under Medicare" By Alan M. Scarrow, MD., Neurosurgical Focus, Vol. 12, No. 4: Article 8 (April 2002), p. 2.

76 "Medicare PFS Locality Configuration" Centers for Medicare & Medicaid Services, September 6, 2023, https://www.cms.gov/medicare/payment/fee-schedules/physician/locality-configuration (Accessed 3/28/24).

77 Scarrow, MD., Neurosurgical Focus, Vol. 12, No. 4: Article 8 (April 2002), p. 2.

78 "Part B Payments: General Limits and Payment Rules" In "2009 Master Medicare Guide" CCH Health Editorial, Wolters Kluwer, 2009, p. 901.

79 "Medicare Access and CHIP Reauthorization Act of 2015" Pub. L. No. 114-10, § 101, 129 Stat. 87, 89-90.

80 "Accreditation of Advanced Diagnostic Imaging Suppliers" Centers for Medicare & Medicaid Services, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Accreditation-of-Advanced-Diagnostic-Imaging-Suppliers.html (Accessed 10/30/23).

81 "Chapter 13 - Radiology Services and Other Diagnostic Procedures" Medicare Claims Processing Manual, Centers for Medicare and Medicaid Services, October 1, 2021, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c13.pdf (Accessed 10/30/23).

82 *Ibid.*

83 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program— Accountable Care Organizations— Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act; Final Rule" Federal Register Vol. 83, No. 226 (November 23, 2018), p. 59462.

84 *Ibid.*

85 *Ibid.*

86 *Ibid*, p. 59517; "GAO: OPPS Imaging Cap Lowered Spending" AAPC, October 13, 2008, https://www.aapc.com/blog/195-gao-opps-imaging-cap-lowered-spending-not-access/ (Accessed 11/1/23).

87 "Interaction of the Multiple Procedure Payment Reduction (MPPR) on Imaging Procedures and the Outpatient Prospective Payment System (OPPS) Cap on the Technical Component (TC) of Imaging Procedures" Centers for Medicare & Medicaid Services, MLN Matters® Number: MM7703, July 2, 2012, https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7703.pdf (Accessed 11/1/23); Federal Register Vol. 83, No. 226 (November 23, 2018), p. 59517.

88 "Declining Medicare Reimbursement for Diagnostic Radiology: A 10-Year Analysis Across 50 Imaging Studies" By Emily Schartz, et al., Current Problems in Diagnostic Radiology, Vol. 51, Issue 5, (September-October 2022), https://www.sciencedirect.com/science/article/pii/S0363018822000081 (Accessed 3/25/24).

89 Federal Register, Vol. 88, No. 220 (November 16, 2023), p. 79468-69.

90 "Industry Report: Diagnostic Imaging Centers in the US" IBISWorld, September 2023, p. 13, 51.

91 *Ibid*, p. 51.

92 "Emergency and Other Outpatient Care Centers in the U.S." By Marley Brocker, IBISWorld, October 2023, p. 8.

93 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 10/27/23).

94 *Ibid.*

95 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 USC § 1320a-7b(b)(1).

96 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf (Accessed 10/27/23), p. 4-5; "U.S. v. Greber" 760 F.2d 68, 69 (3d. Cir. 1985).

97 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 6402, 10606, 124 Stat. 119, 759, 1008 (March 23, 2010).

98 "Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview" By Jennifer A. Staman, Congressional Research Service, September 8, 2014, https://www.fas.org/sgp/crs/misc/RS22743.pdf (Accessed 10/27/23), p. 5.

99 "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" McDermott Will & Emery, April 12, 2010, p. 3; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 6402, 124 Stat. 119, 759 (March 23, 2010).

100 42 USC § 1320a-7b(b)(1); "Civil Monetary Penalties" 42 USC § 1320a-7a(a).

101 "False claims" 31 USC § 3729(a)(1)(G); "Civil Monetary Penalties Inflation Adjustments for 2023" Federal Register, Vol. 88, No. 19 (January 30, 2023), p. 5777.

102 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf (Accessed 10/27/23), p. 5.

103 *Ibid.*

104 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" Federal Register Vol. 64, No. 223 (November 19, 1999), p. 63518, 63520.

105 "Re: Malpractice Insurance Assistance" By Lewis Morris, Chief Counsel to the Inspector General, United States Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, https://oig.hhs.gov/fraud/docs/alertsandbulletins/malpracticeprogram.pdf (Accessed 10/27/23), p. 1.

106 "CRS Report for Congress: Medicare: Physician Self-Referral ("Stark I and II")" By Jennifer O'Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, available at: http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf (Accessed 10/27/23); "Limitation on certain physician referrals" 42 USC § 1395nn.

107 "Limitation on certain physician referrals" 42 USC § 1395nn(a)(1)(A).

108 42 USC § 1395nn(a)(1)(B); "Definitions" 42 CFR § 411.351 (2015).

109 "Limitation on certain physician referrals" 42 USC § 1395nn (a)(2).

110 42 USC § 1395nn (h)(1).

111 42 USC § 1395nn (g).

112 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 10/27/23).

113 "Limitation on certain physician referrals" 42 USC § 1395nn.

114 Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG) (Accessed 10/27/23).

115 This includes MRI and CT scans – it does not include mammography. "Accreditation of Advanced Diagnostic Imaging Suppliers" Centers for Medicare & Medicaid Services, https://www.cms.gov/Medicare/Provider-EnrollmentandCertification/SurveyCertificationGenInfo/Accreditation-of-Advanced-Diagnostic-Imaging-Suppliers.html (Accessed 10/27/23).

116 "Specific Conditions for Coverage" 42 C.F.R. § 416.40-52 (2015).

117 "Accreditation of Advanced Diagnostic Imaging Suppliers" Centers for

Medicare & Medicaid Services, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Accreditation-of-Advanced-Diagnostic-Imaging-Suppliers.html (Accessed 10/27/23).

118 *Ibid.*

119 *Ibid.*

120 "How Much Does an MRI Machine Cost?" Excedr, February 28, 2022, https://www.excedr.com/blog/how-much-does-an-mri-machine-cost (Accessed 11/7/23).

121 "Keys to Success in Designing a Hybrid Cath Lab" By Jack F. Kerr, A/A, Cath Lab Digest, www.cathlabdigest.com/articles/Keys-Success-Designing-a-Hybrid-Cath-Lab (Accessed 6/25/24); "Your Roadmap to the Perfect MRI Installation" By Vikki Harmonay, Atlantis Worldwide, March 6, 2014, https://info.atlantisworldwide.com/blog/bid/338356/Your-Roadmap-to-the-Perfect-MRI-Installation (Accessed 6/25/24).

122 "Designing MRI Suites: Navigating Structural Design Considerations For Success" By John M. Ellingson, HGA, December 13, 2017, https://hga.com/designing-mri-suites-navigating-structural-design-considerations-for-success/ (Accessed 6/25/24).

123 "Medical Equipment and Frozen Capital – A Global Review" Siemens cross sector Financial Services (SFS), February 2011, https://web.archive.org/web/20151129094635/http://finance.siemens.com/financialservices/global/en/press/studies/documents/whitepaper_2011_medical-equipment_frozen-capital.pdf (Accessed 6/25/24).

124 "FDA Clears First 7T MRI System, Magnetom Terra" Imaging Technology News, October 12, 2017, https://www.itnonline.com/content/fda-clears-first-7t-mri-system-magnetom-terra (Accessed 6/25/24).

125 "3T MRI: What It Is and How It's Different From Other MRIs" By Pamela Cagle, Ezra, October 10, 2021, https://ezra.com/blog/3t-mri (Accessed 11/1/23).

126 *Ibid.*

127 *Ibid.*

128 "Time to Upgrade? – Considerations for the Move From 1.5T to 3T" By Keith Loria, Radiology Today, Vol. 17, No. 2 (February 2015), available at: https://www.radiologytoday.net/archive/rt0216p22.shtml, (Accessed 6/25/24), p. 22.

129 "Recent Advances in MRI Technology" By Dave Fornell, Imaging Technology News, September 12, 2016, https://www.itnonline.com/article/recent-advances-mri-technology (Accessed 6/25/24); "Mayo Clinic Installing First FDA-Approved Clinical 7T MRI" Imaging Technology News, October 20, 2017, https://www.itnonline.com/content/mayo-clinic-installing-first-fda-approved-clinical-7t-mri (Accessed 6/25/24).

130 "MRI Technology Advancements: What Do They Mean for You?" American Health Imaging, February 1, 2021, https://americanhealthimaging.com/mri-technology-advancements-what-do-they-mean-for-you/ (Accessed 6/25/24).

131 "An Introduction to CT Scan Image Artifacts" By Gren Lehmann, Principle X-ray Engineer, North Star Imaging, January 9, 2018, https://4nsi.com/blog/2018/01/09/an-introduction-to-ct-scan-image-artifacts/ (Accessed 6/25/24).

132 "Slice of CT Scanners" NeuroLogica, June 23, 2021, https://www.neurologica.com/blog/slice-of-ct-scanners#:~:text=The%20term%20slice%20refers%20to,slice%20CT%20scanners%20(MSCT.) (Accessed 6/25/24).

133 "Technology Improvements in Current Generation CT Systems" By Dave Fornell, Imaging Technology News, September 9, 2015, https://www.itnonline.com/article/technology-improvements-current-generation-ct-systems (Accessed 6/25/24).

134 "CT Scan Slice Types – Guide to CT Scanner Slices" LBN Medical, 2023, https://lbnmedical.com/ct-scan-slice-types/ (Accessed 6/25/24).

135 "Costs vs. Benefits: Comparing 64- Slice to 256, 320-Slice CT" By Dave Fornell, Diagnostic and Interventional Cardiology, July 20, 2010, https://www.dicardiology.com/article/costs-vs-benefits-comparing-64-slice-256-320-slice-ct (Accessed 6/25/24).

136 "Technical aspects of CT Imaging of the spine" By Bernhard Tins, Insights Imaging, No. 1, Vol, 5-6 (November 2010).

137 "Costs vs. Benefits: Comparing 64- Slice to 256, 320-Slice CT" By Dave Fornell, Diagnostic and Interventional Cardiology, July 20, 2010, https://www.dicardiology.com/article/costs-vs-benefits-comparing-64-slice-256-320-slice-ct (Accessed 6/25/24).

138 "Technology Improvements in Current Generation CT Systems" By Dave Fornell, Imaging Technology News, September 9, 2015, https://www.itnonline.com/article/technology-improvements-current-generation-ct-systems (Accessed 6/25/24).

139 *Ibid.*

140 *Ibid.*

141 "What to Consider When Buying a New CT Scanner" By Dave Fornell, Diagnostic and Interventional Cardiology, October 14, 2015, https://www.dicardiology.com/article/what-consider-when-buying-new-ct-scanner (Accessed 6/25/24).

142 Fornell, Imaging Technology News, September 9, 2015.

143 Fornell, Diagnostic and Interventional Cardiology, July 20, 2010.

144 "What to Consider When Buying a New CT Scanner" By Dave Fornell, Diagnostic and Interventional Cardiology, October 14, 2015, https://www.dicardiology.com/article/what-consider-when-buying-new-ct-scanner (Accessed 6/25/24).

145 "Digital vs. Film Screening Mammography" The Susan G. Komen Breast Cancer Foundation, Inc., May 7, 2018, https://web.archive.org/web/20200928133112/https://ww5.komen.org/BreastCancer/Table31Digitalmammographyversusstandardmammographyforbreastcancerscreening.html (Accessed 6/25/24).

146 "Mammography" National Institute of Biomedical Imaging and Bioengineering, https://www.nibib.nih.gov/science-education/science-topics/mammography (Accessed 6/25/24).

147 *Ibid.*

148 "The Evolution of Breast Imaging Technology" By Jeff Zagoudis, Imaging Technology News, October 3, 2017, https://www.itnonline.com/article/evolution-breast-imaging-technology (Accessed 6/25/24).

149 "Digital Breast Tomosynthesis: A Decade of Practice in Review" By Debra Monticciolo, ScienceDirect, February 2023, https://www.sciencedirect.com/science/article/abs/pii/S1546144022006299#:~:text=Digital%20breast%20tomosynthesis%20(DBT%3B%20also,for%20clinical%20use%20in%202011. (Accessed 11/1/23).

150 "The Evolution of Breast Imaging Technology" By Jeff Zagoudis, Imaging Technology News, October 3, 2017, https://www.itnonline.com/article/evolution-breast-imaging-technology (Accessed 6/25/24).

151 "Breast Tomosynthesis" RadiologyInfo.org For Patients, https://www.radiologyinfo.org/en/info.cfm?pg=tomosynthesis (Accessed 6/25/24).

152 "3D Mammography is a new technology that offers many benefits over traditional mammography" Breast Link, http://www.breastlink.com/services/breast-imaging/3d-mammography/ (Accessed 6/25/24).

153 "The type of mammogram you choose matters: 2D vs. 3D" Froedtert & Medical College of Wisconsin, January 24, 2018, https://www.jsonline.com/story/sponsor-story/froedtert/2018/01/23/type-mammogram-you-choose-matters-2d-vs-3d/109733676/ (Accessed 6/25/24).

154 "Effectiveness of Digital Breast Tomosynthesis Compared with Digital Mammography: Outcomes Analysis From 3 Years of Breast Cancer Screening" By Elizabeth McDonald, et al, JAMA Oncology, Vol. 2, No. 6 (June 2016), p.1.

155 "3D Mammograms – Are They Worth the Cost?" By Nissa Simon, American Association of Retired Persons, https://web.archive.org/web/20180102110044/https://www.aarp.org/health/conditions-treatments/info-04-2013/3d-mammograms-risks-benefits.html (Accessed 6/25/24).

156 "Mammography AI can cost patients extra. Is it worth it?" By Michelle Andrews, CBS, January 9, 2024, https://www.cbsnews.com/news/mammogram-ai-cost-patients-is-it-worth-it/ (Accessed 6/25/24).

157 *Ibid.*

158 "Latest Advancements in Ultrasound Imaging Technology" Peconic Bay Medical Center, Northwell Health, May 7, 2019, https://www.pbmchealth.org/news-events/blog/latest-advancements-ultrasound-imaging-technology (Accessed 6/25/24).

159 *Ibid.*

160 *Ibid.*

161 "What's New in Ultrasound Tech – 2023 Edition" By Jennifer Ott, Cassling, October 27, 2022, https://www.cassling.com/blog/whats-new-in-ultrasound-tech-2023-edition (Accessed 6/25/24).

162 *Ibid.*

163 *Ibid.*

164 *Ibid.*

165 "How Is The Future Of Nuclear Medicine Evolving?" By Aishwarya Kulkarni, Outsourced Pharma, July 13, 2023, https://www.outsourcedpharma.com/doc/how-is-the-future-of-nuclear-medicine-evolving-0001 (Accessed 6/25/24).

166 *Ibid.*

167 *Ibid.*

168 *Ibid.*

169 *Ibid.*

170 *Ibid.*

171 *Ibid.*

172 "How Is The Future Of Nuclear Medicine Evolving?" By Aishwarya Kulkarni, Outsourced Pharma, July 13, 2023, https://www.outsourcedpharma.com/doc/how-is-the-future-of-nuclear-medicine-evolving-0001 (Accessed 6/25/24).

173 *Ibid.*

174 "Diagnostic Imaging Centers Industry in the US" By Marley Brocker, IBISWorld, September 2023, p. 12.

175 "Industry Report: Diagnostic Imaging Centers in the US" IBISWorld, September 2023, p. 13, 51.

176 "Emergency and Other Outpatient Care Centers in the U.S." By Marley Brocker, IBISWorld, October 2023, p. 8.

Multispecialty Surveys for Physician Compensation Released

[Excerpted from the article published in August 2024.]

It's the most wonderful time of the year – Survey Season! Beginning in late May each year, numerous industry normative benchmark physician production and compensation surveys begin publishing the most recent year's reports. These healthcare and specialty specific surveys annually report specific types of physician compensation and productivity metrics across the country for various specialties and are widely used by hospitals, physician practices, and healthcare compensation and valuation experts, are often used for the determination of Fair Market Value (FMV) physician compensation for regulatory compliance purposes. Additionally, the government has referenced and utilized industry normative benchmark compensation surveys (including those listed below) in reviewing and litigating physician compensation arrangements, indicating their reliance on this data as well.

Annual compensation amounts are reported by the following well-known industry compensation and production surveys:

(1) Medical Group Management Association (MGMA);
(2) American Medical Group Association (AMGA);
(3) SullivanCotter;
(4) Gallagher;
(5) MDRanger; and
(6) Economic Research Institute (ERI).

Each are briefly discussed below in turn.

MGMA

MGMA is the oldest and largest membership organization representing medical group practice administrators.[1] MGMA provides members with resources and solutions including educational certifications, benchmarking data and statistics, and access to industry experts.[2] The *Provider Compensation and Productivity Report* annually reports comparative data from more than 350,000 providers from 60,000 medical practices.[3]

AMGA

AMGA represents the interests of physicians working in group practice settings. The *Medical Group Compensation and Productivity Survey* annually reports data from 459 medical groups, representing 190,000 providers from 197 physician and other specialties, as well as 61 executive positions.[4]

SullivanCotter

SullivanCotter provides compensation advisory services focused on healthcare, and in particular, executive and physician compensation.[5] The *Physician Compensation and Productivity Survey* annually reports comparative data from 541 healthcare organizations representing 215,400 individual practitioners.[6]

Gallagher

Gallagher, formerly known as Integrated Healthcare Strategies (IHS), publishes compensation survey reports from their Human Resources and Compensation Consulting practice annually.[7] The *Physician Compensation and Productivity Survey* annually reports data from 110,000 physicians, across 156 specialties and 1,370 sites of service.[8]

MD Ranger

MD Ranger, recently acquired by healthcare consulting firm ECG Management Consultants, compiles more than 350 non-clinical, non-salary physician service payments (i.e., telemedicine, emergency department call coverage, and clinical hourly rates), more than 15 hospital-based stipends by specialty, and reports productivity and salary benchmarks for over 145 specialties, with their data representing over 100,000 physicians nationwide.[9]

ERI

ERI compiles salary, cost of living, and executive compensation survey data, with updated market data, for over 10,000 job titles, 1,100 industries, and 9,000 locations.[10] ERI collects salary survey data from internal surveys, third-party salary surveys, and public sources (such as proxies and 10-Ks) to calculate geographic salary differentials and assist with compensation planning.[11] ERI provides employer-reported compensation survey data through its Salary Assessor compensation tool.[12]

Next Wave of Physician Compensation Benchmarking Tools

In addition to the long-standing physician compensation benchmarking surveys, new benchmarking tools are beginning to hit the market. One example is DataRise Provider Compensation Data (PCD), a platform that exclusively reports provider compensation for various local markets, allowing users to filter provider compensation ranges based on numerous practice characteristics.[13] PCD reports data for over 385,000 data points representing more than 100 physician specialties and over 250 local markets.[14]

Another example of innovative physician compensation benchmarking tools is Phairify, which provides physicians and physician recruiters with benchmarking specific to various specialties, helping physicians find jobs and understand their value.[15] Phairify's benchmarking data is specialty-specific, physician-sourced, up-to-date, and filterable.[16] Physicians that utilize this platform can do so anonymously, and Phairify will match them with job opportunities that match their interests.[17]

Other Sources

Healthcare providers, e.g., hospitals and medical practices, can engage firms to assist them in identifying and recruiting a doctor to fill a staffing need. These firms are commonly referred to a physician recruiting firms. AMN Healthcare's Physician Solutions division, formerly known as Merritt Hawkins, issues an annual review of the search and consulting assignments the firm conducts on behalf of its clients.

For physicians serving as faculty in academic medical centers, the Association of American Medical Colleges (AAMC) publishes an annual report of full-time medical school faculty compensation. The report presents the total compensation attributable to teaching, patient care, and research for over 130,000 full-time faculty, as reported by over 150 accredited medical schools in the U.S.

The United States Bureau of Labor Statistics (BLS) calculates and publishes National Occupational Employment and Wage Estimates from data collected from employers in all industry sectors in metropolitan and nonmetropolitan areas in every state and the District of Columbia.

There are several on-demand compensation databases available to companies and job-seekers to assist with the management of, and expectations for, compensation levels. Well-known salary aggregators include, but are not limited to:

(1) Doximity;
(2) ZipRecruiter;
(3) Salary.com;
(4) Physicians Thrive;
(5) Medscape; and
(6) Glassdoor.

Conclusion

A common method used to determine and support the FMV of physician compensation arrangements involves the use of multiple physician compensation surveys listed above. In the most recent Stark regulations, the Centers for Medicare & Medicaid Services (CMS) stated, "[c]onsulting salary schedules or other hypothetical data is an appropriate starting point in the determination of fair market value, and in many cases, it may be all that is required."[18] However, as physician compensation arrangements are including incentives for quality and value of care at an increasing rate, the reliance on historical benchmark survey data alone may not result in a supportable FMV opinion.

When consulting benchmarking survey data for assessing physician compensation arrangements for FMV, it is important to understand and critically evaluate the quality of the data, as well as the numerous variables that affect the compensation and production as reported by the surveys; consider the credibility of the reported data; and ensure the data selected match the tasks, duties, responsibilities and accountabilities required of the physician, as the determination of FMV is highly dependent on the specific facts and circumstances of the subject arrangement.

---

1 "Overview & Mission" Medical Group Management Association, 2024, https://www.mgma.com/overview-mission (Accessed 7/22/24).
2 *Ibid.*
3 "Provider Compensation and Productivity" Medical Group Management Association, May 2024, https://www.mgma.com/getkaiasset/252744ee-c63b-4a96-9211-8a5d6b908b39/MGMA-2024-Provider-Compensation-Data-Report.pdf (Accessed 7/22/24).
4 "Medical Group Compensation and Productivity Survey" AMGA, https://www.amga.org/amgaconsulting/our-data/medical-group-comp-productivity/ (Accessed 7/29/24).
5 "Physician Compensation and Productivity Survey" Sullivan Cotter, 2024, https://sullivancotter.com/surveys/physician-compensation-and-productivity-survey/ (Accessed 7/22/24).
6 *Ibid.*
7 "Compensation Survey Reports" Gallagher, https://www.ajg.com/us/services/compensation-survey-reports/ (Accessed 7/29/24).
8 *Ibid.*
9 "Home" MD Ranger, https://www.mdranger.com/ (Accessed 7/22/24).
10 "About ERI" Economic Research Institute, https://www.erieri.com/abouteri (Accessed 7/22/24); "Products" Economic Research Institute, https://www.erieri.com/products (Accessed 7/22/24).
11 *Ibid.*
12 *Ibid.*
13 "DataRise™ Provider Compensation Data Platform" Health Contract, https://health-contract.com/downloads/datarise-provider-compensation-data/ (Accessed 7/22/24).
14 *Ibid.*
15 "How-It-Works" Phairify, https://phairify.com/how-it-works/for-physicians/ (Accessed 7/22/24).
16 *Ibid.*
17 *Ibid.*
18 "Medical Program; Modernizing and Clarifying the Physician Self-Referral Regulations: Final rule" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77557

Take A Break To Learn More About HCC!

Health Capital Consultants (HCC) is a nationally recognized healthcare economic and financial consulting firm specializing in the valuation of healthcare enterprises, assets, and services. For over 30 years, HCC has provided its clients with the following professional services:

Valuation of Healthcare Businesses

- Hospitals and Health Systems
- Physician Medical Practices
- Service Lines of Hospitals and Practices
- Ambulatory Surgical Centers (ASCs)
- Diagnostic Imaging Centers
- Managed Care Organizations
- Long-Term Care Providers
- Accountable Care Organizations (ACOs)
- Home Healthcare and Hospice Providers
- Radiation Oncology Centers
- Rehabilitation Centers
- Other Healthcare Enterprises

Valuation of Healthcare Business Assets

- Tangible Personal Property (i.e., furniture, fixtures and equipment)
- Trained and Assembled Workforce
- Custodial Rights of Medical Charts and Records
- Noncompete Covenants
- Certificates of Need
- Managed Care and Provider Service Agreements
- Lease Agreements
- Intellectual Property
- Accountable Care Organization Participation
- Branding Rights
- Other Healthcare Tangible and Intangible Assets

Valuation of Healthcare Services

- Professional Physician Services
- Service Line Co-Management Services
- Management Services
- Medical Directorship Services
- Physician On-Call Coverage Services
- Advanced Practice Clinician (APC) Services
- Physician Administrative, Executive, and Management Services
- POD Compensation Models
- Value-Based Payment Compensation
- Income Guarantee Arrangement Models
- Other Healthcare Services

The HCC team of qualified, experienced and certified healthcare valuation professionals with: specific healthcare industry focus; in-depth understanding of, and extensive experience with, the healthcare market on a local, regional, and national basis; and, strong dedication to in-depth research and analysis, sets us apart from otherwise qualified "*generalists*" in the valuation profession.

HCC
HEALTH CAPITAL CONSULTANTS

WEB: www.healthcapital.com ♦ **PHONE:** (800) FYI-VALU [394-8258] ♦ **E-MAIL:** solutions@healthcapital.com

Reimbursement Topics

CMS Unveils New Payment Model

[Excerpted from the article published in September 2023.]

On September 5, 2023, the Centers for Medicare & Medicaid Services (CMS) announced the establishment of the States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model, in an effort to support health equity within states.[1] The goal of the new voluntary total cost of care model is to reduce disparities in health outcomes by advancing health equity, curb the growth in healthcare costs by collaborating with states, and improve population health.[2] This Health Capital Topics article will discuss the new AHEAD Model and its implications for the healthcare industry.

CMS will support states that participate in a variety of AHEAD Model components, with a focus on providing financial stability for hospitals, increasing investment in primary care, and supporting the connection of Medicare and Medicaid beneficiaries to resources within the community.[3] The model will include streams of payment for primary care practices and hospitals, while patients will also be able to obtain more referrals and screenings for community resources (e.g., housing and transportation).[4]

Participating states will have to meet total cost of care targets in the AHEAD Model, which will be determined by CMS prior to implementation.[5] By meeting the targets, participating states will be incentivized to control unnecessary spending by providing care in the safest settings and reorienting care to focus on prevention.[6] States will also set a shared expectation for healthcare cost growth, encouraging alignment with payor efforts to deliver transformative change while slowing the cost of healthcare.[7]

States that apply for the AHEAD Model will have to select one of three cohorts depending on how quickly they can implement the model.[8] The three cohorts are as follows:

- Cohort 1: States may select this cohort if they can implement the AHEAD Model as soon as possible. The performance year for Cohort 1 will begin in January 2026, with nine total years of performance.
- Cohort 2: States may select this cohort if they are ready to apply, but need more time to prepare for the model implementation, such as: (1) developing Medicaid components; (2) developing data infrastructure; and/or (3) recruiting providers to participate. The second cohort's performance year will begin in January 2027, with eight total years of performance.
- Cohort 3: States that need more time to apply for the AHEAD Model would select this cohort. The first performance year for this cohort would also be January 2027, with a total of eight years of performance.[9]

The AHEAD Model will operate for a total of 11 years, from 2024 through 2034, with CMS providing cooperative agreement funding to selected states for six years to support their participation in the model.[10] States can receive a maximum of $12 million in funding, with performance years slated to begin either in January 2026 or January 2027.[11] States will have 90 days from CMS's announcement to apply, with another application window opening in the spring of 2024.[12]

States have implemented similar programs over the past decade, with goals of limiting unnecessary healthcare spending, incentivizing preventative care to keep patients out of the hospital, and buoying rural hospitals with low patient volumes.[13] The AHEAD Model was based partially on models from Pennsylvania, Maryland, and Vermont.[14] Examples include the following:

- Maryland added a global budget to its long-standing hospital all-payor payment system in 2014. With this provision, the state set the fixed payment amount based on the historical net revenue of hospitals, changes in the population of patients, and services provided. The model, which also updated rates to reflect inflation, helped cut the spending of hospitals by more than $781 million from 2019 through 2021.
- Vermont designed their voluntary all-payor accountable care organization (ACO) model based on Maryland's program for global budgeting. Vermont's ACO covers Medicare, Medicaid, and commercial payors, and requires all model participants to pay standardized rates for all services provided.

- The Center for Medicare and Medicaid Innovation (CMMI) piloted a program for hospitals in rural Pennsylvania, in which Medicare, Medicaid, and commercial insurers paid a fixed amount to hospitals to cover both inpatient and outpatient hospital-based services. Between 2019 and 2021, the program resulted in lower costs of care per beneficiary, with 83% of participating hospitals reducing the frequency of hospital acquired infections, and another 80% improving spending which was avoidable.[15]

Overall, the model is designed to test the accountability of states in controlling healthcare expenditure growth while simultaneously improving the health of the overall population and investing in primary care.[16] CMS administrator Chiquita Brooks-LaSure stated in a press release that "the AHEAD Model is a critical step toward addressing disparities in both healthcare and health equity while improving overall population health."[17]

---

1 "CMS launches AHEAD model to enhance healthcare management" Hospital Management, September 6, 2023, https://www.hospitalmanagement.net/news/cms-ahead-model-healthcare-management/?cf-view (Accessed 9/6/23).
2 "States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model" Centers for Medicare and Medicaid Services, September 5, 2023, https://innovation.cms.gov/innovation-models/ahead (Accessed 9/6/23).
3 Hospital Management, September 6, 2023.
4 "CMS unveils new model aimed at chronic disease" By Noah Tong, Fierce Healthcare, September 5, 2023, https://www.fiercehealthcare.com/payers/new-cms-model-chronic-disease-and-behavioral-health-released (Accessed 9/6/23).
5 "CMS Announces Transformative Model to Give States Incentives and Flexibilities to Redesign Health Care Delivery, Improve Equitable Access to Care" Centers for Medicare and Medicaid Services, September 5, 2023, https://www.cms.gov/newsroom/press-releases/cms-announces-transformative-model-give-states-incentives-and-flexibilities-redesign-health-care (Accessed 9/6/23).
6 *Ibid.*
7 *Ibid.*
8 Centers for Medicare and Medicaid Services, September 5, 2023.
9 *Ibid.*
10 *Ibid.*
11 *Ibid.*
12 Kacik, Modern Healthcare, September 5, 2023.
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
16 Centers for Medicare and Medicaid Services, September 5, 2023.
17 Kacik, Modern Healthcare, September 5, 2023.

Price Discrepancies in Hospital Services Revealed

[Excerpted from the article published in September 2023.]

On September 18, 2023, the Journal of the American Medical Association (JAMA) published a study comparing online hospital pricing and pricing given over the telephone for shoppable hospital services.[1] Hospitals in the U.S. are required to post pricing online for specified services, but it was unknown whether or not hospitals quoted the same prices to telephone callers as they posted online.[2] This Health Capital Topics article will discuss the topic of price discrepancy and the difficulties with cost comparison.

As healthcare costs continue to rise, price transparency has become a focus of regulatory rulemaking. In 2021, the Centers for Medicare & Medicaid Services (CMS) implemented a final rule that mandated all U.S. hospitals to publicly display prices.[3] Hospitals were required to post on their website 300 shoppable services and their corresponding prices in a consumer-friendly manner.[4] However, as of February 2023, just over two years after the final rule went into effect, only about 25% of hospitals were in compliance with all of the rule's requirements.[5] The final rule currently allows for fines up to $2 million for hospitals that do not post prices, but there is no mechanism through which CMS can audit hospitals to determine if they are posting misleading prices and erroneous data.[6] To date, 14 hospitals have been fined a total of $4.6 million by CMS for noncompliance with the rule.[7]

The JAMA study, conducted in 2022, over one year after the enactment of the Hospital Price Transparency Rule, found poor correlation between prices that were offered over the telephone to secret shoppers and prices that were posted online by hospitals.[8] Results highlighted the ongoing issues in hospitals communicating their pricing, as well as for patients who shop comparatively for healthcare.[9] The study analyzed prices for two services – vaginal childbirth and brain magnetic resonance imaging (MRI) – across 60 representative hospitals classified as either: a top-ranked hospital, a safety-net hospital, or a non-top-ranked, non-safety-net hospital. Of the 60 hospitals analyzed, only 22 (just over one-third of hospitals) provided both online and phone pricing estimates for vaginal childbirth, and only three of those hospitals provided matching estimates.[10] Nine hospitals provided pricing estimates via phone that differed by more than 50% from the online price, and ten hospitals provided estimates that were within 25% of the online price.[11] For brain MRI, 47 of the 60 hospitals provided both online and phone pricing estimates, but only nine provided matching estimates. Twelve hospitals provided phone price estimates that differed by at least 50% from their online estimates, and 31 hospitals provided phone price estimates within 25% of the online price. [12]

Overall, safety-net hospitals had the lowest online prices of the three hospital categories for both vaginal childbirth and brain MRI, but similar telephone prices compared to the other two hospital categories. Online pricing for vaginal childbirth varied widely among hospitals, with prices ranging from $0 to $55,221 among highly-ranked institutions and from $4,361 to $14,377 among safety-net hospitals.[13] Online prices for brain MRIs had a somewhat tighter range, with price estimates between $481 and $7,307 at highly-ranked hospitals and between $418 and $6,864 at safety-net hospitals. The study's findings highlighted the implausibility and inaccuracy of the online pricing, providing an example of the same hospital quoting the cost of childbirth as $0 and the cost of a brain MRI as $166,000.[14] According to the study, a variety of factors account for the discrepancies in pricing. For example, hospital billing staff may not be adequately trained or may be unaware of the online price estimator tool.[15]

Notably, the study was co-authored by affiliates of the University of Texas's Medical Branch, the Baylor College of Medicine, and Mark Cuban, billionaire entrepreneur and co-founder of the Mark Cuban Cost Plus Drug Company, who has been a big advocate for transparent and affordable pricing on drugs.[16]

This newest study is in line with other analyses of the Hospital Price Transparency Rule, which found various issues with reported services and prices. For example, inconsistencies exist in which services corresponded with which prices, making price comparisons difficult.[17] Critical information for interpreting price applicability, such as the payor class and contracting method, was often missing.[18] The quality of data also varied widely, with some hip and knee replacement data suggesting hospital prices were under $1,000 for the procedure, while other data suggested prices

exceeding $1 million.[19] While CMS provides suggested guidelines regarding the formatting, validation, and quality of data, hospitals are not required to comply with those suggestions.

While federal policy related to hospital price transparency is certainly not perfect, CMS's final rule did succeed in making publicly available some data related to negotiated charges between providers and payers, regardless how reliable.[20] As the JAMA authors note, the study's "results illustrate the promise of and substantial barriers to translating newly available hospital price data into actionable information that ultimately facilitates comparison shopping."[21] Whether further regulations will be enacted to ensure true price comparison remains to be seen.

---

1 "Comparison of Hospital Online Price and Telephone Price for Shoppable Services" By Merina Thomas, et al, Journal of the American Medical Association, September 18, 2023, https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2809589 (Accessed 9/27/23).
2 *Ibid.*
3 "Secret shopper' study finds errors, discrepancies in inquiries about hospital prices" UTMB Health, September 18, 2023, https://www.utmb.edu/news/article/utmb-news/2023/09/18/secret-shopper-study-finds-errors-discrepancies-in-inquiries-about-hospital-prices (Accessed 9/27/23).
4 "Hospitals share differing medical prices online versus over the phone, secret shopper survey finds" By Rebecca Pifer, Healthcare Dive, September 18, 2023, https://www.healthcaredive.com/news/hospital-price-variation-online-phone-transparency/693866/#:~:text=Price%20discrepancies%20could%20be%20due,hospital's%20online%20price%20estimator%20tool. (Accessed 9/27/23).
5 "Fourth Semi-Annual Hospital Price Transparency Report" Patient Rights Advocate, February 2023, available at: https://www.patientrightsadvocate.org/february-semi-annual-compliance-report-2023 (Accessed 9/27/23).
6 UTMB Health, September 18, 2023.
7 Pifer, Healthcare Dive, September 18, 2023.
8 Thomas, et al, Journal of the American Medical Association, September 18, 2023.
9 *Ibid.*
10 "Mark Cuban-backed study finds price discrepancies in hospital services" By Caroline Hudson, Modern Healthcare, September 22, 2023, https://www.modernhealthcare.com/finance/mark-cuban-jama-study-hospital-price-variations (Accessed 9/27/23).
11 *Ibid.*
12 *Ibid.*
13 *Ibid.*
14 UTMB Health, September 18, 2023.
15 Pifer, Healthcare Dive, September 18, 2023.
16 Hudson, Modern Healthcare, September 22, 2023.
17 "Ongoing challenges with hospital price transparency" By Justin Lo, Gary Claxton, Emma Wager, Cynthia Cox, and Krutika Amin, Kaiser Family Foundation, February 10, 2023, https://www.healthsystemtracker.org/brief/ongoing-challenges-with-hospital-price-transparency/#Distribution%20of%20negotiated%20rates%20for%20hip%20and%20knee%20replacement (Accessed 9/27/23).
18 *Ibid.*
19 *Ibid.*
20 *Ibid.*
21 Thomas, et al, Journal of the American Medical Association, September 18, 2023.

MPFS Final Rule Cuts Physician Payments

[Excerpted from the article published in November 2023.]

On November 2, 2023, the Centers for Medicare & Medicaid Services (CMS) released its finalized Medicare Physician Fee Schedule (MPFS) for calendar year (CY) 2024. While the finalized fee schedule cuts payments to physicians, there are a number of other (more positive) provisions in the final rule. This Health Capital Topics article explores the various changes and updates included in the MPFS final rule.

Payment Rate Updates for MPFS

The overall MPFS payment rates will be reduced in CY 2024 by 1.25%.[1] The conversion factor will decline by $1.15, to $32.74 (a nearly 3.4% reduction from 2023's conversion factor of $33.89),[2] the fourth straight year that physician payment rates have experienced a decrease. The conversion factor converts a relative value unit (RVU) – a geographically-adjusted number that represents the amount of resources required to perform each procedure listed in the MPFS – into a payment amount for a given service.[3] This conversion factor is updated yearly by a formula that takes into account: (1) the previous year's conversion factor; (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.[4] All physician services, except anesthesia services, use a single conversion factor.[5] The CY 2024 conversion factor decrease is the result of: a 0% statutory update; a -2.18% budget neutrality adjustment; and a "funding patch" included in the *Consolidated Appropriations Act of 2023* (CAA).[6]

Changes to the Medicare Shared Savings Program (MSSP)

CMS finalized a number of changes to the Medicare Shared Savings Program (MSSP) in the MPFS final rule.[7] For performance year 2024 and following years, CMS established a new option for reporting quality measures: Medicare Clinical Quality Measures (CQMs) for Accountable Care Organizations Participating in the MSSP.[8] CMS intends for this new data collection type to act as a transitional step in "helping ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all-payer/all-patient" CQMs[9] and moving ACOs "toward digital measurement of quality."[10]

CMS also finalized changes to ACO financial benchmarking methodologies.[11] Beginning January 1, 2024, CMS will: (1) cap the risk score growth in an ACO's regional area of service; (2) apply the same methodology for risk adjustment to both the performance and benchmark years; and (3) eliminate any overall regional adjustment that may be negative for the benchmark, which would aim to encourage the participation of ACOs serving high-cost, medically complex beneficiaries.[12] The aim of changing the methodology for financial benchmarking is to encourage ACOs that serve complex populations to participate in the MSSP.[13]

CMS also finalized methodology changes for beneficiary assignment that would promote access to accountable care for beneficiaries who rely on nurse practitioners, clinical nurse specialists, and physician assistants for their primary care needs.[14] The change would place more importance on the role of clinical nurse specialists, nurse practitioners, and physician assistants in their delivery of primary care services.[15]

Telehealth Changes

CMS is finalizing the implementation of multiple telehealth-related provisions included in the 2023 CAA, including:

(1) The temporary expansion of the scope of originating telehealth sites (for any services which may be furnished via telehealth) to include any site in the nation where the beneficiary is located at the time when services rendered;
(2) The expansion of the current definition of a telehealth practitioner to include qualified audiologists, speech-language pathologists, physical therapists, and occupational therapists;
(3) The continued payment for services furnished through telehealth by federally qualified health centers (FQHCs) and rural health centers (RHCs) using the same methodology which was established during the COVID-19 public health emergency (PHE);

(4) Delaying requirements for in-person visits with a practitioner or provider within six months before initiating telehealth services related to mental health; and
(5) The continuation of payment and coverage for telehealth services included on the Medicare Telehealth Services List.[16]

All these telehealth flexibilities will continue at least until the end of 2024.[17] However, one change that will occur, beginning in CY 2024, is that telehealth services rendered to Medicare beneficiaries in their homes will be paid at the lower, non-facility MPFS rate (currently, they are paid at the higher, facility MPFS rate).[18]

Other Provisions

CMS is finalizing their proposal for payments to practitioners that train caregivers to assist patients with certain illnesses or diseases in carrying out plans of treatment.[19] These services will be paid for by Medicare when furnished by a physician, non-physician practitioner, or therapist.[20] Medicare will also advance their health equity efforts by separately paying for services related to social determinants of health risk assessments, community health integration, and principal illness navigation.[21] Payments will include and account for resources when clinicians work alongside healthcare support staff (such as care navigators, peer support specialists, and community health workers) to furnish care.[22]

CMS finalized the implementation of a separate payment for healthcare common procedure coding system (HCPCS) add-on code G2211: "*visit complexity inherent to evaluation and management [E/M] associated with medical care services that serve as the continuing focal point for all needed healthcare services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition*."[23] The add-on code, for which providers can start billing beginning January 1, 2024, will help providers better recognize the costs related to evaluation and management (E/M) visits for longitudinal and primary care, which necessarily relies on the long-term relationship between the patient and the physician.[24] The add-on payment aims to better recognize clinicians' costs related to a patient's ongoing care for a serious or complex condition.[25] CMS provided a situational example of when the code may be used: "a patient has a primary care practitioner that is the continuing focal point for all healthcare services [i.e., has a long-term relationship with the provider], and the patient sees this practitioner to be evaluated for sinus congestion."[26] CMS stated that

> "*the inherent complexity that this code (G2211) captures is not in the clinical condition itself—sinus congestion—but rather the cognitive load of the continued responsibility of being the focal point for all needed services for this patient…The primary care practitioner must decide—what course of action and choice of words in the visit itself, would lead to the best health outcome in this single visit, while simultaneously building up an effective, trusting longitudinal relationship with this patient for all of their primary health care needs.*"[27]

CMS also revised the definition of "substantive portion" of a shared or split E/M visit. E/M codes capture time the healthcare provider spends in a hospital or other facility setting (not in the office) "evaluating or managing a patient's health."[28] E/M visits are often performed by both a physician and an advanced practice clinician (APC), such as a nurse practitioner or a physician assistant. Who can bill for the time spent evaluating and managing a patient is important because only one provider can bill for the service, and Medicare reimburses physicians a higher amount for E/M visits than APCs. CMS requires that the provider who performs a "substantive portion" of a shared (or split) E/M visit bill for their time (at their rate).[29] The final rule revised "substantive portion" to be defined as over half of the total amount of time spent with a physician or non-physician practitioner that is performing the shared or split visit, or a major portion of the decision making.[30] Previously, the term was defined "as one of the following: either one of the three key E/M elements (that is, history, exam, or [medical decision making]) or more than half of total time."[31]

Comments from Stakeholders

Industry trade associations strongly condemned the cuts to physician payments contained in the MPFS final rule. The Medical Group Management Association (MGMA) implored Congress to act to avoid cuts to physician payments, stating that the reduction would be increasing "the gap between physician practice expenses and reimbursement rates, and dangerously impeding beneficiary access to care."[32] The President of the American Medical Association (AMA) stated that "the Medicare physician payment schedule released today is an unfortunate continuation of a two-decade march in making Medicare unsustainable for patients and physicians."[33] The AMA and other physician groups criticized the rule before it was even finalized, taking their case to Congress to argue that Medicare physician fees should not be reduced.[34]

However, some associations did praise other provisions. The National Association of ACOs (NAACOS) President and CEO Clif Gaus stated that the "NAACOS appreciates that CMS continues to support the growth of value-based care."[35] Gaus also expressed NAACOS's support of CMS's leadership to "create stronger pathways for clinicians and health systems who want to provide higher quality, more cost effective, coordinated care for patients."[36]

Conclusion

According to CMS Administrator Chiquita Brooks-LaSure, "CMS remains steadfast in [its] commitment to supporting physicians and ensuring that people with Medicare have access to the care they need to stay healthy as well as navigate health conditions they are facing."[37] However, providers believe that cuts to physician payments will in fact have the opposite effect – reduced patient access to care. On November 8, 2023, after provider trade associations lobbied for the government to override the MPFS final rule cuts, the Senate Finance Committee approved legislation which included language that scaled back the Medicare payment cuts for physicians.[38] While the legislation would not completely reverse the cut, it would soften the impact by replacing the 3.4% reduction with a 2.15% cut.[39] The effect on physician payment rates will be determined by CMS once the legislation is enacted.[40]

1 "Calendar Year (CY) 2024 Medicare Physician Fee Schedule Final Rule" Centers for Medicare & Medicaid Services, November 2, 2023, https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-medicare-physician-fee-schedule-final-rule (Accessed 11/15/23).
2 *Ibid.*
3 "Physician Reimbursement Under Medicare" By Alan M. Scarrow, MD., Neurosurgical Focus, Vol. 12, No. 4: Article 8 (April 2002), p. 2.
4 "Part B Payments: General Limits and Payment Rules" In "2009 Master Medicare Guide" CCH Health Editorial, Wolters Kluwer, 2009, p. 901.
5 *Ibid*, p. 900.
6 "Policy Update: CMS Releases CY 2024 Physician Fee Schedule Final Rule" By Jeffrey Davis, et al., McDermott+ Consulting, November 6, 2023, available at: https://www.mcdermottplus.com/insights/cms-releases-cy-2024-physician-fee-schedule-final-rule/ (Accessed 11/20/23).
7 Centers for Medicare and Medicaid Services, November 2, 2023.
8 *Ibid.*
9 "2024 CMS Proposed Rule: Introducing Medicare CQMs as a New Reporting Option for ACOs" MDinteractive, July 15, 2023, https://mdinteractive.com/mips-blog/2024-cms-proposed-rule-introducing-medicare-cqms-new-reporting-option-acos (Accessed 11/27/23).
10 Centers for Medicare and Medicaid Services, November 2, 2023.
11 *Ibid.*
12 *Ibid.*
13 "AMA: Medicare physician payment proposal a wake-up call for Congress" American Medical Association, July 13, 2023, https://www.ama-assn.org/press-center/press-releases/ama-medicare-physician-payment-proposal-wake-call-congress (Accessed 11/22/23).
14 "Calendar Year (CY) 2024 Medicare Physician Fee Schedule Proposed Rule" Centers for Medicare and Medicaid Services, July 13, 2023, https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-medicare-physician-fee-schedule-proposed-rule (Accessed 11/14/23).
15 Centers for Medicare and Medicaid Services, November 2, 2023.
16 *Ibid.*
17 *Ibid.*
18 "CMS Issues Physician Fee Schedule Final Rule with Payment Rate Cut" American Health Law Association, November 3, 2023, https://www.americanhealthlaw.org/content-library/health-law-weekly/article/e144866d-b571-4b10-98d0-530c46f3f5e7/CMS-Issues-Physician-Fee-Schedule-Proposed-Rule-wi?Token=549ef0b5-a159-47d3-abab-87e5b19e8876 (Accessed 11/15/23).
19 "CMS Finalizes 1.25% Cut To Medicare Physician Fee Schedule" By Jacqueline LaPointe, RevCycleIntelligence, November 3, 2023, https://revcycleintelligence.com/news/cms-finalizes-1.25-cut-to-medicare-physician-fee-schedule (Accessed 11/15/23).
20 *Ibid.*
21 Centers for Medicare & Medicaid Services, November 2, 2023.
22 *Ibid.*
23 *Ibid*; "2024 MPFS final rule includes cuts to conversion factor, implementation of new add-on visit code" Nahri, November 8, 2023, https://nahri.org/articles/2024-mpfs-final-rule-includes-cuts-conversion-factor-implementation-new-add-visit-code (Accessed 11/22/23).
24 Centers for Medicare & Medicaid Services, November 2, 2023; "Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program" Federal Register, Vol. 88, No. 220 (November 16, 2023), p. 78973.
25 LaPointe, RevCycleIntelligence, November 3, 2023.
26 "Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program" Federal Register, Vol. 88, No. 220 (November 16, 2023), p. 78973.
27 *Ibid*, p. 78973-78974.
28 "Evaluation and Management (E/M) Coding" American Medical Association, 2023, https://www.ama-assn.org/topics/evaluation-and-management-em-coding# (Accessed 7/26/23).
29 "CMS issues CY 2024 physician fee schedule proposed rule" American Hospital Association, July 13, 2023, https://www.aha.org/news/headline/2023-07-13-cms-issues-cy-2024-physician-fee-schedule-proposed-rule (Accessed 7/14/23).
30 Centers for Medicare & Medicaid Services, November 2, 2023.
31 Federal Register, Vol. 88, No. 220 (November 16, 2023), p. 78983.
32 "MGMA statement on CMS' final 2024 Medicare Physician Fee Schedule" By Anders Gilberg, Senior Vice President, Government Affairs, Medical Group Management Association, November 2, 2023, https://www.mgma.com/press-statements/november-2-2023-mgma-statement-on-cms-final-2024-medicare-physician-fee-schedule (Accessed 11/15/23).
33 "Physicians hit with Medicare pay cut under final rule" By Alison Bennett, Modern Healthcare, November 2, 2023, https://www.modernhealthcare.com/policy/medicare-physician-fee-schedule-final-rule-2024-cuts-payment (Accessed 11/15/23).
34 *Ibid.*
35 "NAACOS Statement on Final 2024 Medicare Physician Fee Schedule" National Association of ACOs, November 2, 2023, https://www.naacos.com/press-release--naacos-statement-on-final-2024-medicare-physician-fee-schedule (Accessed 11/15/23).
36 *Ibid.*
37 "Physician groups decry finalized Medicare payment cuts for 2024 as expenses rise" By Heather Landi, Fierce Healthcare, November 2, 2023, https://www.fiercehealthcare.com/providers/physician-groups-decry-finalized-medicare-payment-cuts-2024-expenses-rise (Accessed 11/17/23).
38 "Senate moves to delay $16B hospital cut, trim doctor pay hit" By Michael Mcauliff, Modern Healthcare, November 8, 2023, https://www.modernhealthcare.com/politics-policy/medicare-physician-pay-cuts-medicaid-dsh-cuts-senate-bill (Accessed 11/27/23).
39 *Ibid.*
40 *Ibid.*

OPPS Final Rule Issued by CMS

[Excerpted from the article published in November 2023.]

On November 2, 2023, the Centers for Medicare & Medicaid Services (CMS) released its finalized Outpatient Prospective Payment System (OPPS) for calendar year (CY) 2024.[1] The finalized payment update increases payments to outpatient facilities and finalizes changes to their hospital price transparency rule, among other provisions.[2] This Health Capital Topics article discusses the various OPPS changes and updates included in the final rule.

Payment Rate Updates

For CY 2024, CMS will increase OPPS payment rates to hospital outpatient departments (HOPDs) and ambulatory surgery centers (ASCs) that meet specific quality reporting criteria by 3.1% – higher than the proposed increase of 2.8%, but lower than the CY 2023 increase of 3.8%.[3] For CY 2024, the ASC conversion factor is $53.514, and the HOPD conversion factor is $87.382.[4] The finalized update is based on a projected hospital market basket percentage of 3.3% and a productivity adjustment of -0.2%.[5]

Hospital Price Transparency

As healthcare costs continue to rise, price transparency has become an increasing focus of regulatory rulemaking. In 2021, CMS implemented a final rule mandating all U.S. hospitals to publicly display prices.[6] Hospitals were required to post on their website 300 shoppable services and their corresponding prices in a consumer-friendly manner.[7] However, as of February 2023, just over two years after the final rule went into effect, only about 25% of hospitals were in compliance with all of the rule's requirements.[8] The final rule currently allows for fines up to $2 million for hospitals that do not post prices, but there is no mechanism through which CMS can audit hospitals to determine if they are posting accurate prices and data.[9] To date, 14 hospitals have been fined a total of $4.6 million by CMS for noncompliance with the rule.[10]

In response to CMS's problems enforcing meaningful performance, the CY 2024 OPPS final rule includes a number of provisions to streamline price transparency enforcement.[11] Starting in 2024, CMS will communicate directly with hospital leadership should price transparency performance be insufficient, and the agency will reserve the right to post any measures of enforcement online.[12] To improve public understanding, compliance, and the automated use of hospital information, CMS finalized changes to how hospitals must display their standard charges (i.e., the hospital's regular rate for a given item or service).[13] CMS Administrator Chiquita Brooks-LaSure stated that "[t]he final rule strengthens hospital price transparency by improving the standardization of hospital standard charges and enhancing CMS' enforcement capabilities, thereby better enabling the American people to understand and meaningfully use hospital standard charges for items and services."[14]

Rural Emergency Hospital Designation

Consistent with CMS's overarching equity goals, the agency established the Rural Emergency Hospital (REH) provider type in 2023.[15] Medicare-participating hospitals are eligible to convert to an REH if they are a rural or critical access hospital with no more than 50 beds.[16] Converted REHs receive enhanced rates for services and a monthly fixed facility payment.[17]

In the CY 2024 OPPS final rule, CMS implemented a policy that Indian Health Service (IHS) and Tribal facilities that convert to REHs will receive payment under the same all-inclusive-rate that would apply to services performed by IHS and Tribal facilities that are not REHs.[18] This approach is expected to bring stability to IHS and Tribal facilities that convert their statuses to REHs, and overall promote better access to the IHS and Tribal facilities.[19]

Intensive Outpatient Program

The OPPS final rule also included a policy to improve access to behavioral health. CMS originally established payment for Intensive Outpatient Program (IOP) services to resolve a gap in coverage which was faced by patients when they required more intensive care than outpatient therapy, but less care than an inpatient hospitalization would provide.[20] IOP services can be furnished in community mental health centers (CMHCs), hospital outpatient departments, federally qualified health centers (FQHCs), opioid treatment programs, and rural health clinics. [21]

340B Payment

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.[22] 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.[23]

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%.[24] In the 2018 OPPS, however, CMS finalized a reduction to this reimbursement rate, specific to 340B participants only, of ASP minus 22.5%.[25] Hospitals and hospital associations subsequently sued CMS to challenge the cuts, and the U.S. Supreme Court unanimously found in June 2022 that CMS exceeded its authority in changing drug reimbursement rates for a subset of hospitals.[26]

For CY 2024, consistent with CY 2023, CMS finalized their proposal to continue payment for 340B acquired biologicals and drugs at the default statutory rate, which is generally 6% added to the ASP.[27] The payment rate for 340B-acquired biologicals and drugs will not be different from the payment rate for biologicals and drugs that are not acquired through the 340B program.[28]

CMS acknowledged in the OPPS final rule that, in accordance with the Supreme Court ruling, it issued a separate final rule outlining the remedy for the unlawful reduced payments made between 2018 and 2022. The remedy is comprised of two components:

(1) The Department of Health & Human Services (HHS) will repay the 340B hospitals that were unlawfully underpaid between 2018 and 2022 via a single-lump sum payment in or around the beginning of CY 2024; and
(2) HHS will recoup funding from hospitals that were overpaid between 2018 and 2022 by adjusting the OPPS conversion factor for those facilities by -0.5% beginning in CY 2026, continuing the adjustment until the amount has been offset in full. HHS anticipates the recoup to take a total of 16 years.[29]

Stakeholder Comments

Stakeholders' reactions to the 2024 OPPS final rule were somewhat mixed. The executive vice president of the American Hospital Association (AHA) stated that:

> "*The AHA is concerned that CMS has again finalized an inadequate update to hospital payments. Today's increase for outpatient hospitals of only 3.1% comes in spite of persistent financial headwinds facing the field. Most hospitals across the country continue to operate on negative or very thin margins that make providing care and investing in their workforce very challenging day to day.*"[30]

Further, "hospitals' and health systems' ability to continue caring for patients and providing essential services for their communities may be in jeopardy, which is why the AHA is urging Congress for additional support by the end of the year."[31] The Ambulatory Surgery Center Association's (ASCA) Chief Executive Officer, Bill Prentice, expressed his appreciation for the final ruling, and stated the following: "We thank CMS for heeding our request to move additional surgical procedures—including total shoulder arthroplasty—onto the ASC payable list."[32] Prentice also said that "doing so benefits both Medicare beneficiaries, who now have a lower-cost choice for the care they need, and the Medicare program itself, which will save millions of dollars as volume moves to the high-quality surgery center site of service."[33]

1 "Fact sheet: CY 2024 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS 1786-FC)" Centers for Medicare and Medicaid Services, November 2, 2023, https://www.cms.gov/newsroom/fact-sheets/cy-2024-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0 (Accessed 11/17/23).

2 *Ibid.*

3 *Ibid*; "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction" Centers for Medicare and Medicaid Services, July 31, 2023, https://www.federalregister.gov/documents/2023/07/31/2023-14768/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment (Accessed 11/17/23). "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19" Federal Register, Vol. 87, No. 225 (November 23, 2022), p. 71751.

4 "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Hospital Outpatient Departments, Community Mental Health Centers, Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction" Centers for Medicare and Medicaid Services, November 11, 2023, https://www.federalregister.gov/documents/2023/11/22/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment#p-80 (Accessed 11/22/23).

5 Centers for Medicare and Medicaid Services, November 2, 2023.

6 "Secret shopper' study finds errors, discrepancies in inquiries about hospital prices" UTMB Health, September 18, 2023, https://www.utmb.edu/news/article/utmb-news/2023/09/18/secret-shopper-study-finds-errors-discrepancies-in-inquiries-about-hospital-prices (Accessed 11/22/23).

7 "Hospitals share differing medical prices online versus over the phone, secret shopper survey finds" By Rebecca Pifer, Healthcare Dive, September 18, 2023, https://www.healthcaredive.com/news/hospital-price-variation-online-phone-transparency/693866/#:~:text=Price%20discrepancies%20could%20be%20due,hospital's%20online%20price%20estimator%20tool. (Accessed 11/22/23).

8 "Fourth Semi-Annual Hospital Price Transparency Report" Patient Rights Advocate, February 2023, available at: https://www.patientrightsadvocate.org/february-semi-annual-compliance-report-2023 (Accessed 11/22/23).

9 UTMB Health, September 18, 2023.

10 "Hospitals share differing medical prices online versus over the phone, secret shopper survey finds" By Rebecca Pifer, Healthcare Dive, September 18, 2023, https://www.healthcaredive.com/news/hospital-price-variation-online-phone-transparency/693866/#:~:text=Price%20discrepancies%20could%20be%20due,hospital's%20online%20price%20estimator%20tool. (Accessed 11/22/23).

11 "CMS bumps up pay increase to 3.1% in final FY24 OPPS rule" By Paige Minemyer, Fierce Healthcare, November 2, 2023, https://www.fiercehealthcare.com/regulatory/cms-bumps-pay-increase-31-final-fy24-opps-rule (Accessed 11/17/23).

12 *Ibid.*

13 Centers for Medicare and Medicaid Services, November 2, 2023.

14 "CMS Makes Hospital Prices More Transparent and Expands Access to Behavioral Health Care" Centers for Medicare and Medicaid Services, November 2, 2023, https://www.cms.gov/newsroom/press-releases/cms-makes-hospital-prices-more-transparent-and-expands-access-behavioral-health-care (Accessed 11/17/23).

15 Centers for Medicare and Medicaid Services, November 2, 2023.

16 *Ibid.*

17 *Ibid.*

18 *Ibid.*

19 *Ibid.*

20 "CMS Will Issue OPPS Providers Lump-Sum Payments to Remedy 340B Losses" By Victoria Bailey, RevCycleIntelligence, November 3, 2023, https://revcycleintelligence.com/news/cms-will-issue-opps-providers-lump-sum-payments-to-remedy-340b-losses (Accessed 11/17/23).

21 *Ibid.*

22 "Supreme Court Will Determine Whether 340B Hospitals Retain Discounts on Medicare Part B Drugs" Allison Hoffman, Commonwealth Fund, November 21, 2021, https://www.commonwealthfund.org/blog/2021/supreme-court-340b-hospitals-discounts-medicare-part-b (Accessed 11/17/23).

23 "340B Drug Pricing Program", HRSA, October 2023, https://www.hrsa.gov/opa/index.html (Accessed 11/17/23).

24 "Federal Court Says 2018 OPPS 340B Program Rate Cuts Unlawful, Orders Briefing to Avoid Havoc on Medicare Program" By Lee Nutini, JDSupra, January 3, 2019, https://www.jdsupra.com/legalnews/federal-court-says-2018-opps-340b-87971/ (Accessed 11/17/23).

25 "CMS Issues Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs Changes for 2018 (CMS-1678-FC)" Centers for Medicare & Medicaid Services, November 1, 2017, https://www.cms.gov/newsroom/fact-sheets/cms-issues-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-payment (Accessed 11/17/23).

26 "American Hospital Association et al. v. Becerra, Secretary of Health and Human Services, et al." 596 U.S. ___ (2022), Slip Opinion, Certiorari to the United States Court of Appeals for the District of Columbia Circuit, available at: https://www.supremecourt.gov/opinions/21pdf/20-1114_09m1.pdf (Accessed 11/17/23).

27 Centers for Medicare and Medicaid Services, November 2, 2023.

28 *Ibid.*

29 "CMS Proposes Remedy for 340B-Acquired Drug Payment Policy for CY 2018-2022 " By Anil Shankar and Stephanie Schwartz, July 26, 2023, https://www.foley.com/insights/publications/2023/07/cms-remedy-340b-acquired-drug-payment-policy/ (Accessed 11/22/23); "HHS issues final remedy for its unlawful 340B payment cuts from 2018 to 2022" American Hospital Association, November 2, 2023, https://www.aha.org/news/headline/2023-11-02-hhs-issues-final-remedy-its-unlawful-340b-payment-cuts-2018-2022#:~:text=2%20issued%20a%20final%20rule,a%20single%2Dlump%20sum%20payment. (Accessed 11/17/23).

30 "In OPPS rule, CMS increases payment rates by 3.1%, modifies price transparency rules" American Hospital Association, November 2, 2023, https://www.aha.org/news/headline/2023-11-02-opps-rule-cms-increases-payment-rates-31-modifies-price-transparency-rules (Accessed 11/17/23).

31 *Ibid.*

32 "CMS Releases 2024 Final Payment Rule" Ambulatory Surgery Center Association, November 2, 2023, https://www.ascassociation.org/asca/news-and-publications/news/2023/cms-releases-2024-final-payment-rule-2023-11-01 (Accessed 11/2/23).

33 *Ibid.*

Healthcare Spending Grew in 2022

[Excerpted from the article published in December 2023.]

On December 13, 2023, the Centers for Medicare & Medicaid Services (CMS) released its annual report on healthcare spending in the U.S., highlighting the growth in private insurance and Medicaid spending in 2022, which was offset by the declines in supplemental federal funding as a result of the COVID-19 pandemic.[1] This Health Capital Topics article reviews the notable healthcare spending findings in CMS's report.

Overall, healthcare spending grew 4.1% in 2022 (to $4.5 trillion), much faster than the 3.2% increase in 2021.[2] Healthcare spending as a share of the U.S. gross domestic product (GDP) declined from 18.2% in 2021 to 17.3% in 2022.[3] The overall GDP increased 9.1% in 2022, slower than the 10.7% increase in 2021.[4]

Examining the expenditures across service categories, hospital expenditures grew 2.2% in 2022 (comprising 30% of overall healthcare spending), approximately half the growth rate observed in 2021 (4.5%).[5] This was a result of decreases in private health insurance spending, Medicare, Medicaid, and other private revenue.[6] Similarly, expenditures on physician and clinical services increased 2.7% (comprising 20% of healthcare spending), which was nearly half of the 5.3% growth in 2021.[7] Much like hospital care, the slow growth in physician and clinical services was attributed to a decline in federal funding, private health insurance, and out-of-pocket spending.[8] In contrast, retail prescription drug expenditures increased 8.4% in 2022 (comprising 9% of healthcare spending), a faster rate than 2021's spending increase of 6.8%.[9] This increase was attributed to the growth in the number of prescriptions, as well as an increase in prescription drug prices.[10]

Analyzing expenditures by sponsor, the federal government predictably continued to account for the largest share of healthcare spending (33%), followed by households (28%), private businesses (18%), state and local governments (15%), and other private revenues (6%).[11] Federal government spending increased 1.0% in 2022, after a 3.4% decline in 2021.[12] Household health spending increased 6.9% in 2022, similar to the 6.8% increase in 2021.[13] State and local governments experienced a slight spending growth in 2022, with spending increasing by 6.5% compared to the 6.2% increase in 2021, driven by the increase in state Medicaid spending.[14] Finally, spending by private businesses increased 6.0% in 2022, which was slower than the 7.6% increase in 2021.[15] This was largely due to the increase in contributions to employer-sponsored private health insurance premiums.[16]

In terms of insurance coverage, the number of uninsured individuals in 2022 decreased to 26.6 million from the 2021 total of 28.5 million.[17] Enrollment increased in Medicare, Medicaid, and the Affordable Care Act (ACA) Marketplace plans.[18] In fact, the insured portion of the U.S. population reached a record high of 92% in 2022. However, the subsequent end of the COVID-19 public health emergency in May 2023 resulted in a reversion to previous Medicaid criteria, resulting in the loss of Medicaid coverage for an estimated three million Americans.[19]

There is significant uncertainty as to what these trends may mean for 2023 healthcare spending. While economic growth is expected to slow from the highs seen after the COVID-19 pandemic, economy-wide inflation is expected to recede. Growth in future healthcare spending is expected to be driven by health-specific factors such as:

(1) The intensity and use of medical care;
(2) Medical specific inflation in pricing; and
(3) Demographic impacts associated with the continuing Medicare enrollment of Baby Boomers.[20]

Trends in spending growth are slowly stabilizing, and federal government funding for COVID-19 has largely ceased; as a result, the U.S. is experiencing growth similar to pre-pandemic rates.[21] With the current volatility of the U.S. economy, and the unknown impact of 2023's inflation, there are many variables subject to change, which may have substantial impact on overall GDP and healthcare spending.

1 "National Health Expenditures 2022 Highlights" Office of the Actuary, Centers for Medicare and Medicaid Services, December 13, 2023, https://www.cms.gov/newsroom/fact-sheets/national-health-expenditures-2022-highlights (Accessed 12/19/23).
2 *Ibid.*
3 "National Health Care Spending In 2022: Growth Similar To Prepandemic Rates" By Micah Hartman, et al., Health Affairs, December 13, 2023, available at: https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.01360 (Accessed 12/19/23).
4 *Ibid.*
5 Centers for Medicare and Medicaid Services, December 13, 2023.
6 *Ibid.*
7 *Ibid.*
8 *Ibid.*
9 *Ibid.*
10 *Ibid.*
11 Hartman, et al., Health Affairs, December 13, 2023.
12 *Ibid.*
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
16 *Ibid.*
17 Centers for Medicare and Medicaid Services, December 13, 2023.
18 Hartman, et al., Health Affairs, December 13, 2023.
19 "Key Facts about the Uninsured Population" By Jennifer Tolbert, et al., Kaiser Family Foundation, December 18, 2023, https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/ (Accessed 12/19/23).
20 Hartman, et al., Health Affairs, December 13, 2023.
21 *Ibid.*

Congress Increases 2024 Medicare Physician Pay

[Excerpted from the article published in March 2024.]

On March 9, 2024, President Biden signed into law a $460 billion spending package to continue funding the federal government for the remainder of the 2024 fiscal year.[1] Contained within the spending package was legislation to cut in half the 2024 Medicare physician payment update of approximately -3.4%.[2] This Health Capital Topics article discusses the payment update, other healthcare provisions contained in the bipartisan spending bills, and responses from stakeholders.

For calendar year (CY) 2024, the Medicare Physician Fee Schedule (MPFS) conversion factor declined $1.15, to $32.74 – a nearly 3.4% reduction from 2023's conversion factor of $33.89 – the fourth straight year that physician payment rates have experienced a decrease.[3] The conversion factor converts a relative value unit (RVU), a geographically-adjusted number that represents the amount of resources required to perform each procedure listed in the MPFS, into a payment amount for a given service.[4] This conversion factor is updated annually by a formula that takes into account:

(1) The previous year's conversion factor;
(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.[5]

All physician services, except anesthesia services, use a single conversion factor.[6] The CY 2024 conversion factor decrease was the result of: a 0% statutory update; a -2.18% budget neutrality adjustment; and a "funding patch" included in the *Consolidated Appropriations Act of 2023*.[7]

While physicians will not be completely relieved of the significant Medicare reimbursement cut that originally took effect on January 1, 2024, the payment bump of 1.68% (resulting in a reimbursement decrease of approximately 1.7% for the remainder of 2024) softens the blow.[8] This physician pay adjustment, which took effect March 9, 2024,[9] is among a number of healthcare programs and payment policies that are legislatively extended through the end of fiscal year 2024.[10] In total, six spending bills totaling approximately $460 billion were passed on March 8, 2024 (the last day to pass any legislation before the government would have had to partially shut down) to fund the government.[11] Other healthcare-related provisions in the spending bills include:

- An $8 billion cut to the Medicaid Disproportionate Share Hospital (DSH) program was pushed back to January 1, 2025;
- An additional $270 million was included to fund community health centers, bringing total funding to $4.27 billion per year;
- A one-year extension for incentive payments that encourage participation in certain alternative payment models was reduced from a 3.5% bonus to a 1.88% bonus;
- Funding was extended through December 31, 2024 for the National Health Service Corps, with a $35 million increase, and for the Special Diabetes Program, with a $10 million increase;
- The Teaching Health Center Graduate Medical Education program received a $48.5 million increase;
- Medicaid is required to cover medication-assisted treatment for patients with substance use disorders.
- A boost in the geographic index pay (adjustments that are made to physician reimbursement based on where physician services are provided) was for Medicare physician reimbursement.
- For certain low-volume hospitals, extra pay was extended.
- The Medicare-dependent hospital program was extended.
- National health security programs were extended.
- An adjustment to Medicare hospice caps (the maximum reimbursement a hospice can be reimbursed for Medicare hospice services) was extended.
- Funding for Federally Qualified Health Centers (FQHCs) is being extended for four years.
- Food and Drug Administration (FDA) discretionary spending is being held flat at $3.5 billion.[12]

In addition to the six spending bills passed on March 8th, Congress also passed a second set of six spending bills in the early hours of March 23, 2024, to fund the remainder of government programs, including $117 billion to fund the Department of Health and Human Services (HHS), for the remainder of the fiscal year.[13]

Industry trade associations expressed their strong disappointment in the only slight amelioration of Medicare physician payment cuts for 2024. Anders Gilberg, Senior VP of the Medical Group Management Association stated that "anything less than a full reversal of the 3.4% cut is appallingly inadequate."[14] Gilberg also said that MGMA was "deeply disappointed with Congress' half-hearted attempt to remedy the devastating blow physician practices were dealt by the 2024 Medicare Physician Fee Schedule."[15] The American Academy of Family Physicians also expressed their disappointment with the proposed increase for physician payments.[16] AAFP stated that they "repeatedly told Congress that the 3.4% Medicare payment reduction that went into effect on January 1 is untenable for family physicians and threatens patients' access to primary care."[17] The AAFP also said that "while we appreciate the partial relief, family physicians continue to face an annual threat of payment cuts that are detrimental to practices and patients."[18] The American Medical Association added that this latest cut to Medicare physician reimbursement highlights "the need to stop the annual cycle of pay cuts and patches and enact permanent Medicare payment reforms."[19] The AMA "challenged Congress to work on systemic reforms" to the MPFS, and long-term solutions have been floating around Capitol Hill. However, whether any proposed reforms have traction, especially in a presidential election year, remains to be seen.

---

1 "Biden Signs Legislation to Extend Funding for Critical Departments" By Peter Baker, New York Times, March 9, 2024, https://www.nytimes.com/2024/03/09/us/politics/biden-signs-spending-legislation.html (Accessed 3/11/24).

2 "Biden signs $460B spending bill with doc pay bump, delayed DSH cuts and community health funding" By Dave Muoio, Fierce Healthcare, March 10, 2024, https://www.fiercehealthcare.com/providers/congress-reaches-spending-deal-doc-pay-bump-delayed-dsh-cuts-and-more (Accessed 3/11/24).

3 "Calendar Year (CY) 2024 Medicare Physician Fee Schedule Final Rule" Centers for Medicare & Medicaid Services, November 2, 2023, https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-medicare-physician-fee-schedule-final-rule (Accessed 3/6/24).

4 "Physician Reimbursement Under Medicare" By Alan M. Scarrow, MD., Neurosurgical Focus, Vol. 12, No. 4: Article 8 (April 2002), p. 2.

5 "Part B Payments: General Limits and Payment Rules" in "2009 Master Medicare Guide" CCH Health Editorial, Wolters Kluwer, 2009, p. 901.

6 *Ibid*, p. 900.

7 "Policy Update: CMS Releases CY 2024 Physician Fee Schedule Final Rule" By Jeffrey Davis, et al., McDermott+ Consulting, November 6, 2023, available at: https://www.mcdermottplus.com/insights/cms-releases-cy-2024-physician-fee-schedule-final-rule/ (Accessed 3/6/24).

8 "Hospitals, health centers, doctors get relief in funding deal" By Michael Mcauliff, Modern Healthcare, March 4, 2024, https://www.modernhealthcare.com/politics-policy/spending-bill-dsh-cut-physician-payment-community-health-centers (Accessed 3/6/24).

9 "Latest Medicare physician pay cut shows desperate need for overhaul" By Kevin B. O'Reilly, American Medical Association, March 6, 2024, https://www.ama-assn.org/practice-management/medicare-medicaid/latest-medicare-physician-pay-cut-shows-desperate-need (Accessed 3/8/24).

10 "Congress gives doctors Medicare pay bump, sets up December fight in new funding package" By John Wilkerson and Rachel Cohrs, STAT, March 3, 2024, https://www.statnews.com/2024/03/03/doctors-medicare-pay-increase-congress/?utm_campaign=KHN%3A%20First%20Edition&utm_medium=email&_hsmi=296679336&_hsenc=p2ANqtz-9y88O0RNmIf4eVt5ltY3Ak1pWTqB-Gjj6V4IH6FB4h2Bh7RJbm6j8CcR4soLjYuljdC1jgx64dNkxLV3XMF1wrcrX-MTHA&utm_content=296679336&utm_source=hs_email (Accessed 3/6/24).

11 "Congress unveils long-awaited funding bills ahead of shutdown threat" By Aris Folley, The Hill, March 3, 2024, https://thehill.com/homenews/senate/4505075-congress-reveals-long-awaited-bills-ahead-of-next-weeks-shutdown-threat/ (Accessed 3/6/24); "Biden signs $460B spending bill with doc pay bump, delayed DSH cuts and community health funding" By Dave Muoio, Fierce Healthcare, March 10, 2024, https://www.fiercehealthcare.com/providers/congress-reaches-spending-deal-doc-pay-bump-delayed-dsh-cuts-and-more (Accessed 3/11/24).

12 "Congress reaches spending deal with doc pay bump, delayed DSH cuts and more" By Dave Muoio, Fierce Healthcare, March 4, 2024, https://www.fiercehealthcare.com/providers/congress-reaches-spending-deal-doc-pay-bump-delayed-dsh-cuts-and-more (Accessed 3/6/24); "Hospitals, health centers, doctors get relief in funding deal" By Michael Mcauliff, Modern Healthcare, March 4, 2024, https://www.modernhealthcare.com/politics-policy/spending-bill-dsh-cut-physician-payment-community-health-centers (Accessed 3/6/24); "DSH cut delay, doctor pay fix, health center funding bill passes House" By Michael Mcauliff, Modern Healthcare, https://www.modernhealthcare.com/politics-policy/spending-bill-house-dsh-cut-physician-payment?adobe_mc=MCMID%3D83778894198600157600872323146686741432%7CMCORGID%3D138FF-F2554E6E7220A4C98C6%2540AdobeOrg%7CTS%3D1709798272&CSAuthResp=1%3A%3A1126048%3A7461%3A24%3Asuccess%3AB5BA4330F-B53E79A404D9A337185F55B (Accessed 3/6/24).

13 Congress passes $1.2T spending bill that includes HHS funding" By Michael McAuliff, Modern Healthcare, March 23, 2024, https://www.modernhealthcare.com/politics-policy/spending-bill-passes-hhs-funding (Accessed 3/25/24).

14 "Proposed Medicare Pay Bump Falls Short, Doc Groups Say" By Kerry Dooley Young, MedScape, March 6, 2024, https://www.medscape.com/viewarticle/proposed-medicare-pay-bump-falls-short-doc-groups-say-2024a10004ah?form=fpf (Accessed 3/6/24).

15 *Ibid.*

16 *Ibid.*

17 *Ibid.*

18 *Ibid.*

19 "Latest Medicare physician pay cut shows desperate need for overhaul" By Kevin B. O'Reilly, American Medical Association, March 6, 2024, https://www.ama-assn.org/practice-management/medicare-medicaid/latest-medicare-physician-pay-cut-shows-desperate-need (Accessed 3/8/24).

CMS Proposes Increasing Inpatient & Long Term Care Payments

[Excerpted from the article published in May 2024.]

On April 10, 2024, the Centers for Medicare & Medicaid Services (CMS) released its proposed rules for the payment and policy updates for the Medicare inpatient prospective payment system (IPPS) and long-term care hospital prospective payment system (LTCH PPS) for fiscal year (FY) 2025.[1] This Health Capital Topics article will discuss the proposed rule and the implications for stakeholders.

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

CMS proposes increasing the IPPS base rate by 2.6%, which is $3.2 billion in additional funding for FY 2025.[5] This percentage increase is comprised of a projected FY 2025 hospital market basket increase of 3.0%, reduced by 0.4% due to a productivity adjustment.[6] This proposed increase is slightly lower than the FY 2024 payment increase of 2.8%.[7] For FY 2025, the LTCH standard payment rate is expected to increase by 2.8%, with the rate decreasing 2.0% for LTCHs that do not submit quality reporting data.[8] For FY 2024, the LTCH PPS payments increased by 3.3%.[9] CMS is currently seeking comment on the methodology utilized to determine the LTCH PPS outlier threshold for the patient discharges that are paid the LTCH standard payment rate.[10]

Additional to the proposed increase in pay, CMS announced new policies and equity incentives for hospitals.[11] The agency will increase payments to hospitals treating patients who are experiencing homelessness by changing severity designations for seven diagnosis codes.[12] This change will "more accurately reflect each health care encounter for hospitals that take care of persons who have inadequate housing or have housing instability, and also improve the reliability and validity of the coded data including in support of efforts to advance health equity."[13] CMS also plans to increase add-on payments for new technology, specifically for (1) novel gene therapies that target sickle cell disease.[14] Additionally, a separate payment will be added for small independent hospitals that maintain a stock of essential medicines, and a requirement will be added that at least half of 200 new graduate medical education slots (available in 2026) will go towards psychiatry.[15]

The proposed rule also outlined the agency's plan for a new, mandatory Transforming Episode Accountability Model (TEAM).[16] The model would aim to "quality of care for people with Medicare undergoing certain high-expenditure, high-volume surgical procedures, reducing rehospitalization and recovery time while lowering Medicare spending and driving equitable outcomes."[17] Liz Fowler, Deputy Administrator at CMS, stated that "the model is a direct response to post-discharge care breakdowns that lead to complications and increased utilization down the line."[18] Fowler also said that "by bundling all the costs of care for an episode, this proposed rule can incentivize care coordination, improve patient care transitions, and decrease the risk of an avoidable readmission."[19] The agency plans to use this model to test whether episode-based payments for five costly and common procedures would preserve and enhance the quality of care while reducing Medicare expenditures.[20]

The proposed rule also supports emergency preparedness by implementing a data reporting structure for infectious diseases like respiratory syncytial virus, influenza, and COVID-19.[21] CMS believes that "sustained data collection and reporting of respiratory illnesses outside of emergencies will help hospitals and CAHs gain important insights related to their evolving infection control needs."[22] CMS proposes that hospitals and CAHs would report this data on a weekly basis, outside of a public health emergency (PHE).[23]

Healthcare industry stakeholders have expressed frustration with CMS's proposals, arguing that the proposed payment increase will not be enough to cover the rising costs to provide care. The American Hospital Association (AHA) stated

that the IPPS update, "is woefully inadequate, especially following years of high inflation and rising costs for labor, drugs and equipment."[24] Premier Inc., a hospital group purchasing network, stated that "with a mere 2.6% payment increase that fails to align with the stark realities of inflation and operational costs, persistent labor shortages and an aging demographic, the sustainability of our healthcare system is jeopardized."[25] Additionally, the Federation of American Hospitals (FAH) issued a similar statement, asserting that more support would be needed from Medicare. FAH President and CEO, Chip Kahn, stated that "just like last year, with inflation still stubbornly high, CMS fails to meet the moment."[26] Kahn also stated that Congress needs "to examine the inability of current payments to keep up with rising costs outside hospitals' control, which ultimately jeopardizes patient care at a time when hospitals are being threatened with Medicare cuts."[27] Kahn also expressed concern that "these cuts could lead to closures in rural and underserved areas."[28]

The financial challenges resulting from the proposed payment rates may continue the hospital affiliation and divestiture trends observed in recent years. For hospitals in financial distress have represented a larger share of the seller market, as compared to past years.

---

1 "CMS Proposes New Policies to Support Underserved Communities, Ease Drug Shortages, and Promote Patient Safety" HHS Press Office, Department of Health and Human Services, April 10, 2024, https://www.hhs.gov/about/news/2024/04/10/cms-proposes-new-policies-support-underserved-communities-ease-drug-shortages-promote-patient-safety.html (Accessed 4/18/24).

2 "FY 2025 Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) Proposed Rule - CMS-1808-P Fact Sheet" Newsroom, Centers for Medicare and Medicaid Services, April 10, 2024, https://www.cms.gov/newsroom/fact-sheets/fy-2025-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospital-prospective (Accessed 4/18/24).

3 *Ibid.*

4 *Ibid.*

5 *Ibid.*

6 *Ibid.*

7 "CMS Releases FY 2025 Inpatient Prospective Payment System Proposed Rule" By Miranda Franco, Holland & Knight, April 16, 2024, https://www.hklaw.com/en/insights/publications/2024/04/cms-releases-fy-2025-inpatient-prospective-payment-system (Accessed 4/19/24).

8 *Ibid.*

9 "FY 2024 Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) Final Rule — CMS-1785-F and CMS-1788-F Fact Sheet" Newsroom, Centers for Medicare and Medicaid Services, August 1, 2023, https://www.cms.gov/newsroom/fact-sheets/fy-2024-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospital-prospective-0 (Accessed 4/19/24).

10 Proposed Rule - CMS-1808-P Fact Sheet" Newsroom, Centers for Medicare and Medicaid Services, April 10, 2024.

11 "CMS proposes 2.6% bump to inpatient pay in fiscal 2025" By Dave Muoio, Fierce Healthcare, April 10, 2024, https://www.fiercehealthcare.com/providers/cms-proposes-26-bump-inpatient-pay-fiscal-2025 (Accessed 4/24/24).

12 *Ibid.*

13 Proposed Rule - CMS-1808-P Fact Sheet" Newsroom, Centers for Medicare and Medicaid Services, April 10, 2024.

14 Muoio, Fierce Healthcare, April 10, 2024.

15 *Ibid.*

16 *Ibid.*

17 "Overview Fact Sheet: Transforming Episode Accountability Model" Centers for Medicare & Medicaid Services, https://www.cms.gov/files/document/team-model-fs.pdf (Accessed 4/24/24).

18 "CMS Proposes New Policies to Support Underserved Communities, Ease Drug Shortages, and Promote Patient Safety" Newsroom, Centers for Medicare and Medicaid Services, April 10, 2024, https://www.cms.gov/newsroom/press-releases/cms-proposes-new-policies-support-underserved-communities-ease-drug-shortages-and-promote-patient#:~:text=%E2%80%9CBy%20bundling%20all%20the%20costs,risk%20of%20an%20avoidable%20readmission.%E2%80%9D (Accessed 4/24/24).

19 *Ibid.*

20 *Ibid.*

21 Muoio, Fierce Healthcare, April 10, 2024.

22 Proposed Rule - CMS-1808-P Fact Sheet" Newsroom, Centers for Medicare and Medicaid Services, April 10, 2024.

23 *Ibid.*

24 "AHA Statement on FY 2025 Proposed IPPS & LTCH Payment Rule" By Ashley Thompson, American Hospital Association, April 10, 2024, https://www.aha.org/press-releases/2024-04-10-aha-statement-fy-2025-proposed-ipps-ltch-payment-rule (Accessed 4/19/24).

25 "Statement on the FY 2025 Hospital Inpatient Prospective Payment System Proposed Rule" By Soumi Saha, Premier Inc., April 10, 2024, https://premierinc.com/newsroom/policy/statement-on-the-fy-2025-hospital-inpatient-prospective-payment-system-proposed-rule (Accessed 4/19/24).

26 ""Here we go again" – FAH Leader Reacts to Release of IPPS Proposed Rule" By Chip Kahn, Federation of American Hospitals, April 10, 2024, https://www.fah.org/blog/here-we-go-again-fah-leader-reacts-to-release-of-ipps-proposed-rule/ (Accessed 4/19/24).

27 *Ibid.*

28 *Ibid.*

Health Expenditures Projected to Approach $8 Trillion by 2032

[Excerpted from the article published in June 2024.]

On June 12, 2024, the Centers for Medicare & Medicaid Services (CMS) released their health insurance enrollment and national health expenditure (NHE) projections for 2023 through 2032.[1] The annually-updated NHE is the official U.S. estimate of insurance enrollment and health spending.[2] CMS projects that, between 2023 and 2032, the NHE's annual growth rate of 5.6% will surpass the U.S. gross domestic product (GDP) annual growth rate of 4.3%.[3] As a result, health spending as a share of the U.S. GDP is expected to jump from 17.3% in 2022 to 19.7% in 2032.[4] This Health Capital Topics article reviews the notable findings from CMS's projections.

Future healthcare spending and insurance enrollment trends are expected to be influenced by recent legislation.[5] During the COVID-19 public health emergency, states were prohibited from removing anyone from their Medicaid rolls, even if that individual was no longer Medicaid-eligible.[6] Medicaid enrollment is anticipated to significantly decline in 2024, now that states are restarting their Medicaid eligibility redeterminations.[7] In contrast, private health insurance enrollment is expected to increase due to the extension of enhanced Marketplace premium tax credit subsidies included in the *Inflation Reduction Act (IRA) of 2022*, as well as a temporary enrollment period for qualified beneficiaries who lost Medicaid coverage after the aforementioned eligibility redeterminations.[8] The IRA is also expected to impact spending trends by reducing out-of-pocket costs for Medicare Part D beneficiaries, limiting drug price increases, and decreasing the cost of certain high-priced pharmaceuticals through Medicare's negotiations (as Medicare was just recently allowed to directly negotiate some prices with drug manufacturers).[9] These various legislative initiatives spurred by the pandemic are largely expected to reduce future healthcare spending.[10]

For Medicare and Medicaid, the average annual expenditure growth rates from 2023 through 2032 are projected to be 7.4% and 5.2% (similar to last year's projections), respectively, while the growth rates for private health insurance spending are projected to average 5.6%.[11] Starting in 2025, beneficiaries will pay no more than $2,000 in out-of-pocket costs for prescription medications.[12] Due to the cap on out-of-pocket spending for Medicare Part D beneficiaries, payment responsibility will shift to Medicare, likely resulting in Medicare spending increases.[13]

In 2022, enhanced Marketplace plan subsidies expanded the financial assistance available to those who could not afford coverage and improved affordability, resulting in an enrollment increase of 2.5 million.[14] Once those subsidies expire, the additional enrollees who signed up to obtain lower premiums may not be able to afford their insurance anymore, potentially leading to a decline in private health insurance enrollment and spending.[15] With the enhanced Marketplace plan subsidies under the IRA set to expire at the end of 2025, and enrollment expected to slow as a result, private health insurance spending is expected to slow considerably, from a growth rate of 8.1% in 2024 to 5.3% in 2025, and then to 2.4% in 2026.[16] While decelerated healthcare spending is often a positive trend, in this case it may be due to patients delaying/declining care, not decreasing prices.

In addition to overall payor spending continuing to grow over the next decade, spending in various settings is also expected to increase. Hospital spending, driven by increasing utilization, is expected to grow substantially between 2023 and 2032, at an annual average rate of 5.7%, similar to the projections from last year.[17] The spending growth from the hospital sector is expected to overtake spending in the physician and clinical services sector (5.6%), but will remain lower than spending in the prescription drug sector (6.0%), both of which rates are similar to last year's projections.[18] Medicare spending for physician and clinical services will exceed that of the private health insurance spending, due largely to an uptick in Medicare enrollment (i.e., Baby Boomers aging into Medicare).[19] Prescription drug expenditure growth is projected to slow between 2024 (6.8%) and 2032 (5.9%), reflecting the impacts of prescription drug cost-shifting due to the IRA's cap on enrollee out-of-pocket spending and lower cost sharing on Medicare-negotiated drugs.[20]

While national healthcare spending slowed during the COVID-19 pandemic due to disruptions in the delivery of care, the NHE is expected grow over $2 trillion over the next decade, from $5.05 trillion in 2024 to $7.7 trillion by 2032.[21] The sunsetting of pandemic-era provisions, such Medicaid continuous enrollment and IRA Marketplace subsidies, have a mixed impact on CMS's projections in the near-term, with the number of insured expected to drop significantly.[22] However, in the longer-term, these impacts will subside, but spending will still continue to increase, driven largely "by traditional economic and demographic factors."[23] Ultimately, by 2032, for every $5 spent in the U.S. economy, $1 will account for health spending.[24]

---

1 "CMS Releases 2023-2032 National Health Expenditure Projections" Centers for Medicare and Medicaid Services, June 12, 2024, https://www.cms.gov/newsroom/press-releases/cms-releases-2023-2032-national-health-expenditure-projections (Accessed 6/24/24).
2 *Ibid.*
3 *Ibid.*
4 *Ibid.*
5 "National Health Expenditure Projections, 2023–32: Payer Trends Diverge As Pandemic-Related Policies Fade" By Jacqueline A. Fiore, et al., Health Affairs, June 12, 2024, https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00469 (Accessed 6/24/24).
6 "FAQ: CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency" Centers for Medicare and Medicaid Services, https://www.modernhealthcare.com/policy/covid-19-public-health-emergency-phe-end-telehealth-medicare-reimbursements (Accessed 6/24/24).
7 Fiore, et al., Health Affairs, June 12, 2024.
8 *Ibid.*
9 *Ibid*; "CMS Releases 2023-2032 National Health Expenditure Projections" Centers for Medicare and Medicaid Services, June 12, 2024, https://www.cms.gov/newsroom/press-releases/cms-releases-2023-2032-national-health-expenditure-projections (Accessed 6/24/24).
10 "U.S. health spending projected to exceed $7T in 2031" By Victoria Turner, Modern Healthcare, June 14, 2023, https://www.modernhealthcare.com/policy/cms-national-health-expenditures-projections-2022-2031-health-affairs (Accessed 6/24/24).
11 Centers for Medicare and Medicaid Services, June 12, 2024.
12 "Millions of People with Medicare Will Benefit from the New Out-of-Pocket Drug Spending Cap Over Time" By Tricia Neuman, Juliette Cubanski, and Anthony Damico, February 8, 2024, https://www.kff.org/medicare/issue-brief/millions-of-people-with-medicare-will-benefit-from-the-new-out-of-pocket-drug-spending-cap-over-time/#:~:text=Pocket%20Drug%20Spending%E2%80%A6-,Millions%20of%20People%20with%20Medicare%20Will%20Benefit%20from%20the%20New,Drug%20Spending%20Cap%20Over%20Time&text=In%202025%2C%20Medicare%20beneficiaries%20will,D%2C%20Medicare's%20outpatient%20drug%20benefit. (Accessed 6/25/24).
13 Centers for Medicare and Medicaid Services, June 12, 2024.
14 "Five Things to Know about the Renewal of Extra Affordable Care Act Subsidies in the Inflation Reduction Act" By Cynthia Cox, Krutika Amin, and Jared Ortaliza, https://www.kff.org/policy-watch/five-things-to-know-about-renewal-of-extra-affordable-care-act-subsidies-in-inflation-reduction-act/ (Accessed 6/25/24); "What will happen if ARP's insurance subsidies expire?" By Louise Norris, HealthInsurance.Org, March 29, 2022, https://www.healthinsurance.org/blog/what-will-happen-if-arps-insurance-subsidies-expire/ (Accessed 6/24/24).
15 "What will happen if ARP's insurance subsidies expire?" By Louise Norris, HealthInsurance.Org, March 29, 2022, https://www.healthinsurance.org/blog/what-will-happen-if-arps-insurance-subsidies-expire/ (Accessed 6/24/24).
16 Fiore, et al., Health Affairs, June 12, 2024.
17 Centers for Medicare and Medicaid Services, June 12, 2024.
18 *Ibid.*
19 Fiore, et al., Health Affairs, June 12, 2024.
20 *Ibid.*
21 "7 Takeaways from CMS Projections for U.S. Healthcare Spending" By Logan Lutton and Peter Wehrwein, Managed Healthcare Executive, June 24, 2024, https://www.managedhealthcareexecutive.com/view/7-takeaways-from-cms-projections-for-u-s-healthcare-spending?slide=2 (Accessed 6/24/24); "National Health Expenditure Projections, 2023–32: Payer Trends Diverge As Pandemic-Related Policies Fade" By Jacqueline A. Fiore, et al., Health Affairs, June 12, 2024, https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00469 (Accessed 6/24/24).
22 Fiore, et al., Health Affairs, June 12, 2024.
23 *Ibid.*
24 *Ibid.*

2025 Proposed Physician Fee Schedule Cuts Payments Again

[Excerpted from the article published in July 2024.]

On July 10, 2024, the Centers for Medicare & Medicaid Services (CMS) released its proposed Medicare Physician Fee Schedule (MPFS) for calendar year (CY) 2025. In addition to the agency's suggested cut to physician payments, the proposed rule also announced new covered services.[1] According to CMS, the proposed rule "reflect[s] a broader Administration-wide strategy to create a more equitable health care system that results in better accessibility, quality, affordability, empowerment, and innovation for all Medicare beneficiaries."[2]

For CY 2025, CMS proposes to *decrease* the MPFS conversion factor by $0.93, to $32.36 (a 2.80% reduction from the 2024 conversion factor of $33.29).[3] Conversion factors are applied to relative value units (RVUs), i.e., the resources required to furnish a service, to become payment rates. This decrease reflects: the expiration of the 0.00% conversion factor update under the Medicare Access and CHIP Reauthorization Act (MACRA); a 0.05% adjustment for budget neutrality; and a 2.93% statutory increase in payment for CY 2024.[4] If finalized as proposed, this will be the fifth straight year that the conversion factor has been decreased.

In addition to payment rate changes, CMS proposes establishing coding and payments for a new set of Advanced Primary Care Management (APCM) services.[5] Physicians and non-physician practitioners (NPPs) who participate in advanced primary care models can begin billing for APCM services on January 1, 2025.[6] The services would include parts of existing care management and communication technology-based services and reflect the essential parts of advanced primary care delivery, including chronic care management, transitional care management, and principal care management.[7] CMS anticipates that these new codes will "better recognize and describe advanced primary care services, encourage primary care practice transformation, help ensure that patients have access to high quality primary care services, and simplify billing and documentation requirements."[8]

CMS also proposes adding several services to the Medicare Telehealth Services List.[9] Beginning CY 2025, CMS plans to allow interactive telecommunications, which includes two-way, real-time, audio-only communication tools, for any telehealth services provided to beneficiaries in their home.[10] Providers who are technically capable of using a telecommunications system may use this method if their patient does not consent or is not able to use video technology.[11] CMS also plans to continue permitting distant site practitioners to use the location where they are enrolled as a practitioner, rather than their home address, when providing telehealth services.[12] Further, CMS proposes extending the definition of direct supervision – which requires practitioners to be physically present for certain services – to include virtual presence, through real-time visual and audio communications.[13] CMS also intends to continue their policy of allowing teaching physicians to be virtually present for services furnished virtually from a teaching setting, through December 31, 2025.[14]

Other proposals CMS suggested for 2025 include, but are not limited to:

(1) Codifying the *Inflation Reduction Act of 2022*'s mandate that drug companies pay "inflation rebates" if they raise prices for certain Medicare Part B and D drugs faster than the rate of inflation.[15]
(2) Requesting feedback for a proposed model that would engage specialist providers in value-based care through the Merit-based Incentive Payment System's (MIPS') Value Pathways;
(3) A request for information on CMS's community health integration services, social determinants of health risk assessment, and principal illness navigation services;
(4) New payments and codes for caregiver training and support that could be provided via telehealth; and
(5) Flexibilities for opioid treatment programs (OTPs), including allowing telehealth and audio-only visits for follow-up appointments.[16]

Numerous healthcare stakeholders have expressed significant concerns about the MPFS's continuing trend of physician payment cuts. The American Medical Association (AMA) called for a congressional response to the proposed rule, stating that with "CMS estimating a fifth consecutive year of Medicare payment reductions—this time by 2.8%—

it's evident that Congress must solve this problem."[17] The AMA added that "rural physicians and those treating underserved populations see this CMS warning as another reminder of the painful challenges they face in keeping their practices open and providing care. It's crucial that we ensure both continue."[18] Similarly, the Medical Group Management Association (MGMA) is concerned about the likely impact of the proposed conversion factor reduction, maintaining that this reduction causes significant concern for medical groups, as Medicare reimbursement rates are starting to undermine physician practices' sustainability.[19] Similar to the AMA, MGMA called on Congress to "pass the Strengthening Medicare for Patients and Providers Act to implement an annual inflation-based physician payment update tied to the Medicare Economic Index, and modernize Medicare's antiquated budget neutrality policies by enacting the Provider Reimbursement Stability Act."[20]

The Medicare Sustainable Growth Rate (SGR) was created by the *Balanced Budget Act of 1993* to (1) ensure patient access to physician services and (2) predictably control federal spending on Medicare Part B.[21] Under the SGR formula, if physician costs exceeded target expenditures, payments would be cut.[22] The SGR formula indicated downward adjustments to the MPFS every year since 2002. However, in what became a ritual, annual response to intense pressure from providers and advocates for the Medicare population, Congress consistently intervened and stepped in at the last moment to override the mandated decreases to the MPFS, typically replacing scheduled cuts with increases in payment. The SGR had many inefficiencies, such as: (1) making physician payments uncertain on a year-to-year basis; (2) disregarding group and individual performance; (3) distracting Congress from other legislative priorities; and (4) deferring actual improvements to the program.[23] In an effort to fix these problems and inefficiencies, CMS replaced the SGR formula in 2015 with scheduled updates to the MPFS.[24]

The last few years of threatened Medicare physician payment cuts and subsequent congressional intervention are beginning to mirror the issues encountered with the SGR formula. MACRA was supposed to alleviate the issues encountered with the SGR formula, but it has largely failed to do so. As a result, a number of federal legislators have called for another overhaul of physician payment updates. Two bills are currently being considered by Congress:

- The *Strengthening Medicare for Patients & Providers Act* would tie annual physician payment updates to the Medicare Economic Index (MEI), an index that accounts for inflation, the costs of running a practice, increases in office rent, professional liability insurance premiums, and employee wages.[25]
- The *Provider Reimbursement Stability Act* would reform the MPFS budget neutrality policies by (1) raising the budget neutrality threshold from $20 million to $53 million in 2025, and increasing the threshold every five years by the MEI, beginning in 2030; (2) requiring CMS to analyze utilization estimates compared to actual utilization by September 1st of each year; (3) mandating that CMS update the direct cost inputs for practice expense relative value units (RVUs) of staff wage rates, medical supplies, and equipment at least every five years; and (4) limiting the increases/decreases to the conversion factor by no more than 2.5% every year.[26]

While other reforms may still be necessary, these bills have gained bipartisan support on Capitol Hill, as well as support from the physician community.[27] However, it is unlikely that any bill will be passed this year given the presidential election (a notoriously hard time to pass bipartisan legislation), likely delaying any wholesale changes to the MPFS for at least another year.

1 "Fact Sheet: Calendar Year (CY) 2025 Medicare Physician Fee Schedule Proposed Rule (CMS-1807-P)-Medicare Shared Savings Program Proposals" Centers for Medicare and Medicaid Services, July 10, 2024, https://www.cms.gov/newsroom/fact-sheets/fact-sheet-calendar-year-cy-2025-medicare-physician-fee-schedule-proposed-rule-cms-1807-p-medicare (Accessed 7/15/24).
2 *Ibid.*
3 "Calendar Year (CY) 2025 Medicare Physician Fee Schedule Proposed Rule" Centers for Medicare and Medicaid Services, July 10, 2024, https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2025-medicare-physician-fee-schedule-proposed-rule (Accessed 7/15/24).
4 "CMS issues CY 2025 physician fee schedule proposed rule" American Hospital Association, July 10, 2024, https://www.aha.org/news/headline/2024-07-10-cms-issues-cy-2025-physician-fee-schedule-proposed-rule#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid,to%20%2433.29%20in%20CY%202024. (Accessed 7/15/24).
5 *Ibid.*
6 *Ibid.*
7 *Ibid.*
8 *Ibid.*
9 *Ibid.*
10 *Ibid.*
11 *Ibid.*
12 *Ibid.*
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
16 *Ibid*; "CMS' proposed 2.8% physician pay decrease for CY2025 earns quick condemnation from docs" By Dave Muoio, Emma Beavins, and Noah Tong, Fierce Healthcare, July 10, 2024, https://www.fiercehealthcare.com/providers/cms-proposed-28-physician-pay-decrease-fy2025-earns-quick-condemnation-docs (Accessed 7/15/24).
17 "Latest proposed cut—2.8%—shows need for Medicare pay reform" American Medical Association, July 10, 2024, https://www.ama-assn.org/practice-management/medicare-medicaid/latest-proposed-cut-28-shows-need-medicare-pay-reform#:~:text=%E2%80%9CThe%20death%20by%20a%20thousand,that%20we%20ensure%20both%20continue.%E2%80%9D (Accessed 7/15/24).
18 *Ibid.*
19 "MGMA statement on proposed 2025 Medicare Physician Fee Schedule" By Anders Gilberg, Medical Group Management Association, July 10, 2024, https://www.mgma.com/press-statements/july-10-2024-mgma-statement-on-proposed-2025-medicare-physician-fee-schedule (Accessed 7/15/24).
20 *Ibid.*
21 "A primer on Medicare physician payment reform and the SGR" By Keith Fontenot et al., Brookings, February 2, 2015, https://www.brookings.edu/articles/a-primer-on-medicare-physician-payment-reform-and-the-sgr/ (Accessed 7/15/24).
22 *Ibid.*
23 *Ibid.*
24 "MACRA (SGR Fix) Updates" American Academy of Allergy, Asthma, and Immunology, November 2016, https://www.aaaai.org/about/advocacy/regulatory-actions/sustainable-growth-rate-fix (Accessed 7/15/24); "MACRA, the Sustainable Growth Rate (SGR) Reform Bill, Signed into Law" By Miranda Franco, Holland & Knight, April 30, 2015, https://www.hklaw.com/en/insights/publications/2015/04/macra-the-sustainable-growth-rate-sgr-reform-bill (Accessed 7/15/24).
25 "Congress Passes Partial Fix to Medicare Physician Payment" American Academy of Ophthalmology, March 7, 2024, https://www.aao.org/advocacy/eye-on-advocacy-article/congress-poised-pass-partial-fix-medicare-payment (Accessed 7/19/24).
26 "Is Medicare Physician Fee Schedule Reform on the Horizon?" By Larry Buchson, M.D., November 1, 2023, https://bucshon.house.gov/news/documentsingle.aspx?DocumentID=4467 (Accessed 7/19/24).
27 American Academy of Ophthalmology, March 7, 2024.

CMS Proposes Updates to the OPPS

[Excerpted from the article published in July 2024.]

On July 10, 2024, the Centers for Medicare & Medicaid Services (CMS) released the proposed rule for the Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System for calendar year (CY) 2025.[1] The agency proposes increased payments to all outpatient providers, updates to current programs, and a new standard to address the ongoing maternal health crisis.

For CY 2025, CMS proposes to increase OPPS payment rates to hospital outpatient departments (HOPDs) that meet specific quality reporting criteria by 2.6% – calculated from the proposed hospital inpatient market basket percentage increase of 3.0% minus the proposed productivity adjustment of 0.4%.[2] This calculation results in a proposed OPPS conversion factor of $89.379.[3] ASCs that meet the required quality criteria will also receive proposed payment rate increases of 2.6%, by way of the same calculation described above for OPPS payment rates.[4] Consequently, the proposed ASC conversion factor for 2025 is $54.675.[5] For both HOPDs and ASCs, the CY 2025 proposed payment rate increase is 0.2% less than the CY 2024 OPPS/ASC payment rate increase of 2.8%.[6]

In the CY 2019 OPPS/ASC final rule, CMS began applying productivity-adjusted hospital market basket updates (i.e., the updates used for HOPD payment rate updates) to ASC payment rates for a test period of five years,[7] in order to assess changes in the migration of services and determine if the data trends were consistent.[8] Because of abnormal healthcare utilization in 2020 due to the COVID-19 public health emergency (PHE), CMS proposes to extend the five-year period for an additional two years, until CY 2025.[9] This will allow CMS to gather data unrelated to the COVID-19 PHE to determine if utilizing the hospital market basket update achieved one of its goals of shifting services from the hospital to the ASC setting.[10]

Citing the growing maternal health crisis, which "has not only led to a maternal mortality rate that is among the highest in high-income countries but also disproportionately affects racial and ethnic minorities," CMS proposes new Conditions of Participation (CoPs) for critical access hospitals (CAHs) and regular hospitals for obstetrical services.[11] The proposed CoPs include requirements for maternal quality assessment and performance improvement (QAPI), annual staff training on evidence-based maternal health practices, and baseline standards for the staffing, organization, and delivery of care in obstetrical units.[12] Starting in 2025, hospitals or CAHs that provide obstetric services will be required to utilize CMS's QAPI program to improve and assess health disparities and outcomes among obstetrics patients on a consistent basis.[13] The new staff training standard would require the hospitals and CAHs to develop policies to ensure the appropriate staff members have some baseline training.[14] Training materials would reflect the complexity of services offered by each respective hospital, including, but not limited to, evidence-based best practices and protocols to improve maternal care delivery.[15] The new organization and staffing standard would require the hospitals and CAHs adhere to national acceptable standards of practice.[16] To ensure better delivery of care, the standards also include requirements that obstetrics services remain consistent with the resources and needs of their respective facilities.[17]

Other proposals CMS suggested for 2025 include, but are not limited to:

(1) Helping tribal and Indian Health Services (IHS) facilities afford high-cost pharmaceuticals;
(2) Authorizing federal reimbursement for certain Medicaid clinic services delivered outside of a tribal clinic or freestanding IHS facility;
(3) Increasing accessibility to healthcare for recently-incarcerated individuals;
(4) Expanding and adjusting quality reporting programs for inpatient and outpatient hospitals, rural emergency hospitals, and ASCs; and
(5) Potentially modifying the Overall Hospital Quality Star Rating methodology for the Safety of Care measure group.[18]

CMS will receive comments and information on the OPPS/ASC proposed rule until September 9, 2024, and the final rule is expected to be released in November 2024.[19]

1 "CY 2025 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS 1809-P)" Centers for Medicare and Medicaid Services, July 10,2024, https://www.cms.gov/newsroom/fact-sheets/cy-2025-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center#:~:text=In%20the%20CY%202025%20OPPS,July%201%2C%202023%2C%20through%20June (Accessed 7/11/24).
2 *Ibid.*
3 "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; etc. " Centers for Medicare & Medicaid Services, July 22, 2024, unpublished version, available at https://public-inspection.federalregister.gov/2024-15087.pdf (Accessed 7/18/24).
4 Centers for Medicare and Medicaid Services, July 10,2024.
5 Centers for Medicare & Medicaid Services, July 22, 2024.
6 "CY 2024 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS 1786-P)" Centers for Medicare and Medicaid Services, July 13, 2023, https://www.cms.gov/newsroom/fact-sheets/cy-2024-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center (Accessed 7/12/24).
7 Centers for Medicare and Medicaid Services, July 10,2024.
8 "CMS-1695-FC (PDF)" Centers for Medicare and Medicaid Services, https://www.cms.gov/node/671966 (Accessed 7/18/24).
9 Centers for Medicare and Medicaid Services, July 10,2024.
10 *Ibid.*
11 *Ibid.*
12 *Ibid.*
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
16 *Ibid.*
17 *Ibid.*
18 "CMS floats 2.6% annual outpatient, ASC pay increase, new obstetrics Conditions of Participation" By Dave Muoio, Fierce Healthcare, July 10, 2024, https://www.fiercehealthcare.com/providers/cms-floats-26-annual-outpatient-asc-pay-increase-new-obstetrics-conditions-participation (Accessed 7/12/24).
19 Centers for Medicare and Medicaid Services, July 10, 2024.

Hospital Operations Finally Rebound Post-COVID

[Excerpted from the article published in September 2024.]

For the first time since the COVID-19 pandemic, hospitals are finally reporting sustained, improved financial and operational performance. To date in 2024, hospitals have seen better margins, increased patient utilization, and a more stabilized workforce. Another result of this improved performance has been an increase in hospital transactional activity. This Health Capital Topics article reviews the hospital sector performance to date, factors driving this improvement, and the impact on hospital transactional activity.

Hospitals were arguably the providers most acutely affected by the COVID-19 global pandemic. In April 2020, for example, hospital operating margins nosedived to -40%.[1] Despite receiving billions of dollars in government funding to offset substantial financial losses during the worst of the pandemic,[2] hospitals continued to suffer for years after, with the worst year for hospitals financially not occurring until 2022. That year, hospitals experienced declines in nearly every financial metric.[3] Although hospitals continue to struggle to return their operations to pre-COVID metrics, recent reports from hospitals suggest that better days may have returned, culminating a 4 ½-year journey back to normal.

Post-pandemic, hospitals have reported continuing (albeit improving) labor shortages, capacity issues, and increasing expenses. While some providers attribute these challenges directly to the pandemic, others consider such headwinds the "new status quo."[4] At the same time, these challenges are partially ameliorated by increases in hospital utilization that have resulted in increased revenues.[5]

Credit rating agency Fitch Ratings predicted that hospitals' operating margins would increase an average of 1.6% in 2024, compared to a growth of only 0.5% to 0.7% in 2023.[6] As of July 2024, hospitals' median operating margin was 4.1%, significantly outperforming expectations.[7] These trends have been confirmed by multiple health systems in their mid-year reports.[8] While operating margins are still below pre-pandemic levels, they are predicted to fully rebound by 2026.[9] Other measures of financial performance are similarly trending better. The median monthly operating index through July 2024 was 3.8%, much higher than the index at the same time in 2023 (1.3%) and 2022 (-0.98%),[10] and hospitals' cash on hand is at 220 days (median), close to pre-pandemic levels.[11]

Despite these encouraging trends, industry analysts note that this growth is not uniform; there is a growing division between the hospitals that are performing well and those that continue to struggle.[12] Up to 40% of hospitals are still operating in the red.[13] The main differences between the "haves" and the "have nots" is largely that the stronger-performing hospitals have embraced the shift to outpatient care, which tends to generate a higher margin.[14]

Operating margin improvements are being driven by stabilization in labor (typically the largest expense for hospitals), increases in patient volume, and decreases in average lengths of stay.

A September 2024 Fitch Ratings report found that hospitals' labor problem has largely stabilized. Wage inflation has "cool[ed] to more sustainable levels," with average wages growing approximately 3% in 2024, compared to 4.2% in 2023 and 8% in 2021-2022.[15] Wages escalated quickly during the pandemic in an effort to reflect the increased hazard of front-line work, meet the changing demand for healthcare services, and counter high turnover rates. To fill those labor gaps, many hospitals were forced to utilize costlier outside labor (e.g., locum tenens).[16] Notably, the demand for healthcare services has remained high over the last couple years due to pent-up demand, i.e., increased utilization from patients who deferred care during the pandemic, which has resulted in a continuing, critical need for healthcare workers. In addition to stabilizing wages, hospital job openings have also decreased, although they are not yet at pre-pandemic levels.[17] Fitch Ratings predicts that healthcare labor, particularly for non-profit hospitals, will return to "some semblance of normal" by the end of 2024.[18]

Patient volume in hospital emergency departments (EDs) grew approximately 4% from 2023 to 2024, back to pre-pandemic levels, which helped to improve operating margins by 21% during that time.[19] Over the next decade, ED utilization is expected to increase another 4%[20] as the Baby Boomers, nearly all of whom have aged into the age 65+ age cohort, will require more healthcare services. While ED utilization increased, the average lengths of stay in hospitals

decreased 3% for the year,[21] likely due to reduced patient acuity with the abatement of the pandemic, improved patient throughput across the healthcare delivery system, and the continued shift in care to the outpatient setting. Reducing the length of stay has the dual effect of decreasing hospital expenses and improving outcomes (which can result in additional incentives from Medicare).[22]

Improved financial performance across the hospital sector, and particularly among potential hospital acquirers, is driving increased transactional activity.[23] With extra cash on hand due to improved profitability, many transactional advisors predict that the number of hospital deals will increase. There were 20 hospital transactions announced, totaling $12 billion, in the first quarter of 2024 – the highest number since before the pandemic.[24] That activity slowed to only 11 transactions in the second quarter; however, the total number of hospital transactions for the year is expected to be similar to 2023's total of 65 announced deals.[25] For context, hospital transactional activity hit its peak in 2017, with 117 announced transactions; that level of activity is not expected to return, due not just to pandemic-related financial struggles, but also to increased regulatory oversight and enforcement of hospital transactions.[26] Nevertheless, industry analysts expect increased acquisitions of community hospitals by academic medical centers and transactional activity from large health systems selling off less-profitable hospitals or – in the case of Steward Health – all of its 33 hospitals as part of its Chapter 11 bankruptcy case.[27]

On September 18, 2024, the Federal Reserve cut interest rates by 0.5%, the first rate reduction in four years.[28] The federal funds rate now stands at approximately 4.9%, down from an over two-decade high, and is expected to see additional cuts over the next couple of years.[29] This cut will likely have a significant effect on hospitals and their operations. For example, decreasing borrowing costs may further stimulate hospital transactional activity, as hospitals will have access to more capital that could be utilized to expand their facilities or acquire other providers. Lower interest rates can also positively impact hospital valuations. Lower interest rates may be particularly helpful for hospitals that have seen their expenses continue to increase, up an average of 8% from 2023.[30] As interest rates are anticipated to decrease further in the coming months, this may be just what the doctor ordered to bring hospitals back to level footing and the "new normal" in healthcare delivery.

1 "COVID-19 Provider Relief Fund Payments Were Appropriately Targeted And Did Not Boost Selected Hospitals' Profits By Anuj Gangopadhyaya, et al., Health Affairs, Vol. 42, No. 8 (August 2023), https://healthaffairs.org/doi/10.1377/hlthaff.2022.01411 (Accessed 9/18/24).
2 See e.g., "Coronavirus Aid, Relief, and Economic Security Act" H.R. 748; "Paycheck Protection & Health Care Enhancement Act" H.R. 266.
3 "Hospital Financial Health: A Rocky Recovery" By Benjamin Finder, American Hospital Association, AHA Stat, September 27, 2023, https://www.aha.org/news/blog/2023-09-27-hospital-financial-health-rocky-recovery (Accessed 9/18/24).
4 "How healthcare finances are affected by the COVID-19 pandemic" By Caroline Hudson, Modern Healthcare, September 19, 2024, https://www.modernhealthcare.com/providers/covid-19-insurers-providers-finances-labor (Accessed 9/19/24).
5 *Ibid*.
6 "Hospitals' fortunes improving" By Laura Dyrda, Becker's Hospital CFO Report, February 22, 2024, https://www.beckershospitalreview.com/finance/hospitals-fortunes-improving.html (Accessed 9/19/24).
7 "How Have Hospitals Fared Financially So Far in 2024?" By Katie Adams, MedCity News, September 4, 2024, https://medcitynews.com/2024/09/hospital-finance-healthcare-2/ (Accessed 9/19/24).
8 "Here's why hospital deals are heating up" By Alex Kacik, Modern Healthcare, August 2, 2024, https://www.modernhealthcare.com/mergers-acquisitions/ascension-steward-health-chs-hospital-ma-2024 (Accessed 9/19/24).
9 Dyrda, Becker's Hospital CFO Report, February 22, 2024.
10 "Hospital finances are stabilizing, Kaufman Hall data finds" By Hannah Nelson, RevCycleManagement, September 4, 2024, https://www.techtarget.com/revcyclemanagement/news/366609716/Hospital-finances-are-stabilizing-Kaufman-Hall-data-finds (Accessed 9/19/24); Adams, MedCity News, September 4, 2024.
11 Dyrda, Becker's Hospital CFO Report, February 22, 2024.
12 "More hospitals are doing better financially, but gap grows between the strong and struggling" By Ron Southwick, Chief Healthcare Executive, July 19, 2024, https://www.chiefhealthcareexecutive.com/view/more-hospitals-are-doing-better-financially-but-gap-grows-between-the-strong-and-struggling (Accessed 9/19/24).
13 *Ibid*.
14 *Ibid*.
15 "Hospitals Seeing Relief from Declining Wage Inflation, Job Openings" By Jay Asser, HealthLeaders, September 16, 2024, https://www.healthleadersmedia.com/ceo/hospitals-seeing-relief-declining-wage-inflation-job-openings (Accessed 9/19/24).
16 "Hospitals and Healthcare Systems Labor Tracker: September 2024" FitchRatings, September 9, 2024, https://www.fitchratings.com/research/us-public-finance/hospitals-healthcare-systems-labor-tracker-september-2024-09-09-2024 (Accessed 9/18/24).
17 Asser, HealthLeaders, September 16, 2024.
18 "Worst of Labor Downturn Nearing an End for U.S. NFP Hospitals" FitchRatings, September 9, 2024, https://www.fitchratings.com/research/us-public-finance/worst-of-labor-downturn-nearing-end-for-us-nfp-hospitals-09-09-2024 (Accessed 9/18/24).
19 "3 hospital capacity trends to watch for" By Alex Kacik, Modern Healthcare, June 12, 2024, https://www.modernhealthcare.com/providers/hospital-capacity-trends-emergency-departments-kaufman-hall (Accessed 9/19/24).
20 *Ibid*.
21 *Ibid*; "High demand, slimmed length of stay fortify hospitals' margins in July" By Dave Muoio, Fierce Healthcare, September 4, 2024, https://www.fiercehealthcare.com/providers/high-demand-slimmed-length-stay-fortify-hospitals-margins-july (Accessed 9/19/24).
22 "Systematic, Data-Driven Approach Lowers Length of Stay and Improves Care Coordination" Health Catalyst, https://www.healthcatalyst.com/success_stories/reducing-length-of-stay-memorial-hospital-at-gulfport#:~:text=Optimizing%20and%20reducing%20LOS%20improves,risk%20of%20hospital%2Dacquired%20conditions. (Accessed 9/20/24).
23 Kacik, Modern Healthcare, August 2, 2024.
24 "Megamergers help drive M&A upswing in 2024: Kaufman Hall" By Caroline Hudson, Modern Healthcare, April 11, 2024, https://www.modernhealthcare.com/mergers-acquisitions/kaufman-hall-ma-deals-q1-2024 (Accessed 9/19/24).
25 Kacik, Modern Healthcare, August 2, 2024.
26 For more information, see "FTC Scrutiny Results in Several Scrapped Hospital Deals" Health Capital Topics, Vol. 15, Issue 6 (July 2022), https://www.healthcapital.com/hcc/newsletter/06_22/HTML/FTC/convert_ftc-health-capital-topics.php (Accessed 9/19/24); "Novant/CHS Deal Scrapped after FTC Intervenes" Health Capital Topics, Vol. 17, Issue 6 (June 2024), https://www.healthcapital.com/hcc/newsletter/06_24/HTML/NOVANT/convert_novant_chs_scrapped_hospital_deal.php (Accessed 9/49/24).
27 Kacik, Modern Healthcare, August 2, 2024; "10 things to know about Steward Health Care" By Andrew Cass, Becker's Hospital CFO Report, January 26, 2024, https://www.beckershospitalreview.com/finance/10-things-to-know-about-steward-health-care.html#:~:text=Here%20are%2010%20things%20to,with%20more%20than%2033%2C000%20employees. (Accessed 9/19/24).
28 "Emboldened Fed lowers interest rates by half-point" By Taylor Giorno, The Hill, https://thehill.com/business/4886438-federal-reserve-interest-rate-cut/ (Accessed 9/19/24).
29 *Ibid*; "Fed Announces Big Rate Cut" By Jenna Simalek, New York Times, September 19, 2024, https://www.nytimes.com/live/2024/09/18/business/fed-interest-rates (Accessed 9/19/24).
30 Muoio, Fierce Healthcare, September 4, 2024.

Regulatory Topics

MSSP Performance Results Indicate Another Successful Year

[Excerpted from the article published in September 2023.]

On August 24, 2023, the Centers for Medicare & Medicaid Services (CMS) released the financial and quality performance results for the Medicare Shared Savings Program (MSSP) Performance Year (PY) 2022.[1] The results revealed net savings of $1.8 billion for Medicare, marking the sixth consecutive year of savings.[2] In total, 63% of MSSP accountable care organizations (ACOs) achieved savings as a result of their performance.[3] This Health Capital Topics article will discuss the 2022 performance results.

ACOs that participate in the MSSP must enroll in a specific track (either the Basic Track or the Enhanced Track), with each track corresponding to a different level of risk.[4] The Basic Track is divided into five track levels: A, B, C, D, and E.[5] Track levels A and B are one-sided risk models, while the two-sided risk models begin with Level C and progressively increase in risk (as well as in potential shared savings) with each track level.[6] Newly participating ACOs that enroll in the Basic Track can begin in any of the track levels, but will automatically progress to the next track level each year.[7] The only exception to this is that newly participating, low-revenue ACOs[8] are permitted to remain enrolled in Basic Track, Level B for an additional year, provided that they agree to skip to Basic Track, Level E in their fourth year of participation.[9] As of January 2023, the MSSP includes over 573,000 clinicians providing care to over 11 million Medicare beneficiaries.[10] It is CMS's goal for 100% of Traditional Medicare beneficiaries to be assigned to an ACO by 2030.[11]

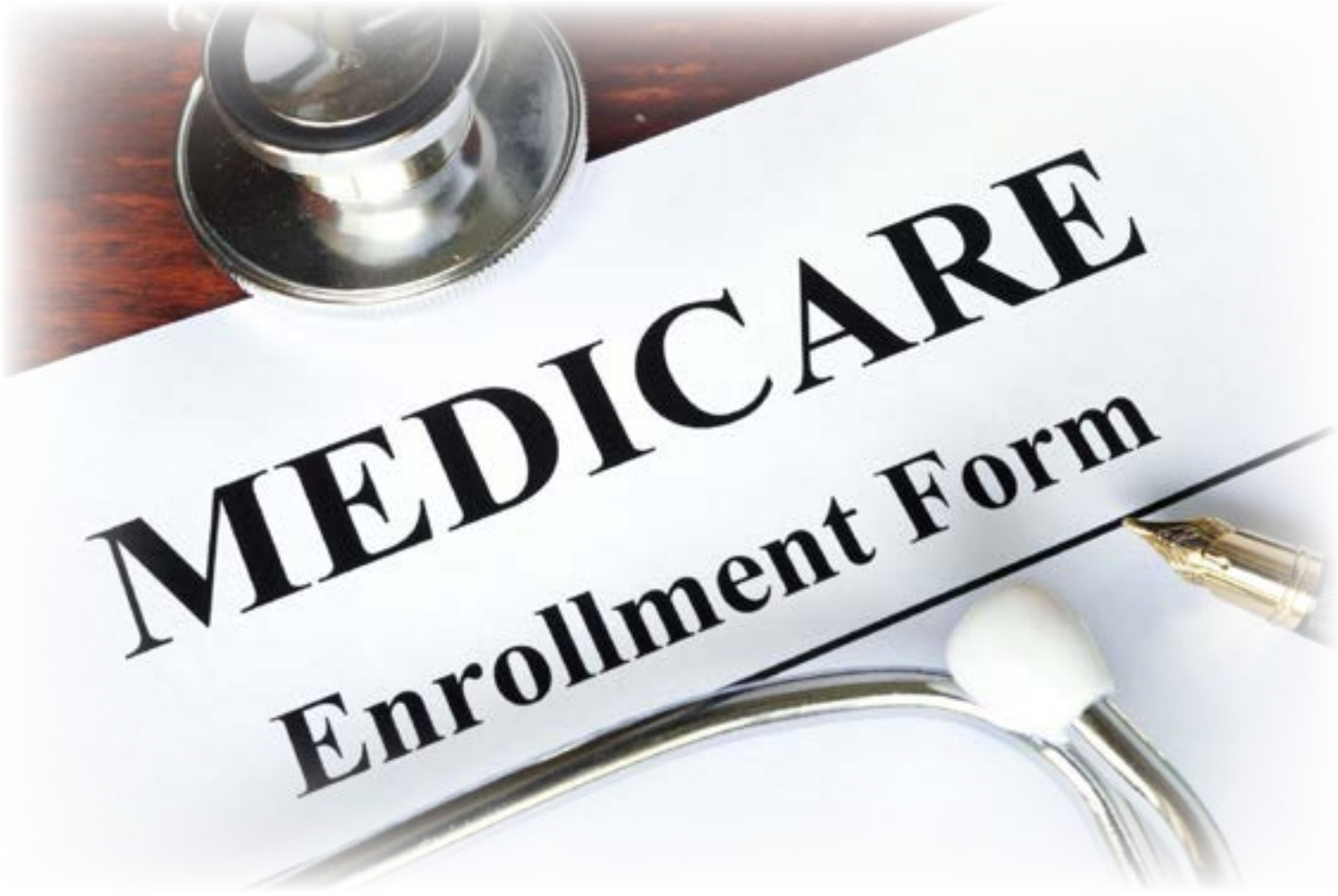
In 2022, approximately 63% of MSSP-participating ACOs earned shared savings for their performance. High-revenue ACOs, which had $140 per capita in net savings, were outperformed by low-revenue ACOs, which had $228 per capita in net savings.[12] Low-revenue ACOs, which are primarily comprised of physicians, may also include a small hospital and service rural areas.[13] Low-revenue ACOs comprised of 75% primary care providers saw $294 per capita in net savings, more than twice the net savings realized by high-revenue ACOs.[14] These results demonstrate how crucial primary care is to the success of the MSSP, as well as how the program benefits primary care providers.[15]

Earlier this year, CMS proposed changes to the MSSP in the CY 2024 Medicare Physician Fee Schedule (MPFS) that would promote access to accountable care for beneficiaries that rely on nurse practitioners, clinical nurse specialists, and physician assistants for their primary care needs.[16] Another proposal would change methodology for financial benchmarking and encourage ACOs that serve complex populations to participate in the MSSP.[17] These proposed changes are expected to increase MSSP participation by approximately 10% to 20% in future years.[18]

Overall, the MSSP has produced the largest savings for CMS, and is the largest ACO model the agency operates. Since the 2012 debut of the MSSP, ACOs have consistently saved the agency money.[19] While the program has resulted in large savings, some ACOs have experienced losses. Empire ACO of New York reported large losses of 15.3% ($23.3 million) for their 6,600 members, while Physicians ACO of Florida reported the largest savings rate of 18.2% ($13.5 million) for their 6,500 members.[20]

In response to the PY 2022 results, CMS Administrator Chiquita Brooks-LaSure stated, "The MSSP helps millions of people with Medicare experience coordinated health care while also reducing costs for the Medicare program. CMS will continue to improve the program, and it is exciting to see that Accountable Care Organizations are continuing to be successful in delivering coordinated, high-quality, affordable, equitable, person-centered care."[21] The National Association of Accountable Care Organizations (NAACOs) commended CMS, with the President and CEO, Clif Gaus, stating that "Every year, the body of data on how ACOs are improving our fragmented health system grows, and this year is no different. ACOs continue to provide more of what patients want and deserve -- affordable, high-quality, coordinated, and personalized care."[22]

1 "Medicare Shared Savings Program Saves Medicare More Than $1.8 Billion in 2022 and Continues to Deliver High-quality Care" Centers for Medicare & Medicaid Services, August 24, 2023, https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-saves-medicare-more-18-billion-2022-and-continues-deliver-high (Accessed 8/28/23).
2 *Ibid.*
3 *Ibid.*
4 "Shared Savings Program Participation Options for Performance Year 2024" Centers for Medicare & Medicaid Services, March 2023, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ssp-aco-participation-options.pdf (Accessed 8/28/23).
5 *Ibid.*
6 *Ibid.*
7 *Ibid.*
8 "NAACOS Assessment of High-Low Revenue Designations" National Association of ACOs, https://www.naacos.com/naacos-assessment-of-high-low-revenue-designations (Accessed 8/28/23).
9 Centers for Medicare & Medicaid Services, March 2023.
10 Centers for Medicare & Medicaid Services, August 24, 2023.
11 *Ibid.*
12 *Ibid.*
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
16 "CMS Physician Payment Rule Advances Health Equity" Centers for Medicare and Medicaid Services, July 13, 2023, https://www.cms.gov/newsroom/press-releases/cms-physician-payment-rule-advances-health-equity#:~:text=CMS%20is%20also%20proposing%20increases,3.34%25%2C%20from%20CY%202023. (Accessed 8/28/23).
17 *Ibid.*
18 *Ibid.*
19 "Shared Savings ACOs cut spending $1.8B in 2022" By Lauren Berryman and Nona Tepper, Modern Healthcare, August 24, 2023, https://www.modernhealthcare.com/accountable-care/medicare-shared-savings-program-aco-2022-report-cms (Accessed 8/30/23).
20 *Ibid.*
21 "ACOs delivered bigger 2022 savins than in 2021: CMS" By Noah Tong, Fierce Healthcare, August 24, 2023, https://www.fiercehealthcare.com/providers/acos-delivered-bigger-2022-savings-2021-cms-announces (Accessed 8/28/23).
22 "Medicare ACOs Saved $4.2 Billion in 2022 Shared Savings ACOs Continue to Deliver Savings, Improve Health" National Association of Accountable Care Organizations, August 24, 2023, https://www.naacos.com/press-release--medicare-acos-saved--4-2-billion-in-2022 (Accessed 8/28/23).



OIG Issues Unfavorable Advisory Opinion on Service Arrangements

[Excerpted from the article published in October 2023.]

On September 25, 2023, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published Advisory Opinion (AO) No. 23-06, evaluating a proposed purchase of the technical component of certain laboratories' anatomic pathology services.[1] In its opinion, the OIG concluded that the proposed arrangement may generate remuneration, which is prohibited under the federal Anti-Kickback Statute (AKS), and could result in the imposition of sanctions.[2]

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

The AKS makes it a felony for any person to "*knowingly and willfully*" solicit or receive, or to offer or pay, any "*remuneration*," directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[3] Criminal violations of the AKS are punishable by up to ten years in prison, criminal fines up to $100,000, or both, and civil violations can result in administrative penalties, including exclusion from federal healthcare programs, and civil monetary penalties plus treble damages (or three times the illegal remuneration).[4] Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited. Consequently, the law contains a number of exceptions, termed *safe harbors*,[5] which set out regulatory criteria that, if met, shield an arrangement from liability, and are meant to protect transactions unlikely to result in fraud or abuse.[6] However, failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[7]

The Requestor of the AO, an operator of anatomic pathology labs across the U.S., was motivated to develop the proposed arrangement after being approached by other laboratories seeking to enter into agreements for the provision of anatomic pathology services to commercially-insured patients. Under the proposed arrangement, the Requestor would purchase the technical component of anatomic pathology from the laboratory.[8] In return, the Requestor would perform the professional component and bill commercial insurance providers for both the professional and technical components.[9] The Requestor would then pay the laboratory a per-specimen, fair market value fee for the technical component.[10] The Requestor reasoned that it would bill both the professional and technical components because some of the laboratories either may not be able to bill certain payors for their services or may not be in-network.[11]

The OIG concluded that the proposed arrangement would violate the AKS and based their conclusion on a number of concerns related to the arrangement. First, in most cases, the Requestor had the ability to perform both the professional and technical components itself, and doing so was much more cost-effective and efficient than utilizing (and paying) a third party to perform the technical component. Second, the proposed arrangement would have allowed other laboratories the chance to bill and receive payment for services they otherwise would not have been able to due to their out-of-network status. Third, because other laboratories did not have contracts allowing them to bill commercial insurers for anatomic pathology services, physician employees and owners of the other laboratories would more than likely refer anatomic pathology services to laboratories (such as the Requestor) that are in-network with commercial insurers. Fourth, entering into the proposed arrangement would likely result in referrals of federal healthcare program business to the Requestor, and if the Requestor did not enter into the proposed arrangement, it would not receive a significant amount of federal healthcare program referrals from the other laboratories.[12]

The OIG acknowledged that the AKS safe harbor for personal services and management contracts and outcomes-based payment arrangements may apply to the proposed arrangement, as the safe harbor allows payment to an agent (other laboratories) from a principal (the Requestor).[13] However, the OIG concluded that the proposed arrangement did not satisfy requirements of the safe harbor because the Requestor "was unable to certify that the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the reasonable business purpose of the services," i.e.:

> "It is difficult to discern any commercially reasonable business purpose for Requestor to enter into the Proposed Arrangement—forgoing the opportunity to bill and retain payment for both components of the anatomic pathology services, in an arrangement that is both less efficient and more costly—other than the possibility that such payment may induce referrals of patients."[14]

In the advisory opinion, the OIG reiterated previous guidance from its "2014 Special Fraud Alert on Laboratory Payments to Referring Physicians"[15] which states that "carve outs" for federal healthcare program beneficiaries or businesses in otherwise questionable arrangements may still violate the AKS by "disguising remuneration for Federal healthcare program business through the payment of amounts purportedly related to non-Federal healthcare program business."[16]

According to legal experts, laboratories may be well-served to evaluate their service arrangements going forward and determine if they present a regulatory risk, based on the OIG's determination, and ensure that any similar arrangements should be thoroughly documented as to its commercial reasonableness.[17]

---

1 "Re: OIG Advisory Opinion No. 23-06 (Unfavorable)" Office of Inspector General, Department of Health and Human Services, September 25, 2023, https://oig.hhs.gov/documents/advisory-opinions/1131/AO-23-06.pdf (Accessed 10/13/23).

2 "OIG Issues Advisory Opinion Nixing Purchased Services Arrangement Between Certain Anatomic Pathology Laboratories" By Samantha Kingsbury and Karen Lovitch, JD Supra, October 4, 2023, https://www.jdsupra.com/legalnews/oig-issues-advisory-opinion-nixing-9785590/ (Accessed 10/13/23).

3 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).

4 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 USC § 1320a-7b(b)(1); "Civil Monetary Penalties" 42 USC § 1320a-7a(a).

5 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, http://oig.hhs.gov/fraud/docs/advisoryopinions/15/AdvOpn15-10.pdf (Accessed 10/16/23), p. 5.

6 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" federal Register, Vol. 64, No. 223 (November 19, 1999), p. 63518, 63520.

7 "Re: Malpractice Insurance Assistance" By Lewis Morris, Chief Counsel to the Inspector General, United States Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf (Accessed 10/16/23), p. 1.

8 "Re: OIG Advisory Opinion No. 23-06 (Unfavorable)" Office of Inspector General, Department of Health and Human Services, September 25, 2023, https://oig.hhs.gov/documents/advisory-opinions/1131/AO-23-06.pdf (Accessed 10/13/23); "OIG Issues Advisory Opinion Nixing Purchased Services Arrangement Between Certain Anatomic Pathology Laboratories" By Samantha Kingsbury and Karen Lovitch, JD Supra, October 4, 2023, https://www.jdsupra.com/legalnews/oig-issues-advisory-opinion-nixing-9785590/ (Accessed 10/16/23).

9 *Ibid.*

10 *Ibid.*

11 *Ibid.*

12 *Ibid*; "OIG Issues Advisory Opinion Nixing Purchased Services Arrangement Between Certain Anatomic Pathology Laboratories" By Samantha Kingsbury and Karen Lovitch, JD Supra, October 4, 2023, https://www.jdsupra.com/legalnews/oig-issues-advisory-opinion-nixing-9785590/ (Accessed 10/18/23).

13 "HHS-OIG Says Anatomic Pathology Lab's Purchased Service Arrangement Could Violate Anti-Kickback Statute" By Jason Schultz, Anne Compton-Brown, Mary Ford, Barnes & Thornburg LLP, October 9, 2023, https://btlaw.com/en/insights/alerts/2023/anatomic-pathology-labs-purchased-service-arrangement-could-violate-anti-kickback-statute (Accessed 10/18/23).

14 *Ibid.*

15 *Ibid.*

16 *Ibid.*

17 *Ibid.*

OIG Issues Favorable Advisory Opinion on Bonus Compensation Agreements

[Excerpted from the article published in October 2023.]

On October 13, 2023, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published Advisory Opinion (AO) No. 23-07, approving a proposal from a physician practice to pay physician-employees bonuses based on profits earned from ambulatory surgery center (ASC) procedures performed by the physician-employees.[1] The OIG concluded that the proposed bonus arrangement would not generate any remuneration that was prohibited because the arrangement met the requirements and was protected by a regulatory safe harbor for bona fide employees.[2]

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

The AKS makes it a felony for any person to "*knowingly and willfully*" solicit or receive, or to offer or pay, any "*remuneration*," directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[3] Criminal violations of the AKS are punishable by up to ten years in prison, criminal fines up to $100,000, or both, and civil violations can result in administrative penalties, including exclusion from federal healthcare programs, and civil monetary penalties plus treble damages (or three times the illegal remuneration).[4] Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited. Consequently, the law has a number of exceptions, termed *safe harbors*,[5] which set out regulatory criteria that, if met, shield an arrangement from liability, and are meant to protect transactions unlikely to result in fraud or abuse.[6] However, failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[7]

The Requestor, a multispecialty physician practice with two ASCs, proposed an arrangement where it would pay each physician-employee a bonus equal to 30% of the net profits from facility fees at ASCs attributable to the procedures rendered by that employee.[8] The bonuses would be added to the employee's base compensation.[9] Interestingly, the Requestor did not ask the OIG to opine on the distributions of the remainder of the ASC's net profits (70%), or distributions related to a corporate restructuring the Requestor would be undertaking.[10]

The OIG concluded that the proposed bonus payments would be protected by the AKS's Employee Bona Fide Safe Harbor because: (1) the Requestor confirmed that the physicians receiving the bonuses would be bona fide employees of the Requestor; and (2) the bonuses were payments for employment in the physicians' furnishing of services or items that would be reimbursed by federal healthcare programs.[11] While the conditions for the safe harbor were met, the OIG did state that "payment structures that tie compensation to profits generated from services furnished to patients referred by the compensated party are suspect" under the AKS.[12] As noted by legal experts, while the Requestor's proposed bonuses fall under the protection of the safe harbor, similar payments to physicians as ownership distributions or to independent contractors could pose fraud and abuse risks.[13]

Compensation arrangements that include physician bonuses are often the subject of fraud and abuse law scrutiny, especially when they are tied to referrals.[14] The OIG's analysis and opinion demonstrates that when arrangements are structured properly to comply with safe harbors, certain bonus compensation arrangements may be considered permissible.[15]

1 "OIG Approves Net Profit-Based Bonuses for Employed Physicians" By Albert Shay, Jacob Harper, and Felicia Alexander, Morgan Lewis, October 26, 2023, https://www.morganlewis.com/pubs/2023/10/oig-approves-net-profit-based-bonuses-for-employed-physicians#:~:text=The%20US%20Department%20of%20Health,procedures%20performed%20by%20the%20physicians. (Accessed 10/27/23); "Re: OIG Advisory Opinion No. 23-07 (Favorable)" Office of Inspector General, Department of Health and Human Services, October 13, 2023, https://oig.hhs.gov/documents/advisory-opinions/1132/AO-23-07.pdf (Accessed 10/27/23).

2 Shay, Jacob Harper, and Felicia Alexander, Morgan Lewis, October 26, 2023.

3 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).

4 *Ibid*; "Civil Monetary Penalties" 42 USC § 1320a-7a(a).

5 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, http://oig.hhs.gov/fraud/docs/advisoryopinions/15/AdvOpn15-10.pdf (Accessed 10/27/23), p. 5.

6 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" federal Register, Vol. 64, No. 223 (November 19, 1999), p. 63518, 63520.

7 "Re: Malpractice Insurance Assistance" By Lewis Morris, Chief Counsel to the Inspector General, United States Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf (Accessed 10/27/23), p. 1.

8 "OIG Approves Paying Employed Physicians Profits from ASCs Operated by Employer " By Justin Brown, Travis Lloyd, William Mathias, and Jennifer Michael, JD Supra, October 19, 2023, https://www.jdsupra.com/legalnews/oig-approves-paying-employed-physicians-8426846/ (Accessed 10/27/23). "OIG Approves Net Profit-Based Bonuses for Employed Physicians" By Albert Shay, Jacob Harper, and Felicia Alexander, Morgan Lewis, October 26, 2023, https://www.morganlewis.com/pubs/2023/10/oig-approves-net-profit-based-bonuses-for-employed-physicians#:~:text=The%20US%20Department%20of%20Health,procedures%20performed%20by%20the%20physicians. (Accessed 10/27/23).

9 *Ibid.*

10 Brown, Travis Lloyd, William Mathias, and Jennifer Michael, JD Supra, October 19, 2023.

11 "Worth the read: Recent HHS-OIG advisory opinion" By Rachel Rose, Physicians Practice, October 26, 2023, https://www.physicianspractice.com/view/worth-the-read-recent-hhs-oig-advisory-opinion (Accessed 10/27/23).

12 "Re: OIG Advisory Opinion No. 23-07 (Favorable)" Office of Inspector General, Department of Health and Human Services, October 13, 2023, https://oig.hhs.gov/documents/advisory-opinions/1132/AO-23-07.pdf (Accessed 10/27/23).

13 Brown, Travis Lloyd, William Mathias, and Jennifer Michael, JD Supra, October 19, 2023.

14 "OIG Issues Favorable Opinion Regarding Physician Group's Proposal to Pay Bonuses to its Employed Physicians Based on Net Profits" By Michael Lisitano and Nathaniel Arden, Robinson & Cole, October 19, 2023, https://www.healthlawdiagnosis.com/2023/10/advisory-opinion-23-7-oig-issues-favorable-opinion-regarding-proposal-to-pay-bonuses-to-its-employed-physicians-based-on-net-profits/ (Accessed 10/27/23).

15 *Ibid.*

OIG Unveils New Healthcare Compliance Guidance

[Excerpted from the article published in December 2023.]

On November 6, 2023, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) released the updated "*General Compliance Program Guidance*" (GCPG).[1] The guidance document is applicable to all healthcare individuals and entities, such as investors, suppliers, manufacturers, and providers.[2] This Health Capital Topics article discusses the new guidance, reactions from healthcare industry stakeholders, and potential implications.

The OIG has updated or released numerous Compliance Program Guidances (CPGs) since 1998, with this update representing the first major update to the OIG's CPGs in 15 years.[3] CPGs focus on participants in the healthcare industry, including pharmaceutical managers, third-party medical billing companies, clinical laboratories, hospitals, home health agencies, hospices, and physician practices.[4] This most recent iteration comes on the heels of the OIG's April 2023 announcement that it would be overhauling its compliance guidance based on stakeholder feedback, with the goal of "modernizing the accessibility and usability of…publically available resources," including the CPGs.[5] This most recent guidance serves as a reference guide for healthcare entities creating and maintaining compliance programs and "discusses general compliance risks and compliance programs."[6]

In discussing those risks and programs, the GCPG addresses applicable federal healthcare laws, including the Health Insurance Portability and Accountability Act (HIPAA), the False Claims Act, the Anti-Kickback Statute, and the Stark Law.[7] In part, HIPAA regulates access to, and the privacy of, individually identifiable health information.[8] The False Claims Act prohibits any person from knowingly submitting false claims to the government.[9] The Anti-Kickback Statute and Stark Law are generally concerned with the same issue – the financial motivation behind patient referrals. The Anti-Kickback Statute 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.[10] Similarly, the Stark Law prohibits physicians specifically from referring Medicare patients to entities with which the physician or their family members has a financial relationship for the provision of certain designated health services (DHS).[11]

The GCPG identifies and discusses the seven elements of what the OIG believes comprises a successful and effective compliance program, which include:

(1) Written procedures and policies;
(2) Compliance oversight and leadership;
(3) Education and training;
(4) Effective communication with disclosure programs and compliance officers;
(5) Enforcing standards;
(6) Risk monitoring, auditing, and assessment; and
(7) Responding to offenses and developing corrective actions.[12]

Other items addressed in the GCPG include:

(1) A general background on the OIG's current and previous compliance guides;
(2) A summary of applicable regulations and laws over which the OIG has oversight;
(3) Tips to ensure the healthcare industry understands the OIG's general views on compliance priorities and structures;
(4) Suggestions for adapting programs for compliance based on the size of the entity;
(5) Discussion on compliance considerations, which indicates the OIG's current focus; and
(6) A list of OIG resources, including compliance toolkits; OIG reports and publications; advisory opinions; special fraud alerts, bulletins, and other guidance; corporate integrity agreements; and OIG self-disclosure information.[13]

In addition to the GCPG, the OIG is expected to publish industry compliance program guidance (ICPG) specific to various suppliers, providers, and participants of the subsectors in the healthcare industry or ancillary industry sectors

that relate to federal healthcare programs.[14] These industry-specific guidance documents will discuss fraud and abuse risks specific to the subsector and identify those measures the subsector can take to reduce risks of noncompliance.[15] ICPGs are expected to be published starting in 2024 and be updated periodically thereafter.[16] The first two ICPGs are anticipated to address nursing facilities and Medicare Advantage.[17]

Remaining consistent with previous approaches, the OIG reminded users that the GCPG is not binding on any entity or individual, and that the GCPG is voluntary guidance – not a directive – that discusses risks surrounding compliance and effective infrastructure for compliance programs.[18] Nevertheless, the OIG explicitly recommended that healthcare entities incorporate patient safety and quality oversight into their compliance programs.[19] The OIG specifically noted the interaction between quality concerns and False Claims Act compliance, stating that "besides patient harm, quality and patient safety concerns, such as excessive services and medically unnecessary services, can lead to overpayments and may cause False Claims Act liability."[20] The OIG also specifically discussed financial arrangements in the healthcare industry, emphasizing that understanding how funds move within a business arrangement can be essential in identifying potential compliance issues.[21] The OIG specifically called out private equity, stating that "the growing prominence of private equity and other forms of private investment in health care raises concerns about the impact of ownership incentives (e.g., return on investment) on the delivery of high quality, efficient health care."[22] The OIG recommends that healthcare entities "scrutinize their operations and incentive structures to ensure compliance with the Federal fraud and abuse laws and that they are delivering high quality, safe care for patients."[23]

The OIG also acknowledges in the GCPG that healthcare entities may manage "a significant volume of financial arrangements and transactional agreements, including those between referral sources and referral recipients," which may implicate federal fraud and abuse laws, including the Anti-Kickback Statute and the Stark Law.[24] In tracking financial arrangements, the OIG stated that "entities should consider what type of centralized arrangements tracking system to establish, depending on the size of their organization, to ensure that proper supporting documentation is maintained, regular legal reviews are conducted, and fair market value assessments are performed and updated routinely as appropriate [emphasis added]."[25]

While most of the established tenets of compliance remain the same from the previous CPG, the updated GCPG elaborates on how the government views the implementation of effective compliance.[26] The GCPG provides healthcare organizations with essential insight into the government's priorities for enforcement, and signifies the increasing emphasis on compliance in the healthcare industry.[27]

---

1 "HHS-OIG Issues Long-Anticipated General Compliance Program Guidance for All Health Care Stakeholders" By Claire Castles, et al., Jones Day, JD Supra, December 1, 2023, https://www.jdsupra.com/legalnews/hhs-oig-issues-long-anticipated-general-7133844/ (Accessed 12/13/23); "General Compliance Program Guidance" Department of Health and Human Services, Office of Inspector General, November 2023, https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf (Accessed 12/13/23).

2 Castles, et al., Jones Day, JD Supra, December 1, 2023.

3 "OIG Releases New 'One-Stop Shop' General Compliance Program Guidance" By Banee Pachuca et al., Morgan Lewis, November 8, 2023, https://www.morganlewis.com/pubs/2023/11/oig-releases-new-one-stop-shop-general-compliance-program-guidance (Accessed 12/20/23).

4 *Ibid.*

5 "Modernization of Compliance Program Guidance Documents: Notice" Federal Register, Vol. 88, No. 79 (April 25, 2023), p. 25000.

6 Department of Health and Human Services, Office of Inspector General, November 2023.

7 "OIG Unveils New General Compliance Program Guidance, First Major Update Since 2008" By Howard Young, Banee Pachucha, and Felicia Alexander, Morgan Lewis, November 6, 2023, https://www.morganlewis.com/blogs/healthlawscan/2023/11/oig-unveils-new-general-compliance-program-guidance-first-major-update-since-2008 (Accessed 12/13/23).

8 "Health Insurance Portability and Accountability Act of 1996" Pub. L. No. 104-191 (August 21, 1996).

9 "The False Claims Act" U.S. Department of Justice, February 2, 2022, https://www.justice.gov/civil/false-claims-act (Accessed 12/13/23).

10 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).

11 "CRS Report for Congress: Medicare: Physician Self-Referral ("Stark I and II")" By Jennifer O'Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, available at: http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf (Accessed 12/8/23); "Limitation on certain physician referrals" 42 U.S.C. § 1395nn.

12 "HHS Releases Groundbreaking General Compliance Program Guidance, Setting New Standards for Healthcare Entities" Bass Berry Sims, December 7, 2023, https://www.bassberry.com/news/hhs-releases-groundbreaking-general-compliance-program-guidance/ (Accessed 12/13/23).

13 *Ibid.*

14 "HHS OIG Announces Changes to Compliance Program Guidance" By Thomas Sullivan, Policy & Medicine, July 31, 2023, https://www.policymed.com/2023/08/hhs-oig-announces-changes-to-compliance-program-guidance.html (Accessed 12/13/23).

15 *Ibid.*

16 *Ibid.*

17 *Ibid.*

18 Morgan Lewis, November 6, 2023.

19 Castles, et al., Jones Day, JD Supra, December 1, 2023.

20 *Ibid*; Department of Health and Human Services, Office of Inspector General, November 2023.

21 "HHS-OIG Issues Long-Anticipated General Compliance Program Guidance for All Health Care Stakeholders" By Claire Castles, et al., Jones Day, JD Supra, December 1, 2023, https://www.jdsupra.com/legalnews/hhs-oig-issues-long-anticipated-general-7133844/ (Accessed 12/13/23).

22 *Ibid*; Department of Health and Human Services, Office of Inspector General, November 2023.

23 Castles, et al., Jones Day, JD Supra, December 1, 2023.

24 *Ibid*; Department of Health and Human Services, Office of Inspector General, November 2023.

25 Castles, et al., Jones Day, JD Supra, December 1, 2023; Department of Health and Human Services, Office of Inspector General, November 2023.

26 Bass Berry Sims, December 7, 2023.

27 *Ibid.*

DOJ Sues Steward for Violating Fraud & Abuse Laws

[Excerpted from the article published in December 2023.]

On December 18, 2023, the Department of Justice (DOJ) filed a complaint against Steward Health Care System, Steward Medical Group (SMG), and St. Elizabeth's Medical Center (SEMC), alleging violations of the physician self-referral law (commonly known as the "Stark Law") and the False Claims Act.[1] Steward, an integrated healthcare system, is one of the largest private, for-profit healthcare networks in the U.S., and the owner of SMG and SEMC.[2] This Health Capital Topics article reviews the government's allegations.

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).[3] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[4] Under the Stark Law, DHS include, but are not limited to, the following:

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

Civil penalties under the Stark Law include overpayment or refund obligations, a potential civil monetary penalty of $15,000 for each service, or up to $100,000 per arrangement or scheme, and exclusion from Medicare and Medicaid programs.[6] Further, violation of the Stark Law can trigger a violation of the False Claims Act (FCA).[7] The FCA prohibits any person from knowingly submitting, or causing to submit, false claims to the government.[8] FCA violators are liable for treble damages (i.e., "three times the government damages"), as well as for a penalty linked to inflation.[9] Not only does the FCA give the U.S. government the ability to pursue fraud, it also enables private citizens to file suit on behalf of the federal government through what is known as a "*qui tam,*" "*whistleblower,*" or "*relator*" suit.[10]

According to the complaint-in-intervention filed in the District of Massachusetts by the Department of Justice, SMG recruited Dr. Arvind Agnihotri, a cardiac surgeon, in 2012 to increase the number of cardiovascular surgeries, and consequently increase revenue, at SEMC.[11] Between January 2013 and March 2022, SMG allegedly paid Dr. Agnihotri total compensation in excess of Fair Market Value. The government noted that, during most of the years of the relevant time period, Dr. Agnihotri's total compensation exceeded the 90th percentile for cardiovascular surgeons in the Eastern Region of the U.S. according to the Medical Group Management Association (MGMA) physician compensation benchmarks.[12] As a result, the defendants allegedly violated the Stark Law, and consequently the False Claims Act, by submitting over 1,000 claims to Medicare, supposedly knowing that the claims for the services were improperly referred and not eligible for any payment by the federal healthcare program.[13] The government alleges that, as a result of SEMC's false claims, Medicare mistakenly paid out tens of millions of dollars to SEMC.[14]

Dr. Agnihotri's aggregate compensation included an incentive compensation component that allegedly took into account the number and volume of referrals to SEMC;[15] this compensation was arguably the largest focus of the government's complaint. Specifically, Dr. Agnihotri's employment agreements during the 2013-2022 timeframe stated that his incentive compensation amount was based on the number of surgeries that were performed at SEMC – both by him personally and by the other surgeons in the Division of Cardiac Surgery.[16] Once the Division met the case threshold in a given year, SMG paid Dr. Agnihotri a lump sum incentive plus an additional amount of money for each case performed in an SEMC operating room above the threshold, up to a ceiling.[17] The employment agreements included tables cross walking the number of surgical cardiovascular cases performed in an SEMC operating room to the amount of incentive compensation to be received by Dr. Agnihotri.[18] In at least some of his employment agreements, the incentive compensation amount per surgical case increased as higher case thresholds were reached.[19] Notably, the

government stated that neither Steward nor its wholly-owned subsidiaries (SMG or SEMC) "perform[ed] a fair market value analysis of the compensation arrangement or any of its amendments, prior to or at the time of execution of the employment agreements."[20] In total, Dr. Agnihotri was allegedly paid over $4.8 million in incentive compensation during the relevant timeframe.[21]

Although the complaint was recently filed, the investigation into Steward began in 2018, after SEMC's former chief financial officer (CFO), Joseph Nocie, filed a *qui tam* action.[22] Nocie, who served as CFO from May 2016 to November 2017, knew that Dr. Agnihotri's incentive compensation took into account the volume of Dr. Agnihotri's referrals to SEMC and other business generated for SEMC, and had even raised his concerns related to physician compensation at budget meetings.[23]

Steward's spokesperson stated that "Steward looks forward to vindicating its positions in court and is confident it will ultimately obtain a favorable outcome."[24] Steward also stated that "the lawsuit does not allege that Steward submitted claims for any medical procedures that were unnecessary, not performed, or billed incorrectly. It does not allege that the physician's employment contract influenced his clinical decision making. And it does not allege any harm to patient safety."[25]

Acting U.S. Attorney Joshua Levy stated that "the government's complaint…alleges that in its drive to increase cardiac surgeries at SEMC, the defendants entered into improper compensation arrangements with a cardiac surgeon, and knowingly submitted false claims to Medicare."[26] Levy also said that the DOJ was "committed to enforcing the Stark Law, and protecting patients and the Medicare program from financial relationships that can corrupt clinical decision making."[27]

---

1 "United States Files Complaint Against St. Elizabeth's Medical Center, Steward Medical Group and Steward Health Care System" United States Attorney's Office, Department of Justice, December 18, 2023, https://www.justice.gov/usao-ma/pr/united-states-files-complaint-against-st-elizabeths-medical-center-steward-medical-group (Accessed 12/19/23), ¶ 1.
2 *Ibid*, ¶¶ 1-3.
3 "CRS Report for Congress: Medicare: Physician Self-Referral ("Stark I and II")" By Jennifer O'Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, available at: http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf (Accessed 12/8/23); "Limitation on certain physician referrals" 42 U.S.C. § 1395nn.
4 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn(a)(1)(A).
5 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a)(1)(B); "Definitions" 42 C.F.R. § 411.351 (2015). Note the distinction in 42 C.F.R. § 411.351 regarding what services are included as DHS: "Except as otherwise noted in this subpart, the term 'designated health services' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)."
6 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn(g).
7 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 12/8/23).
8 "The False Claims Act" U.S. Department of Justice, February 2, 2022, https://www.justice.gov/civil/false-claims-act (Accessed 1/30/23).
9 *Ibid.*
10 *Ibid.*
11 "United States Files Complaint Against St. Elizabeth's Medical Center, Steward Medical Group and Steward Health Care System" United States Attorney's Office, Department of Justice, December 18, 2023, https://www.justice.gov/usao-ma/pr/united-states-files-complaint-against-st-elizabeths-medical-center-steward-medical-group (Accessed 12/19/23), ¶ 58.
12 *Ibid*, ¶¶ 99-102.
13 *Ibid*, ¶¶ 4-8.
14 *Ibid*, ¶ 9.
15 "Steward Health Paid Boston Cardiac Doc Kickbacks, Feds Say" By Cassie Chew, Law360, https://www.law360.com/articles/1778465/steward-health-paid-boston-cardiac-doc-kickbacks-feds-say (Accessed 12/19/23).
16 Department of Justice, December 18, 2023, ¶ 69.
17 *Ibid*, ¶ 109.
18 United States Attorney's Office, Department of Justice, December 18, 2023, ¶ 73.
19 *Ibid.*
20 *Ibid*, ¶ 82.
21 *Ibid*, ¶¶ 6, 106.
22 "United States Complaint-In-Intervention" United States District Court, District of Massachusetts, December 16, 2023, https://www.justice.gov/d9/2023-12/usa_v._steward_health_-_complaint_in_intervention.pdf (Accessed 12/19/23).
23 *Ibid*, ¶ 152.
24 "Steward Health Paid Boston Cardiac Doc Kickbacks, Feds Say" By Cassie Chew, Law360, https://www.law360.com/articles/1778465/steward-health-paid-boston-cardiac-doc-kickbacks-feds-say (Accessed 12/19/23).
25 *Ibid.*
26 United States Attorney's Office, Department of Justice, December 18, 2023.
27 *Ibid.*

FTC and DOJ Release Final Merger Guidelines

[Excerpted from the article published in January 2024.]

On December 18, 2023, the Federal Trade Commission (FTC) and Department of Justice (DOJ) jointly issued their final Merger Guidelines, which guide the agencies in their review of mergers and acquisitions in evaluating compliance with federal antitrust laws.[1] The new Guidelines replace, amend, and consolidate the Horizontal Merger Guidelines and Vertical Merger Guidelines, which were published in 2010 and 2020, respectively.[2] While the final version reflects some notable changes from the proposed Guidelines that were made in response to public comments, the main takeaways from the draft version released in July 2023 remain the same.[3] This Health Capital Topics article discusses the finalized Guidelines and how they may affect healthcare transactions going forward.

Horizontal consolidation is the acquisition or merger of two companies at the same level in the supply chain, while vertical integration is the merger or acquisition of two or more companies in the same line of production, but not at the same level.[4] 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.[5] 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.[6] 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.[7] The U.S. healthcare industry has seen a rise in vertical integration transactions since the passage of the Patient Protection and Affordable Care Act (ACA), particularly among physician groups integrating with health systems or insurers, as providers seek to fill gaps in their continuum of care. This uptick (particularly in 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.[8]

Federal antitrust laws, such as the Clayton Act, Sherman Act, and Fair Trade Commission Act, govern mergers and acquisitions that may restrain trade or result in unfair competition. 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 laws 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 finalized Guidelines expand, clarify, and build on existing frameworks. It includes 11 finalized Guidelines meant to aid the agencies in determining if mergers are anticompetitive and unlawful under current antitrust laws.[13] Notably, two additional Guidelines were proposed in the draft version but ultimately removed or consolidated in the final Guidelines. For example, draft Guideline 6, which stated that "vertical mergers should not create market structures that foreclose competition," was removed.[14] The final Guidelines incorporate this deleted information in a footnote, and instead focus on vertical merger issues in Guideline 5.[15] Draft Guideline 13, which stated that the draft merger guidelines were not exhaustive, was also deleted.[16] While Guideline 13 was removed, the overview still states that the Guidelines "dictate or exhaust the range of theories or evidence" that may be used in merger litigation or reviews, and that they "do not limit the [Agencies'] discretion."[17]

The remaining 11 final Guidelines are as follows:

(1) Mergers raise presumptions of illegality when they increase concentration significantly in a market that is highly concentrated.
(2) Mergers can violate the law when eliminating substantial competition between firms.
(3) Mergers can violate the law when they increase risks of coordination.
(4) Mergers can violate the law when they eliminate potential entrants into a market that is concentrated.
(5) Mergers can violate the law when a firm is created that limits access to services or products that its rivals use to compete.

(6) Mergers can violate the law when they extend or entrench a dominant position.
(7) When an industry undergoes a trend towards consolidation, agencies consider whether it increases the risk that mergers may tend to create a monopoly or substantially lessen completion.
(8) When a merger is associated with a series of multiple acquisitions, the agencies may examine the whole series of acquisitions.
(9) When a merger involves a platform that is multi-sided, the agencies examine competition between the platforms, on the platform, or to displace the platform.
(10) When a merger involves buyers that are competing, the agencies may examine whether it may lessen competition substantially for workers, suppliers, creators, or other providers.
(11) When an acquisition involves minority interests or partial ownership, the agencies may examine its impact on competition.[18]

While these final 11 Guidelines do not significantly deviate from the draft released in July 2023, there are some notable differences.[19] For example, final Guideline 6 contains an expanded discussion of ways in which the acquisition of a competitor can reduce competition by entrenching the acquiring firm's dominant position.[20] If the agencies find that a firm is dominant, they will have latitude to challenge any acquisition that may extend or entrench the dominant firm's position.[21] In final Guideline 7, the agencies clarified how industry consolidation trends can heighten competition concerns for proposed mergers.[22] The clarification is an indication that the agencies will scrutinize not only the mergers that occur in industries experiencing consolidation, but also within industries that trend toward concentration.[23] The final Guidelines also expand on the draft's discussion regarding rebuttal evidence, such as procompetitive efficiencies from a proposed transaction and entry by other firms.[24]

Overall, the final Guidelines "place an emphasis on transactions that tend to create a monopoly," codify new thresholds regarding which transactions will be considered presumptively illegal by the regulatory agencies, and advance new harm theories relating to labor market competition.[25] The Guidelines also suggest that regulatory agencies will focus on transactions within markets that are highly concentrated, and markets where the dealing party may hold a dominant position.[26]

These Guidelines are indicative of the continuing pursuit of aggressive antitrust enforcement, including through the development of novel theories of harm in competition.[27] While the Guidelines may result in enhanced agency scrutiny of proposed deals, they do not have the force of law.[28] However, this enhanced scrutiny can still impact healthcare deals, as the mere threat of litigation can affect the valuation of a company, and/or make an attractive deal stall, be renegotiated, or completely fail.[29] Legal experts suggest that prospective dealmakers should continue to expect that more transactions will receive more scrutiny, increasing the cost and time of transactions, with extended investigations becoming more burdensome and frequent.[30]

1 "DOJ and FTC Release Final 2023 Merger Guidelines Formalizing Aggressive Merger Enforcement Playbook" By Steven Sunshine et al., Skadden, December 21, 2023, https://www.skadden.com/insights/publications/2023/12/doj-and-ftc-release-final-2023-merger-guidelines#:~:text=The%20final%20Guidelines%20add%20additional,evidence%20must%20be%20very%20strong. (Accessed 1/3/24); "Justice Department And FTC Seek Comment on Draft Merger Guidelines" Office of Public Affairs, U.S. Department of Justice, July 19, 2023, https://www.justice.gov/opa/pr/justice-department-and-ftc-seek-comment-draft-merger-Guidelines (Accessed 1/3/24).

2 "US FTC and DOJ announce new merger Guidelines" By Amanda Wait, Gerald Stein, Andrew Eklund, and Marisa Madaras, Norton Rose Fulbright, July 2023, https://www.nortonrosefulbright.com/en/knowledge/publications/6aca1153/us-ftc-and-doj-announce-new-merger-Guidelines (Accessed 1/3/24).

3 Sunshine et al., Skadden, December 21, 2023.

4 "Horizontal Integration" By Will Kenton, Investopedia, August 27, 2022, https://www.investopedia.com/terms/h/horizontalintegration.asp (Accessed 1/3/24)

5 *Ibid.*

6 "Vertical Integration" By Adam Hayes, Investopedia, May 30, 2023, https://www.investopedia.com/terms/v/verticalintegration.asp (Accessed 1/3/24).

7 *Ibid.*

8 "Vertical Merger Enforcement Uncertainty While Antitrust Agencies Review Merger Guidelines" By Brian C. Lewis, Health Law Weekly, March 11, 2022, https://www.americanhealthlaw.org/content-library/health-law-weekly/article/29512ce3-bd80-4760-8449-2ad84cd61f71/Vertical-Merger-Enforcement-Uncertainty-While-Anti?Token=f304e7eb-7b0e-4b84-abbe-e4e21f9defe8 (Accessed 1/3/24).

9 "The Antitrust Laws" Federal Trade Commission, https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/antitrust-laws (Accessed 1/3/24).

10 *Ibid.*

11 *Ibid.*

12 *Ibid.*

13 "DOJ and FTC Finalize New Merger Guidelines" By Daniel Hemli and Jacqueline Java, Bracewell, National Law Review, January 2, 2024, https://www.natlawreview.com/article/doj-and-ftc-finalize-new-merger-guidelines (Accessed 1/3/24).

14 "DOJ and FTC Finalize New Merger Guidelines – What You Need to Know" By Alexander Okuliar et al., Morrison Foerster, December 21, 2023, https://www.mofo.com/resources/insights/231221-new-merger-guidelines-finalized#_ftn5 (Accessed 1/15/24).

15 *Ibid.*

16 "DOJ and FTC release final merger guidelines" DavisPolk, December 20, 2023, https://www.davispolk.com/insights/client-update/doj-and-ftc-release-final-merger-guidelines (Accessed 1/19/24).

17 *Ibid.*

18 Hemli and Jacqueline Java, Bracewell, National Law Review, January 2, 2024.

19 *Ibid.*

20 *Ibid.*

21 "U.S. Antitrust Agencies Propose Sweeping Changes to Merger Guidelines – 5 Key Things You Need to Know" By J. Mark Gidley et al., White & Case, https://www.whitecase.com/insight-alert/us-antitrust-agencies-propose-sweeping-changes-merger-guidelines-5-key-things-you (Accessed 1/9/24).

22 Hemli and Jacqueline Java, Bracewell, National Law Review, January 2, 2024.

23 *Ibid.*

24 *Ibid.*

25 "FTC and DOJ issue revised Merger Guidelines" By Robin Adelstein, Eliot Turner, Abraham Chang, Mark Angland, and Marisa Madaras, Norton Rose Fulbright, December 2023, https://www.nortonrosefulbright.com/en/knowledge/publications/2dcf88d7/ftc-and-doj-issue-revised-merger-guidelines (Accessed 1/3/24).

26 *Ibid.*

27 Sunshine et al., Skadden, December 21, 2023.

28 *Ibid.*

29 "Litigation and Contingent Risks: Unlocking the Value in M&A" AON, June 15, 2023, https://www.aon.com/en/insights/articles/litigation-and-contingent-risks-unlocking-the-value-in-mergers-and-acquisitions#:~:text=The%20threat%20of%20litigation%20can,the%20success%20of%20a%20deal. (Accessed 1/9/24).

30 Sunshine et al., Skadden, December 21, 2023.

DOJ Announces Record-Breaking FCA Settlement with Community Health Network

[Excerpted from the article published in January 2024.]

On December 19, 2023, the U.S. Department of Justice (DOJ) announced that it had entered into a $345 million settlement with Community Health Network Inc. (CHN), a healthcare network headquartered in Indianapolis, to resolve claims that the hospital violated the False Claims Act (FCA) by knowingly submitting Medicare claims for services which were referred in violation of the Stark Law.[1] This settlement is notable in part because it is the largest Stark-related FCA settlement ever reached by the DOJ.[2] This Health Capital Topics article reviews the allegations underlying the case and settlement.

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).[3] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[4] Under the Stark Law, DHS include, but are not limited to, the following:

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

Civil penalties under the Stark Law include overpayment or refund obligations, a potential civil monetary penalty of $15,000 for each service, or up to $100,000 per arrangement or scheme, and exclusion from Medicare and Medicaid programs.[6] Further, violation of the Stark Law can trigger a violation of the False Claims Act (FCA).[7] The FCA prohibits any person from knowingly submitting, or causing to submit, false claims to the government.[8] FCA violators are liable for treble damages (i.e., "three times the government damages"), as well as for a penalty linked to inflation.[9] Not only does the FCA give the U.S. government the ability to pursue fraud, it also enables private citizens to file suit on behalf of the federal government through what is known as a "*qui tam,*" "*whistleblower,*" or "*relator*" suit.[10]

CHN is a nonprofit healthcare system comprised of ten acute care and rehabilitation hospitals, as well as over 200 sites of care and affiliates throughout Central Indiana.[11] In fiscal year 2022, CHN reported total gains and revenues of $3.1 billion, but $182 million in net asset decreases.[12]

The government's complaint alleged that, starting in 2008 and 2009, senior management at CHN recruited and employed physicians for the illegal purpose of capturing their lucrative downstream referrals.[13] The organization recruited hundreds of specialists, including neurosurgeons, cardiovascular specialists, and breast surgeons, by offering (and ultimately paying) salaries that were "magnitudes higher" – often double – what the specialists earned in private practice.[14] CHN's physician compensation plans included three components: base, retention, and incentive compensation.[15] For each specialty, CHN calculated a "hospital reimbursement differential" (based on each physician's historical utilization and referrals), which calculated the difference between the (lower) Medicare reimbursement the physicians received in private practice and the (higher) amount that CHN would be reimbursed if the physicians furnished those same services in the hospital.[16] This "reimbursement differential" was then allegedly used by CHN to fund the excessive specialist salaries.[17]

The government cited documentation that CHN was aware of the Stark Law's requirements that employed physician compensation must be fair market value and cannot take into account the volume or value of referrals.[18] CHN engaged a valuation firm to analyze the salaries CHN intended to pay their physicians, and the firm repeatedly made it clear that the compensation needed to be within fair market value.[19] The firm stated that "compensation needed to be less than the 75th percentile of national benchmark salary data or the compensation per productivity (measured by physician work units or collections) needed to be less than the 60th percentile of national benchmark salary data," in order to

be within the range of fair market value.[20] CHN also allegedly provided the valuation firm with false compensation figures in order to induce the firm to render a favorable valuation opinion.[21] The government also alleged that CHN "valuation shopped," i.e., sought multiple different valuation opinions in an effort to support the proposed salaries.[22]

In addition to excessive base compensation, CHN also allegedly paid physicians incentive compensation in the form of financial performance bonuses, based on the physicians reaching target referrals to CHN's network.[23] The incentive compensation had three components: service line financial performance, physician-driven metrics, and network financial performance.[24] The physician-driven component represented 50% of the incentive compensation, and the network financial performance and service line performance each accounted for 25%.[25] CHN allegedly awarded the service line financial performance portion of the incentive payment based on meeting targeted revenues, which were generated by the physician's referrals to the hospital.[26] As a result, during the term of their employment agreements, physicians made DHS referrals to CHN, e.g., referrals for outpatient and inpatient hospital services.[27] By conditioning incentive compensation on meeting certain revenue targets based on referrals to CHN and their affiliates and subsidiaries, CHN took into account the value or volume of referrals in determining physician compensation, in direct violation of the Stark Law.[28]

Pursuant to the settlement agreement, CHN must pay the federal government a settlement amount of $345 million, $167 million of which is restitution, plus interest at a rate of 4.75% per annum.[29] Additionally, CHN entered into a five-year corporate integrity agreement (CIA) with the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG), which requires, among other items: (1) an independent review organization (IRO) to perform reviews of both arrangements and fee-for-service claims; and (2) a compliance expert to review the effectiveness of CHN's compliance program each year and report to the Board of Directors of CHN.[30] The compliance expert's reports must be reviewed by the Board and submitted to the OIG.[31] Notably, it is unusual for the OIG to require IROs for both arrangement reviews and claims reviews; it is also uncommon for the OIG to require a compliance expert be retained.[32]

Although the case was recently settled, the investigation into CHN began in 2014, after a whistleblower complaint was filed by the nonprofit's former chief operating officer and chief financial officer.[33] The complaint was investigated by the Federal Bureau of Investigation (FBI) and the OIG.[34]

Principal Deputy Assistant Attorney General Brian Boynton stated in the settlement announcement that "the Stark Law was enacted to ensure that the clinical judgment of physicians is not corrupted by improper financial incentives."[35] Boynton also said that the "recovery demonstrates the department's resolve to protect the integrity of federal healthcare programs and to safeguard the taxpayer dollars used to support these important programs."[36]

1 "Indiana Health Network Agrees to Pay $345 Million to Settle Alleged False Claims Act Violations" Department of Justice, December 19, 2023, https://www.justice.gov/opa/pr/indiana-health-network-agrees-pay-345-million-settle-alleged-false-claims-act-violations (Accessed 1/3/24).
2 "In Biggest Stark-Based FCA Settlement Ever, Indiana Hospital Pays $345M, Has Unusual CIA" Cosmos, January 8, 2024, https://compliancecosmos.org/biggest-stark-based-fca-settlement-ever-indiana-hospital-pays-345m-has-unusual-cia?authkey=397b654b5ad1def15af0c61ff1eddbf256e768772d89d5ec9b0e8bdc4d298a82&_zs=esOUL1&_zl=ovXK7 (Accessed 1/19/24).
3 "CRS Report for Congress: Medicare: Physician Self-Referral ("Stark I and II")" By Jennifer O'Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, available at: http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf (Accessed 1/3/24); "Limitation on certain physician referrals" 42 U.S.C. § 1395nn.
4 42 U.S.C. § 1395nn(a)(1)(A).
5 42 U.S.C. § 1395nn(a)(1)(B); "Definitions" 42 C.F.R. § 411.351 (2015). Note the distinction in 42 C.F.R. § 411.351 regarding what services are included as DHS: "Except as otherwise noted in this subpart, the term 'designated health services' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)."
6 42 U.S.C. § 1395nn(g).
7 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 1/3/24).
8 "The False Claims Act" U.S. Department of Justice, February 2, 2022, https://www.justice.gov/civil/false-claims-act (Accessed 1/3/24).
9 *Ibid.*
10 *Ibid.*
11 "Community Health Network pays $345M to settle illegal referral scheme allegations" By Dave Muoio, Fierce Healthcare, December 19, 2023, https://www.fiercehealthcare.com/regulatory/community-health-network-pays-345m-settle-illegal-referral-scheme-allegations (Accessed 1/3/24).
12 *Ibid.*
13 "United States' Complaint In Intervention" Department of Justice, January 6, 2020, https://www.justice.gov/opa/media/1329616/dl?inline (Accessed 1/3/24), ¶ 51.
14 *Ibid.*
15 *Ibid*, ¶ 293-296.
16 *Ibid*, ¶ 52.
17 *Ibid.*
18 *Ibid*, ¶ 53.
19 *Ibid.*
20 *Ibid.*
21 *Ibid.*
22 *See* "United States' Complaint In Intervention" Department of Justice, January 6, 2020, https://www.justice.gov/opa/media/1329616/dl?inline (Accessed 1/3/24), ¶¶ 54, 159-162.
23 Department of Justice, January 6, 2020, https://www.justice.gov/opa/media/1329616/dl?inline (Accessed 1/3/24), ¶ 55.
24 *Ibid*, ¶ 293-296.
25 *Ibid*, ¶ 293-296.
26 *Ibid*, ¶ 302-304.
27 *Ibid.*
28 *Ibid.*
29 "Settlement Agreement" Department of Justice, December 18, 2023, https://www.justice.gov/opa/media/1329621/dl?inline (Accessed 1/15/24), ¶ 5, 12.
30 "Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Community Health Network, Inc." available at: https://oig.hhs.gov/fraud/cia/agreements/Community_Health_Network_12182023.pdf (Accessed 1/19/24).
31 *Ibid.*
32 Cosmos, January 8, 2024.
33 Muoio, Fierce Healthcare, December 19, 2023.
34 *Ibid.*
35 *Ibid.*
36 *Ibid.*

2024 Healthcare Industry Outlook

[Excerpted from the article published in January 2024.]

Nearly one year removed from the end of the COVID-19 public health emergency, the healthcare industry expects a number of new opportunities in 2024, despite lingering challenges exposed by the pandemic. For example, healthcare organizations anticipate issues related to workforce shortages and legislative challenges; however, the industry also expects that opportunities emanating from technological advancements will allow them to grow and transform.[1] This Health Capital Topics article reviews anticipated U.S. healthcare industry activity for 2024 as well as trends that may drive change in the industry.

Legislative Landscape

Congress failed to pass any major healthcare legislation in 2023, despite several bills being proposed. Nevertheless, there is hope that significant legislation could be passed in 2024, despite it being a presidential election year (historically an inopportune time in which to pass major legislation).[2] The delay in passing proper appropriations legislation has resulted in the stalling of major healthcare spending, as well as of numerous programs and bills that need to be reauthorized through the legislative process.[3]

On January 18, 2024, Congress passed a short-term funding bill to extend the federal government's spending authority until early March 2024, which will narrowly avoid the partial shutdown of federal agencies once it is signed by President Biden.[4] The bill extends funding for the agencies covered by four appropriation bills until March 1, 2024, and the funding covered by the remaining eight appropriation bills is extended until March 8, 2024.[5]

The legislation includes numerous healthcare provisions, including:

- Extending funding for the Department of Health and Human Services (HHS) through March 8, 2024;
- Extending funding for the Department of Veterans Affairs (VA) and the Food and Drug Administration (FDA) through March 1, 2024.
- Delaying $8 billion in cuts to Medicaid Disproportionate Share Hospitals (DSHs) through March 8, 2024;
- Extending the Work Geographic Index Floor for Medicare physician reimbursement through March 8, 2024, although the pay cut to physician reimbursement for 2024 will be retained;
- Extending certain public health emergency flexibilities through March 8, 2024; and
- Extending special diabetes programs, community health centers, the National Health Service Corps, and the Teaching Health Center Graduate Medical Education Program through March 8, 2024.[6]

Despite these various extensions, the appropriations legislation leaves many other healthcare priorities untouched, such as legislation to stiffen pharmacy benefit manager (PBM) regulation, mandate greater pricing transparency in healthcare, and increase access to telehealth services.[7]

AI Implementation

Technology such as generative artificial intelligence (AI) is expected to present both challenges and opportunities to the healthcare industry in 2024.[8] According to a Deloitte survey, healthcare executives have acknowledged and agree that many of the healthcare sector's most important issues (i.e., patient wait times, claims, staff burnout, and access) could be potentially addressed with AI, and ultimately change the way healthcare is delivered, resulting in potential improvements ranging from better customer experience to improved efficiencies.[9]

The adoption of AI and similar technology will fuel the reinvention of healthcare business models, with providers and payors leveraging AI to enhance provider, member, and patient experiences, while lowering administrative costs and increasing productivity.[10] AI is expected to play a crucial role in achieving more affordable healthcare, with estimations showing that the application of AI could cut annual U.S. healthcare costs by $150 billion by reducing the number of treatments, doctor visits, and hospitalizations, and by focusing AI on overall health management, rather than the treatment of disease.[11]

The sprint toward AI in all industries has raised concern about the technology's risks and the lack of regulatory scrutiny; consequently, regulators have been scrambling to create and modify regulations related to AI usage.[12] On October 30, 2023, President Joseph Biden signed an executive order to establish new standards for AI in the U.S.[13] The executive order focuses on protecting the privacy of Americans and establishes new standards for security and safety in AI.[14] While the executive order is not specific to healthcare, the order contains some healthcare-specific provisions to enable more regulation and oversight on the usage of AI in the healthcare sector.[15]

The level of development and the pace of clinical AI implementation may be directly influenced by the liability faced by practitioners, designers, and health systems, as more liability could discourage the use of AI in healthcare.[16] As the technology continues to be developed and utilized in 2024, new legal pathways will need to be established, especially as increased liability would likely repel practitioners, designers, and health systems from implementing and developing clinical AI models.[17] While generative AI will continue to disrupt the healthcare industry, it aims to ultimately increase the efficacy of the healthcare delivery system.

Mergers & Acquisitions (M&A)

Despite market challenges, the outlook for healthcare sector deals appear cautiously optimistic.[18] While regulatory concerns, interest rates, and valuation gaps have impacted the sector, record levels of non-traditional deals and capital are expected to drive momentum in 2024.[19] Experts suggest that companies may need to invest time in ensuring deals are structured to prepare for potential concessions in the case that a merger is challenged, and to appease regulators.[20]

The COVID-19 pandemic was responsible for a sharp drop in merger and acquisition (M&A) activity, but that activity has largely rebounded, and is expected to continue rebounding into 2024.[21] Larger healthcare organizations have partnered with and acquired non-traditional industry innovators and disruptors (i.e., retail, tech giants, and telecom) as they aim to meet the needs of more empowered healthcare consumers.[22] Some of the new healthcare industry entrants have a stronger focus on consumer needs, and that focus may help health systems transition from their usual business models to offer services that meet the expectations of consumers.[23]

Workforce Shortages & Outsourcing

The U.S. is in the midst of a precarious healthcare workforce shortage that is projected to worsen.[24] By 2030, the country could face shortages of nearly 124,000 physicians and 200,000 nurses; these shortages are due to not just increased demand for healthcare services from the aging population, but also a contracting supply of providers as a result of the aging healthcare workforce and workers leaving due to burnout.[25] As a result, healthcare staffing needs are expected to continue to intensify, as industry leaders struggle to retain and attract talent.[26] To alleviate these staffing needs, employers are expected to turn to off-shoring, outsourcing, and managed care partnerships.[27]

While many in the healthcare industry may be hesitant to outsource given the potential impact on local employees, increasingly compelling drivers such as rising gaps in capabilities, inability to access needed talent, and the combination of financial value proposition, may leave industry leaders with no choice.[28] Experts say that healthcare organizations may benefit from determining what they can do well, and outsourcing other functions that may be done at a lower cost and more efficiently.[29] By analyzing the efficiency, quality, and cost of outsourcing, healthcare organizations may be able to improve efficiencies, reduce costs, and streamline their operations.[30]

According to a Deloitte survey, more than half of healthcare system executives are expecting workforce challenges and shortages in talent that will impact organizational strategy in 2024.[31] Some healthcare executives are aiming to simultaneously address and reduce clinician burnout, while attracting and retaining staff for clinical roles.[32]

Conclusion

In 2024, healthcare M&A is expected to continue rebounding and healthcare systems are expected to continue implementing transformative technology. The healthcare industry will turn to AI technology and outsourcing to address urgent workforce needs and satisfy consumers. Legislative challenges will continue to impact the healthcare industry, and federally-backed healthcare spending and programs may stall as a result. While challenges remain, industry experts predict the healthcare industry will experience transformative changes over the next year.

1 "2024 healthcare services outlook: Challenges and opportunities" By Neil Rao, McKinsey and Company, December 19, 2023, https://www.mckinsey.com/industries/healthcare/our-insights/2024-healthcare-services-outlook-challenges-and-opportunities (Accessed 1/8/24).
2 "PBMs, telehealth, transparency lead Congress' 2024 to-do list" By Michael McAuliff, Modern Healthcare, January 3, 2024, https://www.modernhealthcare.com/politics-policy/pbms-medicare-pay-telehealth-congress-2024 (Accessed 1/8/24).
3 *Ibid.*
4 "House clears stopgap funding extension into March" By Aidan Quigley, Roll Call, January 18, 2024, https://rollcall.com/2024/01/18/senate-passes-stopgap-funding-extension-into-march/ (Accessed 1/19/24).
5 *Ibid.*
6 "Hospitals, community health centers get reprieve from Congress" By Michael McAuliff, Modern Healthcare, January 18, 2024, https://www.modernhealthcare.com/politics-policy/congress-stopgap-funding-bill-dsh-cuts-chcs-community-health-centers (Accessed 1/19/24).
7 *Ibid.*
8 "2024 healthcare services outlook: Challenges and opportunities" By Neil Rao, McKinsey and Company, December 19, 2023, https://www.mckinsey.com/industries/healthcare/our-insights/2024-healthcare-services-outlook-challenges-and-opportunities (Accessed 1/8/24).
9 "2024 Outlook for Health Care Planning for the Future of Health: Top trends for 2024" By Tina Wheeler and Wendy Gerhardt, Deloitte Health Solutions, December 6, 2023, https://www2.deloitte.com/us/en/blog/health-care-blog/2023/outlook-for-health-care.html (Accessed 1/8/24).
10 "Next in health services 2024: Healthcare's big squeeze and the way out" By Thom Bales and Laura Robinette, PWC, 2024, https://www.pwc.com/us/en/industries/health-industries/library/healthcare-trends.html (Accessed 1/8/24).
11 *Ibid.*
12 "US FTC opens investigation into OpenAI over misleading statements –document" Reuters, July 13, 2023, https://www.reuters.com/technology/us-ftc-opens-investigation-into-openai-washington-post-2023-07-13/ (Accessed 1/9/24).
13 "FACT SHEET: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence" The White House, October 30, 2023, https://www.whitehouse.gov/briefing-room/statements-releases/2023/10/30/fact-sheet-president-biden-issues-executive-order-on-safe-secure-and-trustworthy-artificial-intelligence/ (Accessed 1/8/24).
14 *Ibid.*
15 For more information, see "Biden Issues Executive Order on Artificial Intelligence" Health Capital Topics, Vol. 16, Issue 11 (November 2023), https://www.healthcapital.com/hcc/newsletter/11_23/HTML/ORDER/convert_biden_exec_order_ai.php (Accessed 1/19/24).
16 "Dr. Watson, A.I.: The Current Approach to Artificial Intelligence Training in the Medical Field and Legal Considerations for AI Diagnosis Dependence" By Allison Newsome and Jasmeet Singh, American Health Law Association, July 6, 2023, https://www.americanhealthlaw.org/content-library/publications/briefings/d88632df-8f1e-48ce-b5f4-066d19b12aa6/Dr-Watson-A-I-The-Current-Approach-to-Artificial-I?Token=60909932-7f8c-4a43-97b9-8bcb7e610f4e (Accessed 1/8/24).
17 *Ibid.*
18 "Next in health services 2024: Healthcare's big squeeze and the way out" By Thom Bales and Laura Robinette, PWC, 2024, https://www.pwc.com/us/en/industries/health-industries/library/healthcare-trends.html (Accessed 1/8/24).
19 *Ibid.*
20 *Ibid.*
21 Wheeler and Wendy Gerhardt, Deloitte Health Solutions, December 6, 2023.
22 *Ibid.*
23 *Ibid.*
24 "The US is suffering a healthcare worker shortage. Experts fear it will only get worse." By Alejandra O'Connell-Domenech, The Hill, September 28, 2023, https://thehill.com/changing-america/well-being/prevention-cures/4225960-the-us-is-suffering-a-healthcare-worker-shortage-experts-fear-it-will-only-get-worse/ (Accessed 1/9/24).
25 *Ibid.*
26 Bales and Laura Robinette, PWC, 2024.
27 *Ibid.*
28 Rao, McKinsey and Company, December 19, 2023.
29 *Ibid.*
30 *Ibid.*
31 *Ibid.*
32 *Ibid.*

PE-Acquired Hospitals Experience Adverse Patient Outcomes

[Excerpted from the article published in February 2024.]

On December 26, 2023, a study published in the Journal of the American Medical Association (JAMA) found concerning changes in patient outcomes and hospital adverse events associated with private equity (PE) acquisition and ownership of hospitals.[1] This Health Capital Topics article reviews the JAMA study and the impact of PE ownership on the healthcare industry.

Over the past ten years, PE firms have set their sights on hospitals as a lucrative investment opportunity, spending nearly $1 trillion to finance healthcare acquisitions, and purchasing more than 200 hospitals from non-PE owners.[2] Similar to in other healthcare industry subsectors, PE firms will purchase hospitals, push to increase income and decrease expenses, and sell them within a few years to generate a profit.[3] While the model has proved to be profitable for investors and PE firms, it has been scrutinized by providers, academics, and lawmakers,[4] who have argued that the model prioritizes revenue over providing quality care and that physicians under this model may be forced to take on more patients to maintain the stream of income.[5]

The JAMA study, a collaboration between Massachusetts General Hospital, Beth Israel Deaconess Medical Center, Harvard Medical School, and the University of Chicago, examined 662,905 hospitalizations at 51 hospitals acquired by PE firms.[6] Researchers also reviewed over 4.1 million hospitalizations at 259 matched control hospitals (i.e., hospitals not owned by PE firms), utilizing data from the Medicare Part A claims dataset.[7] Researchers analyzed hospital stays between 2009 and 2019, which accounted for three years before and after acquisition by PE firms.[8]

Hospital-acquired conditions (HACs), also referred to as hospital-acquired adverse events, were observed in 10,901 hospitalizations.[9] After hospitals were acquired by PE firms, Medicare beneficiaries admitted to those hospitals experienced a 25.4% increase in HACs compared to those treated at the control hospitals.[10] The study found that the increase in HACs was caused by:

- A 27.3% increase in falls;
- A 37.7% increase in central line-associated bloodstream infections, despite the placement of 16.2% fewer central lines; and
- Surgical site infections doubling from 10.8 to 21.6 per 10,000 hospitalizations, despite an 8.1% reduction in surgical volume.[11]

Researchers found that, compared to Medicare beneficiaries who received treatment at control hospitals, beneficiaries who received care at PE hospitals were younger, transferred to other acute care hospitals after short stays, and less likely to be eligible for both Medicare and Medicaid (i.e., the hospitals' admitted population had a much larger proportion of lower-risk/higher-reimbursing beneficiaries).[12] The researchers also noted that the increase in HACs may be linked to PE hospital staffing practices,[13] as PE hospitals tend to maintain reduced clinical staffing as a way to increase profits. However, reduced clinician staffing has been found to be associated with adverse patient events.[14]

The JAMA study's findings are largely in line with other research regarding the impact of PE ownership of healthcare entities. For example, a July 2023 British Medical Journal literature review of 55 studies between 2000 and 2023 found no beneficial impacts of PE ownership in healthcare.[15] Researchers stated that "the results of this study confirm the need for increased rigorous research on [PE] ownership in healthcare."[16] Researchers also said that the "current body of evidence is robust enough to confirm that [PE] ownership is a consequential and increasingly prominent element in healthcare, warranting surveillance, reporting, and possibly increased regulation."[17]

The research on PE hospital ownership, and its impact on quality of care and patient outcomes, has motivated both lawmakers and federal regulators to investigate PE's impact on the healthcare industry.[18] On December 6, 2023, Senators Chuck Grassley (R-IA) and Sheldon Whitehouse (D-RI) sent letters to PE firm executives and a for-profit PE hospital in Iowa requesting information related to questionable financial transactions that impacted patient care in PE-owned hospitals.[19] Additionally, on December 7, 2023, the White House announced that they would be addressing

anticompetitive "roll ups" (i.e., when PE firms engage in multiple small acquisitions to increase and consolidate their share of the market) by sharing data with the Federal Trade Commission (FTC), the Department of Justice (DOJ), and the Department of Health and Human Services (HHS).[20] Historically, lawmakers, judges and regulators have found it difficult to scrutinize PE transactions (and the motivations behind them) due to their transactional and organizational complexity.[21] However, recent efforts to increase transparency in healthcare may make it easier to decipher – and challenge – these transactions. PE investors currently own nearly 400 hospitals in the U.S., approximately one-third of all for-profit hospitals.[22] As PE's involvement in the U.S. healthcare system grows, regulatory scrutiny and enforcement is sure to follow.

---

1 "Changes in Hospital Adverse Events and Patient Outcomes Associated With Private Equity Acquisition" By Sneha Kannan, Joseph Dov Bruch, and Zirui Song, Journal of the American Medical Association, December 26, 2023, https://jamanetwork.com/journals/jama/article-abstract/2813379 (Accessed 1/17/24).

2 "Falls and infections rise in hospitals after private equity acquisitions, study finds" By Susanna Vogel, Healthcare Dive, January 3, 2024, https://www.healthcaredive.com/news/private-equity-hospitals-healthcare-adverse-events-rise-jama-study/703434/ (Accessed 1/17/24).

3 *Ibid.*

4 *Ibid.*

5 "Why Private Equity In Healthcare Is Receiving Closer Scrutiny By Journalists And Government" By Paul Hsieh, Forbes, July 31, 2023, https://www.forbes.com/sites/paulhsieh/2023/07/31/why-private-equity-in-heathcare-is-receiving-closer-scrutiny-by-journalists-and-government/?sh=1c692128178c (Accessed 1/31/24).

6 Kannan, Joseph Dov Bruch, and Zirui Song, Journal of the American Medical Association, December 26, 2023.

7 Medicare Part A principally covers inpatient hospital stays. "Changes in Hospital Adverse Events and Patient Outcomes Associated With Private Equity Acquisition" By Sneha Kannan, Joseph Dov Bruch, and Zirui Song, Journal of the American Medical Association, December 26, 2023, https://jamanetwork.com/journals/jama/article-abstract/2813379 (Accessed 1/17/24).

8 Kannan, Joseph Dov Bruch, and Zirui Song, Journal of the American Medical Association, December 26, 2023.

9 *Ibid.*

10 *Ibid.*

11 *Ibid.*

12 *Ibid.*

13 "Private equity acquisitions tied to adverse patient outcomes: Study" By Alexis Kayser, Becker's Clinical Leadership, December 26, 2023, https://www.beckershospitalreview.com/patient-safety-outcomes/private-equity-acquisitions-tied-to-adverse-patient-outcomes-study.html#:~:text=Private%20equity%20acquisitions%20tied%20to%20adverse%20patient%20outcomes%3A%20Study,-Alexis%20Kayser%20(Email&text=Patients%20treated%20at%20hospitals%20acquired,26. (Accessed 1/17/24).

14 *Ibid.*

15 "Evaluating trends in private equity ownership and impacts on health outcomes, costs, and quality: systematic review" By Alexander Borsa et al., British Medical Journal, July 19, 2023, https://www.bmj.com/content/382/bmj-2023-075244 (Accessed 1/17/23).

16 *Ibid.*

17 *Ibid.*

18 "Falls and infections rise in hospitals after private equity acquisitions, study finds" By Susanna Vogel, Healthcare Dive, January 3, 2024, https://www.healthcaredive.com/news/private-equity-hospitals-healthcare-adverse-events-rise-jama-study/703434/ (Accessed 1/17/24).

19 "Senate Budget Committee Digs Into Impact Of Private Equity Ownership In America's Hospitals" Office of Senator Chuck Grassley, December 6, 2023, https://www.grassley.senate.gov/news/news-releases/senate-budget-committee-digs-into-impact-of-private-equity-ownership-in-americas-hospitals#:~:text=Grassley%20and%20Whitehouse%20sent%20letters,a%20for%2Dprofit%20Iowa%20hospital. (Accessed 1/17/24).

20 "Senators probe private equity's role in hospital operations" By Susanna Vogel, Healthcare Dive, December 8, 2023, https://www.healthcaredive.com/news/senators-probe-private-equity-hospital-operations/702016/ (Accessed 1/17/24).

21 "'Shell game': When private equity comes to town, hospitals can see cutbacks, closures" By Anna Claire Vollers, Stateline, January 18, 2024, https://stateline.org/2024/01/18/shell-game-when-private-equity-comes-to-town-hospitals-can-see-cutbacks-closures/ (Accessed 1/19/24).

22 *Ibid.*

False Claims Act Recoveries Reach Historic High

[Excerpted from the article published in March 2024.]

Introduction

On February 22, 2024, the U.S. Department of Justice (DOJ) announced their recovery of $2.68 billion in settlements and judgments from civil cases related to the False Claims Act (FCA) for fiscal year (FY) 2023.[1] The FY 2023 overall recoveries were slightly higher than the FY 2022 recoveries of $2.2 billion.[2] Of the $2.68 billion recovered, over $1.8 billion was recouped from the healthcare industry alone, and included recoveries from managed care providers, hospitals, pharmacies, laboratories, physicians, and long-term care facilities.[3] These recoveries reflect the DOJ's focus on new enforcement priorities, including violations of cybersecurity requirements in government-funded grants and contracts and fraud in pandemic relief programs.[4]

Substandard Care & Unnecessary Services

The DOJ pursued a number of cases related to providers allegedly billing federal healthcare programs for unnecessary medical services.[5] Such services waste taxpayer money and can potentially expose patients to harmful treatments or procedures.[6] Various DOJ claims for unnecessary medical services were ultimately settled during FY 2023, including with the following organizations:

- **Smart Pharmacy Inc., SP2 LLC, and Gregory Balotin** paid $7.4 million to resolve allegations that they unnecessarily added an antipsychotic drug (aripiprazole) to topical pain creams to increase federal reimbursement for the creams, and waived patient co-payments. The DOJ alleged that the defendants crushed aripiprazole pills, which were only approved for oral usage, and included them in the creams used for pain treatments, knowing there was no clinical reason to do so.
- **Cornerstone Hospital Medical Center** and related entities paid $21.6 million to resolve allegations that the medical center (formerly a long-term acute care facility) knowingly submitted claims for services furnished by unauthorized and unlicensed students, as well as for services that were effectively worthless or not actually provided.
- **Saratoga Center for Rehabilitation and Skilled Nursing Care**, related entities, and individual owners and operators (Leon Melohn, Alan Schwartz, Jeffrey Vegh, and Jack Jeffa) agreed to pay $7.1 million to resolve allegations that Saratoga Center delivered services that were worthless to residents, which resulted in unnecessary falls, medication errors, and the development of pressure ulcers. Additionally, the facility's physical conditions had deteriorated to such a degree that there was not an adequate linen inventory or disposal of solid waste, and the facility did not consistently maintain hot water.[7]

Unlawful Kickbacks

Several lawsuits were filed in 2023 related to unlawful kickbacks. For example, the DOJ filed suit against multiple office-based labs owned by **Modern Vascular**, its affiliated companies, and its owner, Yury Gampel.[8] The suit alleged that the defendants offered referring physicians various forms of remuneration, including the opportunity to invest in Modern Vascular's labs with the potential for large monetary distributions, specifically to induce them to refer patients to the labs for the treatment of peripheral arterial disease.[9] The complaint also alleged that Gampel pressured interventional radiologists and vascular surgeons employed at the labs to increase the number of invasive surgical procedures.[10] Additionally, **Cardiac Imaging Inc.**, and its founder and CEO, Sam Kancherlapalli, agreed to pay $85.5 million to resolve allegations that, with Kancherlapalli's approval and oversight, Cardiac Imaging paid kickbacks to cardiologists in the form of above-fair market value (FMV) supervision fees, in order to induce the physicians to refer their patients to Cardiac Imaging for PET scans.[11] The DOJ asserted that the fees substantially exceeded FMV for the physician services, and included times the physicians were not physically on-site or in the mobile scanning units.[12]

The DOJ also filed lawsuits involving kickbacks relating to electronic health records (EHR). **NextGen Healthcare Inc.**

agreed to pay $31.2 million to resolve allegations that they misrepresented the capabilities of their EHR software by using a product that was designed specifically to meet government criteria for certification, but which otherwise lacked functionality.[13] The DOJ further alleged that NextGen provided unlawful remuneration in the form of credits – often worth up to $10,000 – as well as tickets to entertainment and sporting events, to customers whose recommendations of the software led to a new sale.[14] The DOJ settled a case with **Modernizing Medicine Inc.**, which agreed to pay $45.4 million to resolve federal allegations that it solicited and received kickbacks from a lab company in exchange for arranging and recommending that Modernizing Medicine's users utilize the lab company's pathology services, conspired with the lab company to improperly donate Modernizing Medicine's EHR to providers, and paid kickbacks to influential sources and customers to recommend their technology and refer customers to Modernizing Medicine.[15] The DOJ also alleged that Modernizing Medicine knew their technology did not allow physicians to record medical records with the appropriate vocabularies, thereby causing certain users to submit false claims for incentive payments under the Department of Health and Human Services (HHS) EHR Incentive Programs.[16]

Additionally, **Carter Healthcare LLC**, a for-profit home health provider, as well as its affiliates, president, and chief operations officer, agreed to pay $22.9 million to settle allegations that Carter Healthcare improperly paid remuneration to physicians under the guise of medical directorships, which in turn induced referrals of home health patients.[17] The DOJ also resolved numerous matters involving laboratories and their recruiters, which allegedly provided physicians kickbacks disguised as legitimate payments.[18] Ten individuals and five corporate entities paid $2.6 million to settle allegations of kickbacks in exchange for laboratory referrals, which included fake investment distributions from management service organizations (MSOs).[19]

Medicare Advantage Fraud

In addition to pursuing cases related to unlawful kickbacks, the DOJ intervened in cases related to Medicare Advantage (MA) (also known as Medicare Part C) plans. Because MA pays providers a set amount per enrolled patient, which amount is then adjusted by several risk factors that affect expected healthcare expenditures (i.e., a plan with more higher-risk patients would receive more reimbursement), the government has a strong interest in ensuring that providers do not manipulate the risk adjustment process. One case was filed against **Cigna,** and other cases continue to be litigated against **UnitedHealth Group**, **Independent Health Corporation**, **Elevance Health**, and the **Kaiser Permanente group**.[20]

Pandemic-Related Fraud

During the COVID-19 pandemic, Congress authorized emergency funding to provide financial assistance directly to state, local, and Tribal governments, as well as to businesses and individuals. The DOJ has pursued cases involving improper payment from the Paycheck Protection Program (PPP), which provided forgivable loans to small businesses (both healthcare and non-healthcare) for payroll, rent, and other operational costs. In FY 2023, the department resolved 270 FCA matters related to improper PPP loans, recovering $48.3 million.[21] The DOJ also pursued cases against other fraud related to the pandemic, including schemes to profit from the pandemic by billing for unnecessary services and tests.[22]

Conclusion

Money recovered by the DOJ through healthcare fraud enforcement is crucial in returning assets back to federally-funded programs such as Medicare, Medicaid, and TRICARE. Of the $2.68 billion recovery, $2.3 billion resulted from lawsuits that were filed under the *qui tam* provisions of the FCA.[23] The FCA's *qui tam*, or whistleblower, provision allows any private citizen to enforce the FCA by filing a complaint, on behalf of the federal government, alleging fraud against the government. The DOJ assumes primary responsibility for prosecuting the claim if it believes the claim has merit, and the whistleblower is entitled to share in a portion of any recovery in the case, whether or not the government becomes involved.[24] The number of lawsuits filed under the *qui tam* provisions has grown significantly since 1986, with 712 *qui tam* suits filed in FY 2023, an increase from the 652 *qui tam* suits filed in FY 2022.[25] Nevertheless, the DOJ's continued active interest and involvement in fraud and abuse cases in 2023 suggests that FCA enforcement will remain high going forward.

Going forward, DOJ Principal Deputy Assistant Attorney General Brian Boynton noted that the DOJ would continue its prosecutorial focus on fraud (specifically as relates to financial relationships under the Stark Law and Anti-Kickback Statute), nursing homes, participants in the MA program (including vendors, plans, and providers), and pandemic spending.[26] Boynton also mentioned the DOJ's interest in third parties (i.e., EHR software providers and coding consultants and private equity investors) and their impact on federal program spending and patient care delivery.[27]

---

1 "False Claims Act Settlements and Judgments Exceed $2.68 Billion in Fiscal Year 2023" Office of Public Affairs, Department of Justice, February 22, 2024, https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023#:~:text=Settlements%20and%20judgments%20under%20the,Associate%20Attorney%20General%20Benjamin%20C (Accessed 2/29/24).
2 *Ibid.*
3 *Ibid.*
4 *Ibid.*
5 *Ibid.*
6 *Ibid.*
7 *Ibid.*
8 *Ibid.*
9 *Ibid.*
10 *Ibid.*
11 *Ibid.*
12 *Ibid.*
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
16 *Ibid.*
17 *Ibid.*
18 *Ibid.*
19 *Ibid.*
20 *Ibid.*
21 *Ibid.*
22 *Ibid.*
23 *Ibid.*
24 "Civil Actions for False Claims" 31 U.S.C. § 3730.
25 Office of Public Affairs, Department of Justice, February 22, 2024; "False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022" Office of Public Affairs, Department of Justice, February 7, 2023, https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022 (Accessed 2/29/24).
26 "DOJ and OIG Actions: 2023 Enforcement Trends Recap" By Tony Maida, Monica Wallace, and Emily Jane Cook, McDermott Will & Emery, February 28, 2024, https://www.mwe.com/insights/doj-and-oig-actions-2023-enforcement-trends-recap/ (Accessed 3/6/24).
27 *Ibid.*

Federal Regulators Launch Inquiry into PE-Backed Healthcare Deals

[Excerpted from the article published in March 2024.]

On March 5, 2024, the Department of Justice's (DOJ's) Antitrust Division, the Federal Trade Commission (FTC), and the Department of Health and Human Services (HHS), announced the launch of a multi-agency inquiry – in the form of a request for information (RFI) and public workshop – focusing on the increasing control of private equity (PE) and other corporations over the healthcare industry.[1] This Health Capital Topics article discusses the agencies recent actions and how it appears to be in line with the government's recent moves to crack down on anticompetitive actions in healthcare.

The RFI poses five major overarching sets of questions relating to healthcare investments by PE funds and other healthcare industry players:

(1) How have transactions involving facilities, healthcare providers, ancillary services or products "by PE funds or other alternative asset managers, health systems, or private payers" impacted patient care, the treatment of private and public payors, employers who provide employees health insurance, and the conditions under which healthcare workers, support staff, and providers work?

(2) What were the claimed business goals for the transaction, and were those objectives post-transaction? Who benefited from the achievement of those objectives post-transaction? Did the transaction require the acquired entity to undergo restructuring or take on additional debt? If the transaction generated surplus profits, did the surplus profits get reinvested in the acquired business, or were they paid to shareholders?

(3) Are there certain types of entities, such as PE funds or health systems, in these transactions that seem to have the greatest adverse impact on private and public payors, patients, providers, or employers that provider health insurance for employees? Are there particular providers, payors, facilities, and ancillary services or products that are most often the target of these harmful transactions, and if so, who are these targets?

(4) What actions should federal agencies take to address and identify transactions that may have major adverse impacts on private and public payors, patients, providers, or employers that provide employees health insurance? Should the agencies promote greater transparency and availability of information to the public on mergers, acquisitions, and other transactions involving ancillary services or products, payors, providers, and healthcare facilities, and if so, how?

(5) Are there any other impacts from transactions in the healthcare market of which the agencies should be aware?[2]

The agencies specifically requested input from various healthcare industry stakeholders, including hospitals, post-acute care providers, physicians, nurses, patients, consumer advocates, healthcare administrators, employers, insurers, pharmacy benefit managers (PBMs), group purchasing organizations (GPOs), and other healthcare providers and facilities.[3] The agencies also welcomed comments from "academics and other experts who have studied market consolidation, corporate control in health care, and related issues."[4] In addition, DOJ, FTC, and HHS are interested in receiving input from healthcare workers and patients on their experiences after a merger or acquisition.[5] Comments in response to the RFI can be submitted through May 6, 2024.[6]

In addition to the RFI, the three agencies participated in a virtual public workshop on March 5, 2024, with practitioners, economists, academics, and other members of the public.[7] The workshop explored the impact of PE in healthcare, and discussed what the government was doing to address any harmful effects.[8]

The concerns expressed within the cross-government inquiry are supported by recent research on the topic. For example, one study found concerning changes in patient outcomes and hospital adverse events associated with PE acquisition and ownership of hospitals.[9] Another study found that the purchasing patterns of PE firms have led to the sharp decline in the number of independent physician practices, with insurers and health systems also acquiring physicians at an accelerated rate over the last ten years.[10] The research on PE involvement in healthcare over the past few years, and specifically its impact on the quality of care and patient outcomes, has motivated both lawmakers and federal regulators to further investigate PE's impact on the healthcare industry increase regulatory scrutiny.[11]

These recent moves by the DOJ, FTC, and HHS are just the latest in the federal government's increasingly emboldened moves in the healthcare antitrust space over the past few years. As discussed in previous Health Capital Topics articles:

- In December 2018, the HHS, Treasury, and Labor, issued a report entitled, "Reforming America's Healthcare System Through Choice and Competition," exploring how to improve the U.S. healthcare delivery system by increasing competition in the healthcare industry;[12]
- The FTC has been challenging an increasing number of hospital mergers and acquisitions, indicating heightened regulatory scrutiny of hospital transactions; [13]
- In August 2022, the 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 asserted that COPAs negatively impact healthcare costs, quality of care, and hospital staff wages; [14]
- In January 2023, the FTC published a proposed rule that would ban employers from imposing non-compete clauses on their employees. A final rule regarding this issue is expected later in 2024;[15]
- On September 21, 2023, the FTC sued U.S. Anesthesia Partners (USAP), a Texas-based anesthesia provider, and Welsh, Carson, Anderson & Stowe (Welch Carson), a PE firm. The FTC alleged that the two companies executed an anticompetitive scheme for multiple years to consolidate anesthesiology practices in Texas, boost their profits, and drive up the price of anesthesia services rendered to patients.[16]

Assistant Attorney General Jonathan Kanter of the DOJ's Antitrust Division stated that "preserving competition in health care markets is a priority for the Justice Department because of its important impact on the health and well-being of Americans."[17] Kanter also said that the RFI "will enable the agencies to accurately understand the modern market realities of the health care industry and forcefully enforce the law against unlawful deals. Hearing from patients, workers and market participants will be critical in developing future enforcement and policy efforts relating to consolidation in the health care sector."[18] FTC Chair, Lina Khan, added that "when private equity firms buy out healthcare facilities only to slash staffing and cut quality, patients lose out."[19] Khan also stated that "through this inquiry, the FTC will continue scrutinizing private equity roll-ups, strip-and-flip tactics and other financial plays that can enrich executives but leave the American public worse off."[20]

Historically, lawmakers, judges and regulators have found it difficult to scrutinize PE transactions (and the motivations behind them) due to their transactional and organizational complexity.[21] However, recent efforts to increase transparency in healthcare may make it easier to decipher – and challenge – these transactions. As PE's involvement in the U.S. healthcare system grows, regulatory scrutiny and enforcement will likely (continue to) follow.

1 "Justice Department, Federal Trade Commission and Department of Health and Human Services Issue Request for Public Input as Part of Inquiry into Impacts of Corporate Ownership Trend in Health Care" Office of Public Affairs, Department of Justice, March 5, 2024, https://www.justice.gov/opa/pr/justice-department-federal-trade-commission-and-department-health-and-human-services-issue (Accessed 3/6/24); "Request for Information on Consolidation in Health Care Markets" Department of Justice, Department of Health and Human Services, Federal Trade Commission, February 29, 2024, https://content.govdelivery.com/attachments/USDOJOPA/2024/03/05/file_attachments/2803589/DOJ-FTC-HHS%20HCC%20RFI%20-%2003.04.24%20-%20FINAL.pdf (Accessed 3/12/24).

2 "Request for Information on Consolidation in Health Care Markets" Department of Justice, Department of Health and Human Services, Federal Trade Commission, February 29, 2024, https://content.govdelivery.com/attachments/USDOJOPA/2024/03/05/file_attachments/2803589/DOJ-FTC-HHS%20HCC%20RFI%20-%2003.04.24%20-%20FINAL.pdf (Accessed 3/12/24).

3 "FTC Hosts Panel and Launches Public Inquiry with DOJ and HHS on Private Equity and Health Care" By Karen Lovitch, Bruce Sokler, Joseph Miller, and Raj Gambhir, Mintz, March 6, 2024, https://www.mintz.com/insights-center/viewpoints (Accessed 3/8/24).

4 Lovitch, Bruce Sokler, Joseph Miller, and Raj Gambhir, Mintz, March 6, 2024.

5 *Ibid.*

6 *Ibid.*

7 "FTC to Host Virtual Workshop on Private Equity in Health Care" Federal Trade Commission, February 14, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/02/ftc-host-virtual-workshop-private-equity-health-care (Accessed 3/12/24).

8 *Ibid.*

9 "Changes in Hospital Adverse Events and Patient Outcomes Associated With Private Equity Acquisition" By Sneha Kannan, Joseph Dov Bruch, and Zirui Song, Journal of the American Medical Association, December 26, 2023, https://jamanetwork.com/journals/jama/article-abstract/2813379 (Accessed 3/6/24).

10 "More physicians are employed by private equity, study shows" By Alex Kacik, Modern Healthcare, March 5, 2024, https://www.modernhealthcare.com/mergers-acquisitions/private-equity-acquire-physician-groups-study-ftc?utm_source=modern-healthcare-daily-finance-tuesday&utm_medium=email&utm_campaign=20240305&utm_content=article5-readmore (Accessed 3/6/24).

11 "Falls and infections rise in hospitals after private equity acquisitions, study finds" By Susanna Vogel, Healthcare Dive, January 3, 2024, https://www.healthcaredive.com/news/private-equity-hospitals-healthcare-adverse-events-rise-jama-study/703434/ (Accessed 3/6/24).

12 "Federal Agencies Recommend Policies to Increase Healthcare Competition" Health Capital Topics, Vol. 11, Issue 12 (December 2018), https://www.healthcapital.com/hcc/newsletter/12_18/HTML/POLICY/convert_policy_recommendations_cite_chked_cataloged_12.20.18_hba.php (Accessed 10/25/23).

13 See, e.g., "FTC Scrutiny Results in Several Scrapped Hospital Deals" Health Capital Topics, Vol. 15, Issue 6 (June 2022), https://www.healthcapital.com/hcc/newsletter/06_22/HTML/FTC/convert_ftc-health-capital-topics.php (Accessed 10/25/23).

14 "FTC Discourages Certificates of Public Advantage Laws" Health Capital Topics, Vol. 15, Issue 8 (August 2022), https://www.healthcapital.com/hcc/newsletter/08_22/HTML/FTC/convert_ftc-policy-against-copas-8.26.22.php (Accessed 10/25/23).

15 "FTC Proposes Banning Non-Compete Clauses" Health Capital Topics, Vol. 16, Issue 1 (January 2023), https://www.healthcapital.com/hcc/newsletter/01_23/HTML/NONCOMPETE/convert_noncompete-proposed-rule-topics-article.php (Accessed 10/25/23).

16 "FTC Lawsuit Targets Private Equity" Health Capital Topics, Vol. 16, Issue 10 (October 2023), https://www.healthcapital.com/hcc/newsletter/10_23/HTML/FTC/convert_ftc_lawsuit_targets_pe.php (Accessed 3/6/24).

17 "Justice Department, Federal Trade Commission and Department of Health and Human Services Issue Request for Public Input as Part of Inquiry into Impacts of Corporate Ownership Trend in Health Care" Office of Public Affairs, Department of Justice, March 5, 2024, https://www.justice.gov/opa/pr/justice-department-federal-trade-commission-and-department-health-and-human-services-issue (Accessed 3/6/24).

18 *Ibid.*

19 *Ibid.*

20 *Ibid.*

21 *Ibid.*

DOJ Antitrust Reportedly Investigating UnitedHealth Group

[Excerpted from the article published in April 2024.]

On February 27, 2024, the Wall Street Journal (WSJ) reported that the Department of Justice (DOJ) has launched an antitrust investigation into UnitedHealth Group (UHG), the owner of the biggest health insurer in the U.S. and the leading manager of drug benefits and one of the largest networks of physician groups.[1] This investigation comes as the Biden administration's antitrust enforcers have ramped up investigations into some of the biggest U.S. companies, including Amazon, Apple, and Google.[2] This Health Capital Topics article reviews the reported government investigation.

In interviews with healthcare industry stakeholders, investigators purportedly have been inquiring into UHG's effect on competition, particularly in healthcare.[3] UHG operates in nearly every healthcare industry subsector: it is one of the largest pharmacy benefit managers (PBMs) in the country and runs a large data analytics and billing business, a sizable network of physicians, and the largest private health insurer in the U.S.[4] Investigators are reportedly focusing on the relationship between Optum, its health services arm, and UnitedHealthcare, its insurance business.[5]

According to sources close to the investigation, antitrust regulators are specifically interested in whether Optum's acquisition of physician practices may be creating an anticompetitive environment for other providers and consumers.[6] Optum has been acquiring provider practices for years, and is currently the largest physician employer in the U.S., with 90,000 employed or aligned physicians.[7] DOJ investigators been examining whether UnitedHealthcare favors Optum's physician groups in their contracting practices, which may have prevented rival providers from participating in certain payment arrangements.[8]

DOJ officials are also investigating UHG's Medicare billing, including company practices related to documenting patient illness.[9] When patients have more health conditions, payments to Medicare plans increase, so aggressive documentation practices by healthcare providers can be lucrative for health insurers like UnitedHealthcare.[10] Investigators have also inquired if the relationship between Optum and UnitedHealthcare may affect UnitedHealthcare's compliance with federal rules that cap how much insurance companies can retain from the premiums they collect from customers.[11] The Patient Protection and Affordable Care Act (ACA) requires insurers to spend at least 80-85% of premiums received on medical care (known as the Medical Loss Ratio, or MLR).[12] In other

words, insurers are not allowed to allocate more than 15-20% of received premium to their profits and administrative costs, with exact percentages varying depending on the type of plan.[13] Anything above the MLR must be rebated back to customers or spent on patient care.[14] When the company owns both the providers who take care of patients and the health insurer, the combined firm may absorb far more than the capped amount, as the providers and the health insurer can each absorb 15-20% of premiums for profits and administrative costs.[15]

This investigation is the latest in the heightened government scrutiny UHG has faced over the past two years in regard to its business practices. In 2022, the DOJ unsuccessfully sued to block UHG from acquiring Change Healthcare, the largest electronic data clearinghouse that connects providers and pharmacies with insurance companies for reimbursement purposes.[16] The DOJ has also been reviewing Optum's plan to purchase home health provider Amedisys Inc. for $3.3 billion, after Optum acquired one of Amedisys's rivals, LHC Group, for $5.4 billion in early 2023.[17] The agency had previously requested additional information regarding the proposed transaction, and has been deposing parties on the particulars.[18] However, on March 20, 2024, it was reported for the first time that the DOJ is considering suing to block the Amedisys acquisition, perhaps because of the resulting consolidation in the home health market, as LHC and Amedisys together would comprise approximately 10% of the home health market.[19] UHG unsurprisingly finds itself the target of antitrust regulators due in part to being the largest healthcare company in the U.S., with a revenue of $372 billion and $23 billion in profits in 2023.[20]

UHG has expanded its strong foothold in the healthcare industry through relentless acquisitions.[21] For example, in 2023, UHG had the largest market share in the commercial health insurance market, at 14%, and in the Medicare Advantage market, at 42%.[22] The DOJ's investigation of UHG highlights regulators' growing concern regarding the anticompetitive effects of vertical consolidation, e.g., when insurers acquire physician practices or other providers.[23]

Regulators have been aggressively cracking down on anticompetitive business practices, and the healthcare sector has been an investigative priority for the past few years.[24] The investigation is still in its early stages, and the DOJ has not alleged any wrongdoing to date.[25] The DOJ and UHG have both declined to comment on the investigation.[26]

---

1 "U.S. Opens UnitedHealth Antitrust Probe" By Anna Wilde Mathews and Dave Michaels, The Wall Street Journal, February 27, 2024, https://www.wsj.com/health/healthcare/u-s-launches-antitrust-investigation-of-healthcare-giant-unitedhealth-ff5a00d2?mod=Searchresults_pos1&page=1 (Accessed 3/14/24).
2 *Ibid.*
3 "UnitedHealth under antitrust investigation by DOJ: reports" By Rebecca Pifer, Healthcare Dive, February 28, 2024, https://www.healthcaredive.com/news/unitedhealth-antitrust-investigation-doj-unitedhealthcare-optum/708727/ (Accessed 3/14/24).
4 *Ibid.*
5 *Ibid.*
6 *Ibid.*
7 *Ibid.*
8 "Our Take: New DOJ investigation into UnitedHealth Group, Optum focuses on potential antitrust practices" Darwin Research Group, March 4, 2024, https://www.darwinresearch.com/our-take-new-doj-investigation-into-unitedhealth-group-optum-focuses-on-potential-antitrust-practices/ (Accessed 3/15/24).
9 Mathews and Michaels, The Wall Street Journal, February 27, 2024.
10 *Ibid.*
11 *Ibid.*
12 "Medical Loss Ratio" Centers for Medicare & Medicaid Services, https://www.cms.gov/marketplace/private-health-insurance/medical-loss-ratio (Accessed 32824).
13 Mathews and Michaels, The Wall Street Journal, February 27, 2024.
14 *Ibid.*
15 *Ibid.*
16 "UnitedHealth Faces Antitrust Probe by US Justice Department" By John Tozzi, Bloomberg Law, February 28, 2024, https://news.bloomberglaw.com/health-law-and-business/unitedhealth-faces-justice-department-antitrust-probe-wsj-says (Accessed 3/15/24).
17 *Ibid.*
18 "Amedisys dips amid report DOJ considering lawsuit" By Joshua Fineman, Seeking Alpha, March 20, 2024, https://seekingalpha.com/news/4081764-amedisys-dips-amid-report-doj-considering-lawsuit-to-block-unitedhealth-deal (Accessed 3/25/24).
19 "DOJ Reportedly Considering Lawsuit To Block Optum-Amedisys Deal" By Andrew Donlan, Home Health Care News, March 20, 2024, https://homehealthcarenews.com/2024/03/doj-reportedly-considering-lawsuit-to-block-optum-amedisys-deal/?euid=a15cb437da&utm_source=hhcn-newsletter&utm_medium=email&utm_campaign=91161e104d&mc_cid=91161e104d&mc_eid=a15cb437da (Accessed 3/25/24).
20 Pifer, Healthcare Dive, February 28, 2024.
21 "Building a Giant" By Krista Brown, Sara Sirota, The American Prospect, December 20, 2023, https://prospect.org/health/2023-12-20-building-a-giant-unitedhealth/ (Accessed 3/15/24).
22 "AMA identifies market leaders in health insurance" American Medical Association, December 12, 2023, https://www.ama-assn.org/press-center/press-releases/ama-identifies-market-leaders-health-insurance (Accessed 3/15/24).
23 Pifer, Healthcare Dive, February 28, 2024.
24 *Ibid.*
25 *Ibid.*
26 *Ibid.*

New Strike Force Targets Unfair & Illegal Pricing

[Excerpted from the article published in April 2024.]

On March 5, 2024, the White House announced plans to launch an interagency strike force to lower costs across the U.S. economy.[1] The Strike Force on Unfair and Illegal Pricing will be co-chaired by the Federal Trade Commission (FTC) and the Department of Justice (DOJ) and aims to strengthen the agencies' efforts to stop illegal corporate behavior that increases prices for Americans through deceptive, anti-competitive, unfair, and fraudulent business practices.[2]

While details are currently sparse, it has been announced that the strike force, on which various additional agencies will participate in addition to the FTC and DOJ, will focus its efforts "on key sectors where corporations may be violating the law and keeping prices high, including prescription drugs and health care, food and grocery, housing, financial services, and more."[3] The strike force will focus primarily on enforcement, and will scrutinize multiple industries, including healthcare.[4] The Department of Health and Human Services (HHS) is also expected to be a part of the strike force, focusing on enforcement actions related to the healthcare industry.[5]

The creation of this strike force is the latest step in the federal government's push (across two presidential administrations) to increase competition in the healthcare industry. In 2018, HHS, the Department of the Treasury, and the Department of Labor issued a 119-page report comprising over 50 recommendations to increase quality, decrease cost, and promote competition in healthcare.[6] In 2021, President Biden issued an executive order to promote competition in the American economy.[7] The executive order was designed to address issues the administration identified as contributing to harmful trends associated with decreased competition and corporate consolidation, which are ultimately harming American consumers.[8] The executive order, which set forth 72 initiatives for multiple federal agencies, did not immediately establish requirements, but rather directed federal agencies to review issues and implement policies to reflect the administration's goals.[9] Pursuant to the executive order, federal agencies have taken action over the past couple of years to lower healthcare and prescription drug costs for consumers as well as increase competition and safety in healthcare facilities.[10] Some of these actions include:

- HHS and the Centers for Medicare & Medicaid Services (CMS) is currently collecting feedback on how the agencies can promote competition, increase transparency, and identify the effects of vertical integration in Medicare Advantage (MA) markets.
- The FTC, DOJ, and HHS published a Request for Information (RFI) to receive feedback and examine the role of corporate influence and private equity in the healthcare industry.
- CMS released ownership data for Federally Qualified Health Centers (FQHCs) in an effort to promote competition and increase transparency.
- HHS published Medicare-certified nursing home ownership data, increasing transparency of and the ability to identify common owners and those that had a history of poor performance.
- HHS announced steps to crack down on nursing homes that put resident safety at risk, including a proposed rule that set minimum staffing levels to ensure a higher quality of life for residents.
- The Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office (USPTO) announced increased scrutiny of pharmaceutical patents that resulted in higher prescription drug costs. The FDA and USPTO also began collaborating on ways to improve the patent system in order to increase access to affordable and safe prescription drugs.
- HHS enacted a rule cracking down on hospitals that failed to disclose their prices pursuant to Hospital Price Transparency requirements, including increasing nearly twentyfold the fine for hospitals that failed to report their prices.[11]

Further, the executive order called for the formation of the White House's Competition Council, comprised of eight cabinet members and seven independent agencies, which "drives the Administration's whole-of-government effort to restore competition and coordinate progress on the Executive Order's 72 initiatives, delivering concrete benefits of increased competition to America's consumers, workers, farmers, and small businesses."[12] The announcement of the strike force is one of three new actions by the Competition Council to promote competition in the American economy.[13]

The announcement of the strike force also followed the appointment of Stacy Saunders on January 8, 2024, who will serve as the HHS's inaugural Chief Competition Officer.[14] In this newly-created role, Saunders will be responsible for identifying, coordinating, and elevating opportunities across HHS to promote competition in healthcare markets.[15] The Chief Competition Officer will also play a role in working with the FTC and DOJ to address healthcare market concentration through reciprocal training programs, data-sharing, and the further development of additional healthcare competition policy initiatives.[16]

In a call with reporters, FTC Chair Lina Khan said that the FTC was "excited to be co-chairing the president's new strike force on unfair and illegal pricing, which builds on the FTC's far-reaching work to promote competition and tackle unlawful business practices that are inflating costs for Americans."[17] Assistant Attorney General for DOJ's Antitrust Division, Jonathan Kanter, stated in the same briefing that the strike force will be a "new chapter in a fight against unfair and anticompetitive pricing."[18]

On March 5, 2024, the U.S. Chamber of Commerce published a statement expressing their concerns with the strike force, and stated that "this effort by the Biden Administration to use regulatory agencies to micromanage how private businesses set prices will have the same result: shortages, fewer choices for consumers, a weaker economy, and less jobs."[19] The statement also asserted that "the strike force will be led by two agencies that, for the past three years, have been openly hostile to market efficiencies — blatantly ignoring lower prices and better outcomes for consumers."[20] While some have concerns with the announcement of the strike force, others view the announcement as simply a symbolic gesture.[21] Stephen Calkins, a professor of law at Wayne State University and former general counsel of the FTC, stated that "this is an exercise in marketing, not competition promotion."[22] Calkins also mentioned that the "strike force" could be a bold term to catch the attention of the public.[23]

Some policy experts believe that the strike force may not be effective, as there is not a set standard for determining if the price of a certain product is too high.[24] The FTC and DOJ have been able to bring enforcement actions in cases where companies engage in price-fixing or other anticompetitive actions, but price regulation has not been previously included in that scope.[25]

Nevertheless, the development of an interagency strike force seems to be yet another indication of the federal government's increasing focus on enhancing competition in the healthcare industry.

1 "FACT SHEET: President Biden Announces New Actions to Lower Costs for Americans by Fighting Corporate Rip-Offs" The White House, March 5, 2024, https://www.whitehouse.gov/briefing-room/statements-releases/2024/03/05/fact-sheet-president-biden-announces-new-actions-to-lower-costs-for-americans-by-fighting-corporate-rip-offs/ (Accessed 3/13/24).
2 *Ibid.*
3 *Ibid.*
4 "White House turns to health care in Biden's latest move against 'corporate greed" By Josh Sisco, Adam Cancryn, and Megan Wilson, Politico, March 4, 2024, https://www.politico.com/news/2024/03/04/biden-health-care-task-force-inflation-00144713 (Accessed 3/20/24).
5 "White House announces 'strike force' on unfair and illegal prices ahead of State of the Union" By Josh Sisco, Politico, March 5, 2024, https://www.politico.com/news/2024/03/05/white-house-announces-strike-force-on-unfair-and-illegal-prices-ahead-of-state-of-the-union-00144829 (Accessed 3/20/24).
6 "HHS Unveils Plans to Increase Healthcare Competition, Choice" By Jacqueline LaPointe, RevCycle Intelligence, December 5, 2018, https://revcycleintelligence.com/news/hhs-unveils-plans-to-increase-healthcare-competition-choice (Accessed 3/12/23).
7 "Executive Order on Promoting Competition in the American Economy" White House Press Release, July 9, 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/ (Accessed 3/13/24).
8 "Unprecedented Executive Order 14036 "Promoting Competition in the American Economy" – a call to action" By Christopher Brennan, Selina Coleman, Brad Funari, and Michelle Mantine, July 15, 2021, https://www.reedsmith.com/en/perspectives/2021/07/unprecedented-executive-order-14036 (Accessed 3/13/24).
9 *Ibid.*
10 "White House Competition Council" White House, 2024, https://www.whitehouse.gov/competition/ (Accessed 3/14/24).
11 *Ibid.*
12 "Readout of the Fifth Meeting of the White House Competition Council" The White House, July 20, 2023, https://www.whitehouse.gov/briefing-room/statements-releases (Accessed 3/27/24); "Readout of the Inaugural Meeting of the White House Competition Council" The White House, September 10, 2021, https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/10/readout-of-the-inaugural-meeting-of-the-white-house-competition-council/ (Accessed 3/28/24).
13 "Biden Administration Announces New Initiative to Challenge Unfair and Illegal Pricing Practices" By Kaylee Racs, Anna Behrmann, and Kathy Osborn, Faegre Drinker, March 18, 2024, https://www.faegredrinker.com/en/insights/publications/2024/3/biden-administration-announces-new-initiative-to-challenge-unfair-and-illegal-pricing-practices (Accessed 3/27/24).
14 "Secretary Becerra Names Chief Competition Officer to Help Identify Areas to Promote Competition in Health Care" HHS Press Office, Department of Health and Human Services, January 8, 2024, https://www.hhs.gov/about/news/2024/01/08/secretary-becerra-names-chief-competition-officer-to-help-identify-areas-to-promote-competition-in-health-care.html (Accessed 3/13/24).
15 *Ibid.*
16 *Ibid.*
17 "DOJ, FTC Lead New White House Strike Force on Unfair and Illegal Pricing" By Maydeen Merino, The National Law Journal, March 5, 2024, https://www.law.com/nationallawjournal/2024/03/05/doj-ftc-lead-new-white-house-strike-force-on-unfair-and-illegal-pricing/ (Accessed 3/20/24).
18 "Biden hopes for political gains from FTC-DOJ task force" By Claude Marx, March 12, 2024, https://www.mlexwatch.com/ftcwatch/articles/1811452/biden-hopes-for-political-gains-from-ftc-doj-task-force (Accessed 3/20/24).
19 "U.S Chamber: White House Strike Force an Attempt to Return to Government Price Controls" U.S. Chamber of Commerce, March 5, 2024, https://www.uschamber.com/finance/antitrust/u-s-chamber-white-house-strike-force-an-attempt-to-return-to-government-price-controls (Accessed 3/27/24).
20 *Ibid.*
21 "President Biden has created a 'strike force' to combat high prices. Experts wonder whether it will work." By Bill Peters, The Wall Street Journal, March 8, 2024, https://www.wsj.com/articles/WP-MKTW-0003068492?mod=article_recs_pos1_sb_hp&next_redirect=true (Accessed 3/27/24).
22 *Ibid.*
23 *Ibid.*
24 "Biden Administration Announces New Initiative to Challenge Unfair and Illegal Pricing Practices" By Kaylee Racs, Anna Behrmann, and Kathy Osborn, Faegre Drinker, March 18, 2024, https://www.faegredrinker.com/en/insights/publications/2024/3/biden-administration-announces-new-initiative-to-challenge-unfair-and-illegal-pricing-practices (Accessed 3/27/24).
25 *Ibid.*

CMS's 2024 Updates to Risk-Adjustment Model

[Excerpted from the article published in April 2024.]

Beginning January 1, 2024, the Centers for Medicare and Medicaid Services (CMS) updated its Medicare Advantage (MA) Capitation Rates, as well as Part C and Part D Payment Policies, which finalized the switch to a revised CMS-Hierarchical Condition Category (HCC) risk-adjustment model, Version 28 (V28).[1] The last version of the CMS-HCC risk-adjustment model, Version 24 (V24), was released in 2020.[2] The changes in the CMS-HCC risk-adjustment model V28 impact multiple programs, including MA, the Medicare Shared Savings Program (MSSP), and the Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health (REACH) Model.[3] This Health Capital Topics article discusses the various changes and updates included in the recently-enacted version of the risk-adjustment model.

HCCs have been used by CMS since 2004 as a part of the risk-adjustment model, which identifies patients with serious acute or chronic conditions.[4] HCCs are sets of medical codes that are tied to certain clinical diagnoses.[5] By using HCCs, CMS is able to project the expected risk from patients, as well as the future cost of care.[6] RAF scores are also an integral part of the risk-adjustment model that CMS uses to estimate the cost of caring for beneficiaries, and the score determines the amount CMS will pay health plans and providers per beneficiary during the corresponding payment year.[7] RAF scores are based on both disease risk scores and demographics.[8] Disease risk scores are based on the diagnoses from patient encounters and their corresponding HCC codes, and the demographic score is based on sex, age, and residence (i.e., in a skilled nursing facility, the community, or other institution).[9] A higher RAF score can indicate a sicker patient, while a lower RAF score can indicate a healthier patient.[10] However, low RAF scores could also indicate inaccuracy in coding due to a gap in care or the patient record lacking information.[11]

In general, CMS updated its CMS-HCC risk-adjustment model to V28 to reflect recent diagnostic, cost, and utilization patterns.[12] Aside from improving payment accuracy, the risk-adjustment model will also reduce differences in coding between fee-for-service (FFS) providers and MA plans.[13] The risk-adjustment model will require greater specificity in code assignment and documentation to ensure the level of all patients' illness severity is appropriately represented.[14] By requiring this level of specificity, CMS will be able to collect data on the severity of patient illnesses, and take the data into consideration when recommending changes in future risk-adjustment models.[15]

CMS-HCC risk-adjustment model V28 will be phased in over three years as follows:

For services provided during 2023, a blend of risk-adjustment model V24 (67%) and risk-adjustment model V28 (33%) was used;

(1) For services provided during 2024, a more updated blend of risk-adjustment model V24 (33%) and risk-adjustment model V28 (67%) is being used; and
(2) For services provided during 2025, solely risk-adjustment model V28 (i.e., 100%) will be used.[16]

Due to changes in the risk-adjustment model V28, navigating both V24 and V28 in concert could create challenges for providers.[17] Conditions that may be considered an HCC in one version may not be considered an HCC in the other.[18] Even if a diagnosis is an HCC in both V24 and V28, the actual risk-adjustment factors (RAFs) and HCC may differ.[19]

The major changes included in V28 include:

(1) An expanded number of HCCs;
(2) A change in how the V28 HCC codes are numbered and named;
(3) Changes to ICD-10-CM code to HCC mappings;
(4) Changes to coefficient values for HCCs;
(5) Addition of 268 diagnosis codes that did not map to payment CMS-HCC in V24; and
(6) Removal of 2,294 diagnosis codes that no longer map to a payment HCC.[20]

The CMS-HCC risk-adjustment model, which is applicable to a specific calendar year, is used to identify a Medicare FFS beneficiary's prospective HCC risk score for the corresponding year.[21] Based on an analysis of the MSSP, CMS found that using different CMS-HCC risk-adjustment models negatively impacts: (1) ACOs with the highest average risk scores; (2) ACOs that have participated in MSSP longer; and (3) ACOs that participate in two-sided models.[22] These changes to the risk-adjustment model impact HCCs, RAF scores, and how medical practices and health plans allocate resources and manage patient risk.[23]

The changes to the CMS-HCC risk-adjustment model are likely to create challenges for MA Organizations (MAOs), MSSP ACOs, REACH ACOs, and other stakeholders.[24] With these changes, the administrative burden on revenue cycle staff could increase, and access to care could be hindered for beneficiaries with chronic conditions.[25] Organizations will need to continue keeping track of member health statuses and analyze how these changes will impact them.[26] The American Medical Group Association (AMGA) expressed its concern with V28, recommending that CMS reconsider their "continued phase-in of the new CMS-HCC model."[27]

Industry experts suggest that providers and health plans should identify the most common HCCs among their patient population to understand the impact of the two versions of the risk-adjustment model.[28] Experts also advise that investing in technology that allows for specificity in documentation and accurate coding of clinical documentation will be vital to enable providers, health plans, and other stakeholders to manage their respective risk-adjustment programs.[29]

---

1 "Calendar Year (CY) 2024 Medicare Physician Fee Schedule Final Rule — Medicare Shared Savings Program Fact Sheet" Centers for Medicare and Medicaid Services, November 2, 2023, https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-medicare-physician-fee-schedule-final-rule-medicare-shared-savings-program (Accessed 3/21/24).
2 "Understanding the Changes in the CMS-HCC Model V28" By Jayashree Selvaraj, January 4, 2024, https://www.agshealth.com/blog/understanding-the-changes-in-the-cms-hcc-model-v28/ (Accessed 3/21/24).
3 "HOW WILL CMS'S V28 HCC MODEL IMPACT RAF SCORES?" By Erin Page, Lightbeam Health Solutions, October 25, 2024, https://lightbeamhealth.com/how-will-cmss-v28-hcc-model-impact-raf-scores/#:~:text=The%20v28%20HCC%20model%20will,(MSSP)%2C%20and%20REACH. (Accessed 3/28/24).
4 "The Purpose of HCC Coding" SummaCare, https://www.summacare.com/-/media/project/summacare/website/document-library/forms-and-resources/provider-forms-and-resources/sum-22-60159-the-purpose-of-hcc-coding.pdf (Accessed 3/29/24).
5 *Ibid.*
6 *Ibid.*
7 "How CMS-HCC Version 28 will impact risk-adjustment factor (RAF) scores" By Michael Stearns, Melissa James, and Kimberly Rykaczewski, Wolters Kluwer, February 27, 2023, https://www.wolterskluwer.com/en/expert-insights/how-cms-hcc-version-28-will-impact-risk-adjustment-factor-raf-scores (Accessed 3/22/24).
8 *Ibid.*
9 *Ibid.*
10 *Ibid.*
11 *Ibid.*
12 Selvaraj, January 4, 2024.
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
16 *Ibid.*
17 "A primer on the CMS-HCC transition from V24 to V28" By June Bronnert, Intelligent Medical Objects (IMO), June 15, 2023, https://www.imohealth.com/ideas/article/a-primer-on-the-cms-hcc-transition-from-v24-to-v28/ (Accessed 3/22/24).
18 *Ibid.*
19 *Ibid.*
20 Stearns, James, and Rykaczewski, Wolters Kluwer, February 27, 2023.
21 Centers for Medicare and Medicaid Services, November 2, 2023.
22 *Ibid.*
23 "Medicare Advantage V28: A Primer on What Providers Can Expect" By Larissa Long, Innovista Health, September 11, 2023, https://innovista-health.com/medicare-advantage-v28/ (Accessed 3/21/24).
24 Stearns, James, and Rykaczewski, Wolters Kluwer, February 27, 2023.
25 "'SIGNIFICANT RAMIFICATIONS': MEDICAL GROUP OPPOSES HCC CODING CHANGES" By Amanda Norris, Health Leaders, March 13, 2023, https://www.healthleadersmedia.com/revenue-cycle/significant-ramifications-medical-group-opposes-hcc-coding-changes (Accessed 3/27/24).
26 Stearns, James, and Rykaczewski, Wolters Kluwer, February 27, 2023.
27 "AMGA Objects to Medicare Advantage Rate Cuts" AMGA, March 1, 2024, https://www.amga.org/about-amga/amga-newsroom/press-releases/3012024-(1) (Accessed 3/28/24).
28 Selvaraj, January 4, 2024.
29 *Ibid.*

UPMC Settles Stark Law Case

[Excerpted from the article published in May 2024.]

On May 9, 2024, the University of Pittsburgh Medical Center (UPMC), a large nonprofit healthcare system that owns a number of hospitals, medical practices, and other subsidiaries, announced that they would pay $38 million to settle a longstanding Stark Law case which had triggered a violation of the False Claims Act (FCA).[1] The lawsuit claimed that several of UPMC's surgeons ordered complex and unnecessary procedures to increase their earnings.[2] This Health Capital Topics article will discuss the UPMC settlement and the allegations underlying the case.

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).[3] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[4] Under the Stark Law, DHS include, but are not limited to, the following:

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

Civil penalties under the Stark Law include overpayment or refund obligations, a potential civil monetary penalty of $15,000 for each service, or up to $100,000 per arrangement or scheme, and exclusion from Medicare and Medicaid programs.[6] Further, violation of the Stark Law can trigger a violation of the False Claims Act (FCA).[7] The FCA prohibits any person from knowingly submitting, or causing to submit, false claims to the government.[8] FCA violators are liable for treble damages (i.e., "three times the government damages"), as well as for a penalty linked to inflation.[9] Not only does the FCA give the U.S. government the ability to pursue fraud, it also enables private citizens to file suit on behalf of the federal government through what is known as a "*qui tam,*" "*whistleblower,*" or "*relator*" suit.[10]

The lawsuit against UPMC was originally filed on behalf of three UPMC-employed medical professionals, J. William Bookwalter, a neurosurgeon, Robert Sclabassi, a neurophysiologist, and Ann Miltina, a surgical technologist.[11] The three plaintiffs had alleged that UPMC incentivized neurosurgeons to perform their surgeries at UPMC's facilities in order to increase the revenue received from the government.[12] In return, the physicians were rewarded with compensation that was above *fair market value*.[13] The suit also alleged that some UPMC neurosurgeons had submitted claims for assisting with procedures which they did not directly supervise, perform, or assist.[14] UPMC had previously claimed that the compensation packages which were offered to physicians, including bonuses for productivity, were all the industry standard.[15]

In 2016, UPMC settled a portion of the claims for $2.5 million, but the federal government had declined to intervene on the rest of the allegations which were brought forth by the plaintiffs.[16] In 2019, after the plaintiffs continued to pursue their claims which were not addressed by the settlement in 2016, an appeal was granted after a district court had previously dismissed the plaintiffs' claims.[17] The Third Circuit Court of Appeals had reversed the decision of the district court, denied the motion to dismiss which was filed by defendants, and ordered the *qui tam* action to proceed to the discovery phase of the lawsuit.[18]

In a statement, UPMC's Chief Communications Officer and Vice President Paul Wood stated that the healthcare system was "pleased to have resolved this matter, twelve years after it first started. The settlement, which includes no admission of liability, allows UPMC to keep its focus where it belongs—on providing world-class care to our patients."[19] The firms representing the plaintiffs said that "this kind of recovery would simply be impossible without the bravery and commitment of whistleblowers willing to incur enormous risk to do the right thing on behalf of the taxpayers."[20] Mark Simpson, founder of the Simpson Law Firm, stated that "The Stark Law was enacted to ensure that the clinical judgment of physicians is not corrupted by improper financial incentives."[21]

As an agreement of the settlement, UPMC will be allowed to deny all allegations of any wrongdoing.[22] The three professionals each will receive $11 million, and the rest of the settlement amount ($27 million) will be paid out to the federal government.[23] The amount that the plaintiffs receive is a reward for whistleblowers that alert the government of fraudulent practices.[24] The $38 million settlement is believed to be one of the largest recoveries in a False Claims Act case where the U.S. declined to intervene.[25]

---

1 "UPMC pays $38M to settle 12-year-old whistleblower case" By Dave Muoio, Fierce Healthcare, May 13, 2024, https://www.fiercehealthcare.com/providers/upmc-pays-38m-settle-12-year-old-whistleblower-case (Accessed 5/15/24); "United States of America ex rel. J. William Bookwalter, III, MD, et al. v. UPMC, et al." No. 18-1693 (3rd Cir. Sept. 17, 2019), p. 7.

2 "University of Pittsburgh Medical Center Settles Whistleblower Lawsuit for $38m" By Ryan Farrick, Legal Reader, May 10, 2024, https://www.legalreader.com/upmc-pittsburgh-whistleblower-lawsuit-settlement/ (Accessed 5/15/24).

3 "CRS Report for Congress: Medicare: Physician Self-Referral ("Stark I and II")" By Jennifer O'Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, available at: http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf (Accessed 5/15/24); "Limitation on certain physician referrals" 42 U.S.C. § 1395nn.

4 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn(a)(1)(A).

5 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a)(1)(B); "Definitions" 42 C.F.R. § 411.351 (2015). Note the distinction in 42 C.F.R. § 411.351 regarding what services are included as DHS: "Except as otherwise noted in this subpart, the term 'designated health services' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)."

6 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn(g).

7 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 5/15/24).

8 "The False Claims Act" U.S. Department of Justice, February 2, 2022, https://www.justice.gov/civil/false-claims-act (Accessed 5/15/24).

9 *Ibid.*

10 *Ibid.*

11 Farrick, Legal Reader, May 10, 2024.

12 Muoio, Fierce Healthcare, May 13, 2024.

13 *Ibid.*

14 "What to know about UPMC's $38M Stark law settlement" By Patsy Newitt, Becker's ASC Review, May 13, 2024, https://www.beckersasc.com/asc-news/what-to-know-about-upmcs-38m-stark-law-settlement.html?origin=SpineE&utm_source=SpineE&utm_medium=email&utm_content=newsletter&oly_enc_id=9207F7402078E2D (Accessed 5/16/24).

15 Muoio, Fierce Healthcare, May 13, 2024.

16 *Ibid.*

17 *Ibid.*

18 "Practice Loss Postulate Perpetuated by Third Circuit" By Jessica Bailey-Wheaton and Todd Zigrang, Health Capital Consultants, https://www.healthcapital.com/hcc/newsletter/10_19/HTML/UPMC/convert_upmc-case-topics-article-10.31.19.php (Accessed 5/15/24).

19 Muoio, Fierce Healthcare, May 13, 2024.

20 Verkamp, May 9, 2024.

21 Farrick, Legal Reader, May 10, 2024.

22 *Ibid.*

23 *Ibid.*

24 "UPMC settles $38M whistleblower lawsuit for Medicare fraud" By Chad Van Alstin, HealthExec, May 10, 2024, https://healthexec.com/topics/healthcare-management/legal-news/upmc-settles-38m-whistleblower-lawsuit-medicare-fraud (Accessed 5/15/24).

25 Verkamp, May 9, 2024.

SCOTUS Rejects Chevron Deference: Healthcare Industry Implications

[Excerpted from the article published in July 2024.]

On June 28, 2024, the U.S. Supreme Court issued a seismic decision explicitly overruling the "*Chevron* doctrine," which will limit the ability of federal agencies to rely on their own interpretation of the laws they administer.[1] Under the *Chevron* doctrine, more commonly referred to as *Chevron* deference, courts were mandated to uphold a federal agency's interpretation of a statute as long as it was reasonable.[2] This Health Capital Topics article discusses the *Chevron* doctrine, the Supreme Court's decision, and the impact of this ruling on the healthcare industry.

Chevron deference is a legal test established in the 1984 Supreme Court case, *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*[3] In this case, the Court ruled that when federal law is ambiguous, and a federal agency issues a regulation interpreting the ambiguity, courts must defer to the agency's interpretation.[4] Under *Chevron* deference, courts first assessed whether Congress directly addressed the question at issue – if so, courts relied on Congress's intent; if not, courts deferred to the federal agency's interpretation of the issue. While the Supreme Court itself has rarely relied on *Chevron* deference, the framework was essential to U.S. administrative law for nearly 40 years and utilized by lower courts in over 18,000 judicial opinions.[5]

The Supreme Court's June 2024 ruling addresses two cases, *Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Department of Commerce*.[6] In both cases, commercial fishing companies challenged the Department of Commerce's rule that held fishing vessels responsible for the cost of federal observers used to monitor potential overfishing.[7] The question at issue before the Court was limited to "whether *Chevron*…should be overruled or clarified."[8]

Chief Justice John Roberts delivered the Court's majority opinion, with Justices Thomas, Alito, Gorsuch, Kavanaugh, and Coney Barrett issuing concurring opinions.[9] In the majority opinion, Chief Justice Roberts asserted that *Chevron* deference is inconsistent with the Administrative Procedure Act (APA), a federal law that dictates federal agency procedure and instructs how courts can review federal agency actions.[10] The Chief Justice stated that "agency interpretations of statutes—like agency interpretations of the Constitution—are *not* entitled to deference."[11] The Chief Justice also stated that under the APA, it "remains the responsibility of the court to decide whether the law means what the agency says."[12] Any suggestion that federal agencies are better equipped to determine ambiguous federal law than courts was rejected by the Court, even when the ambiguous federal law involves scientific or technical questions in which the agency has expertise, reasoning that "Congress expects courts to handle technical statutory questions, and courts did so without issue in agency cases before *Chevron*."[13] While the majority opinion made clear that courts should not defer to agency interpretation for an ambiguous statute, courts can consider the interpretation if it falls within the agency's purview as explicitly granted by Congress.[14]

Justice Gorsuch's concurring opinion added that "the Court returns judges to interpretive rules that have guided federal courts since the Nation's founding."[15] Justice Gorsuch also stated that "all today's decision means is that, going forward, federal courts will do exactly as this Court has since 2016, exactly as it did before the mid-1980s, and exactly as it had done since the founding: resolve cases and controversies without any systemic bias in the government's favor."[16] Justice Thomas's concurrence argued that the *Chevron* doctrine is also a violation of the Constitution's division of power among the federal government's legislative, judicial, and executive branches, and "Chevron deference [permitted] the Executive Branch to exercise powers not given to it."[17]

Justice Elena Kagan filed a dissenting opinion with Justice Sonia Sotomayor. Justice Ketanji Brown Jackson joined with dissent on the *Relentless* case only;[18] she was recused from *Loper Bright* due to having heard oral arguments in the case during her time on the bench of the U.S. Court of Appeals for the D.C. Circuit.[19] Justice Kagan expressed concern that the Court's decision would create a "jolt to the legal system," and that "Congress and agencies alike have relied on *Chevron*—have assumed its existence—in much of their work for the last 40 years."[20]

Justice Kagan also expressed skepticism at the assertion that overturning *Chevron* deference would not call previous decisions into question, stating that "[c]ourts motivated to overrule an old Chevron-based decision can always come up with something to label a 'special justification.'"[21] Justice Kagan reprimanded her colleagues, stating that "in one fell swoop, the majority today gives itself exclusive power over every open issue—no matter how expertise-driven or policy-laden—involving the meaning of regulatory law. As if it did not have enough on its plate, the majority turns itself into the country's administrative czar."[22]

Impact on Healthcare

The dismantling of *Chevron* deference is expected to place significantly more scrutiny on executive agencies such as the Department of Health and Human Services (HHS), which operates federal healthcare programs such as Medicare and Medicaid, and their ability to implement omnibus laws passed by Congress.[23] The likelihood of agency regulations being overturned by courts will increase, and these decisions will incentivize litigants to challenge undesirable agency regulations in court.[24]

The ruling is expected to have a wide-ranging impact on the healthcare industry, particularly in the following areas:

- Administration of Medicare and Medicaid: HHS and the Centers for Medicare and Medicaid Services (CMS) may encounter issues in the administration of Medicare and Medicaid if Congress refines the statutes related to the two programs and/or expands the agencies' authority. Ambiguous language in the Medicare and Medicaid regulations would likely need to be addressed in order to decrease the (high) likelihood of legal action challenging the agencies' statutory interpretations.
- Reimbursement of Medicare: When HHS and its agencies made major changes in regard to prescription drugs, hospital, and physician reimbursement, or introduced new requirements for Medicare coverage, *Chevron* allowed courts to provide agencies with wide latitude, and for the agencies to remain largely protected from legal challenges. Post-decision, providers may have more flexibility to challenge HHS on reimbursement issues (e.g., cuts to physician reimbursement, changes to outpatient and inpatient payment systems).
- Medicare and Medicaid Coverage Disputes: When HHS or CMS made a determination as to whether an item or service qualified for Medicare or Medicaid coverage, courts typically would give weight to the agencies' understanding of their statutes. Post-decision, the number of coverage disputes are likely to increase, and the courts will wield the power to resolve such disputes *de novo*.
- Fraud and Abuse Law: The healthcare industry is heavily regulated by fraud and abuse laws such as the Anti-Kickback Statute (AKS), Stark Law, the False Claims Act (FCA), and the Civil Monetary Penalties Law. Violators of these laws face civil and criminal penalties, as well as exclusion from federal healthcare programs such as Medicare and Medicaid. For years, HHS and its agencies have interpreted these statutes through the regular issuance of updated/revised regulations and guidance (e.g., Special Fraud Alerts & Advisory Opinions). Post-decision, providers' compliance and litigation strategies may change, with enforcement actions potentially decreasing due to uncertainty as to whether a court will uphold agency interpretation.[25]
- Food and Drug Administration (FDA) Decision Making: Under the Food, Drug, and Cosmetic Act (FDCA), the FDA has authority to oversee the safety of cosmetics, medical devices, food, and drugs. *Chevron* deference allowed for the agency to rely on evidence-based decisions regarding medical products and drugs, despite the FDCA's ambiguous language. Post-decision, courts may still defer to the FDA, but the number of appeals will likely increase due to the possibility that courts may choose to interpret ambiguities differently from the FDA.
- Long Term Care Survey and Certification Enforcement: Skilled nursing facilities and other nursing facilities receiving Medicare or Medicaid reimbursement are routinely surveyed by federal and state authorities, and any noncompliance can lead to a plethora of penalties. Post-decision, these compliance regulations may be more easily challenged by facilities.

With *Chevron* deference overruled, the authority to interpret statutes and regulations will shift from federal agencies and legal challenges to all agency actions are likely to increase.[26]

Post-decision, regulatory ambiguities will not be resolved by subject matter experts (such as federal agencies), but by the courts and Congress.[27] Congress will still retain the ability to delegate the task of regulation development to specific administrative agencies; however, regulations from these agencies may now be reviewed by courts without any deference.[28] This major shift in legal framework is expected to drastically increase federal litigation, with every single federal agency's decision having the potential of being challenged in court.[29]

The change in deference to federal agencies could lead to scenarios where courts make inconsistent determinations across the U.S., which will create circuit splits.[30] The *Loper* decision may also lead to difficulties for federal agencies that are trying to expand the scope of certain statutes and reduce the likelihood of new agency requirements.[31] While this ruling will affect all industries regulated by federal agencies, the effect on healthcare will be significant due to the complex regulatory environment in which providers operate.

---

1 "LOPER BRIGHT ENTERPRISES ET AL. v. RAIMONDO, SECRETARY OF COMMERCE, ET AL." Supreme Court of the United States, June 28, 2024, https://www.supremecourt.gov/opinions/23pdf/22-451_7m58.pdf (Accessed 7/12/24); "Supreme Court strikes down Chevron, curtailing power of federal agencies" By Amy Howe, SCOTUSblog, June 28, 2024, https://www.scotusblog.com/2024/06/supreme-court-strikes-down-chevron-curtailing-power-of-federal-agencies/ (Accessed 7/12/24).
2 Howe, SCOTUSblog, June 28, 2024.).
3 "SCOTUS Case Could Weaken the Impact of Regulation on Key Patient and Consumer Protections" By Michelle Long, Justin Lo, and Kaye Pestaina, Kaiser Family Foundation, April 9, 2024, https://www.kff.org/private-insurance/issue-brief/upcoming-scotus-case-could-weaken-impact-regulation-key-patient-consumer-protections/ (Accessed 7/12/24).
4 *Ibid.*
5 "U.S. Supreme Court May Soon Discard or Modify Chevron Deference" By Rich Gold et al., Holland & Knight, May 20, 2024, https://www.hklaw.com/en/insights/publications/2024/05/us-supreme-court-may-soon-discard-or-modify-chevron-deference (Accessed 7/12/24).
6 Howe, SCOTUSblog, June 28, 2024.
7 "Supreme Court Overrules Chevron in Far-Reaching Decision Limiting the Power of Administrative Agencies" By Jason Hicks and Ian Dickinson, National Law Review, June 28, 2024, https://natlawreview.com/article/supreme-court-overrules-chevron-far-reaching-decision-limiting-power-administrative (Accessed 7/12/24).
8 Supreme Court of the United States, June 28, 2024, Syllabus p. 1.
9 *Ibid.*
10 *Ibid.*; Howe, SCOTUSblog, June 28, 2024.
11 Supreme Court of the United States, June 28, 2024; Howe, SCOTUSblog, June 28, 2024.
12 Supreme Court of the United States, June 28, 2024.
13 *Ibid*; Howe, SCOTUSblog, June 28, 2024.
14 *Ibid.*
15 *Ibid.*
16 *Ibid.*
17 *Ibid.*
18 *Ibid.*
19 *Ibid.*
20 *Ibid.*
21 *Ibid.*
22 *Ibid.*
23 "Supreme Court Decision Limiting the Authority of Federal Agencies Could Have Far-Reaching Impacts for Health Policy" By Kaye Pestaina, Michelle Long, and Justin Lo, Kaiser Family Foundation, July 1, 2024, https://www.kff.org/private-insurance/issue-brief/supreme-court-decision-limiting-the-authority-of-federal-agencies-could-have-far-reaching-impacts-for-health-policy/ (Accessed 7/12/24).
24 Kaiser Family Foundation, April 9, 2024.
25 "What the Supreme Court's "Chevron Deference" Ruling Could Mean for Health Care Law" Baker Donelson, June 25, 2024, https://www.bakerdonelson.com/what-the-supreme-courts-chevron-deference-ruling-could-mean-for-health-care-law (Accessed 7/12/24).
26 Hicks and Ian Dickinson, National Law Review, June 28, 2024.
27 Long, Justin Lo, and Pestaina, Kaiser Family Foundation, April 9, 2024.
28 Kaiser Family Foundation, July 1, 2024.
29 "Chevron Deference and Its Impact on the Health Care Industry" O'Connell Aronowitz, https://www.oalaw.com/blog/health-law/chevron-deference-and-its-impact-on-the-health-care-industry/#:~:text=Chevron%20deference%20has%20had%20significant,enforcing%20various%20healthcare%2Drelated%20issues. (Accessed 7/12/24).
30 "U.S. Supreme Court Overturns Chevron – Impact on Health Care and Life Sciences" By Kenya Woodruff et al., Katten, July 3, 2024, https://quickreads.ext.katten.com/post/102jc1d/u-s-supreme-court-overturns-chevron-impact-on-health-care-and-life-sciences (Accessed 7/12/24).
31 *Ibid.*

DOJ Intervenes in Fraud & Abuse Case Against Tennessee Hospital

[Excerpted from the article published in August 2024.]

On July 26, 2024, the U.S. Department of Justice (DOJ) filed a complaint in intervention against Murphy Medical Center, doing business as Erlanger Western Carolina Hospital, and Chattanooga-Hamilton County Hospital Authority, doing business as the Erlanger Health System and Erlanger Medical Center.[1] The government's complaint, filed in the U.S. District Court for the Western District of North Carolina, alleges that Erlanger violated the Stark Law, and subsequently submitted false claims to the Medicare program in violation of the False Claims Act (FCA).[2] This Health Capital Topics article reviews the allegations underlying the case.

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).[3] Under the Stark Law, DHS include, but are not limited to, the following:

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

Civil penalties under the Stark Law include overpayment or refund obligations, a potential monetary penalty of $15,000 for each service, or up to $100,000 per arrangement or scheme, and exclusion from Medicare and Medicaid programs.[5] Further, violation of the Stark Law can trigger a violation of the FCA, which prohibits any person from knowingly submitting, or causing to submit, false claims to the government.[6] FCA violators are liable for treble damages (i.e., "three times the government damages"), as well as a monetary penalty linked to inflation.[7] Not only does the FCA give the U.S. government the ability to pursue fraud, it also enables private citizens to file suit on behalf of the federal government through what is known as a "*qui tam,*" "*whistleblower,*" or "*relator*" suit.[8] This lawsuit was originally filed under the *qui tam* provisions of the FCA.[9]

Chattanooga-Hamilton County Hospital Authority is a public, tax-exempt organization that owned, controlled, and operated several hospitals in Chattanooga, Tennessee from 2014 to 2021.[10] Murphy Medical Center, Inc. is a non-profit corporation located in Cherokee County, North Carolina.[11] In April 2018, the Chattanooga-Hamilton County Hospital became the sole member of Murphy Medical Center Inc., which became a part of the seven-hospital Erlanger Health System (Erlanger).[12]

In 2005, Erlanger agreed to pay $40 million to resolve allegations that they had knowingly submitted false claims to Medicare.[13] As part of the settlement, Erlanger entered into a Corporate Integrity Agreement (CIA) with the Department of Health & Human Services' (HHS) Office of Inspector General (OIG).[14] The CIA, which was in effect from October 2005 through 2010, required Erlanger to establish controls to ensure financial relationships with their physicians did not violate the Stark Law.[15] After the CIA expired, Erlanger allegedly began implementing a strategy to increase profits by employing more physicians and generating downstream revenue.[16] In furtherance of this strategy, the system removed oversight and controls on physician compensation in 2013, leading to the activity alleged in this complaint, through at least 2021.[17]

The government alleges that:

(1) Erlanger knew compensation to physician employees must be consistent with Fair Market Value (FMV) to qualify for a Stark Law exception;
(2) Beginning in 2014, Erlanger employed more physicians to secure downstream revenue, growing from 140 physicians in 2014 to 380 by 2018;

(3) Erlanger eliminated or relaxed physician compensation oversight in order to retain and recruit more physicians with downstream revenue potential;
(4) Erlanger changed its compensation model to include larger salaries for academic and medical director positions;
(5) Erlanger physicians who generated downstream revenue were some of the highest paid physicians in the U.S.;
(6) Erlanger dismissed concerns that it was paying employed physicians more than they were collecting for physician services due to the downstream profitability;
(7) Erlanger disregarded concerns related to quality of care and overutilization bearing on the FMV of compensation to a cardiothoracic surgeon;
(8) Erlanger disregarded warnings in FMV assessments despite knowing that these opinions stated that physician compensation would exceed 75th or 90th percentile; and
(9) Erlanger resisted their chief compliance officer's efforts to engage a consultant to review their employed physicians' compensation.[18]

The investigation into Erlanger began after a whistleblower (relator) complaint was filed by that (former) chief compliance officer and a former chief financial officer.[19] The complaint was investigated by the DOJ with assistance from OIG.[20] The DOJ decided to intervene in part of the action against Erlanger, but declined to intervene in the other part of the complaint,[21] i.e., FCA violations arising from allegedly unlawful referrals from physicians who were not employed by Erlanger.[22] The whistleblowers subsequently informed the court that they would proceed with those non-intervened claims, but would drop other non-intervened claims related to unread test results.[23]

The relators' attorney expects that Erlanger could be liable for up to $70 million if the lawsuit is successful.[24] The DOJ stated in its announcement of the complaint filing that "improper financial relationships between hospitals and physicians threaten the integrity of clinical decision-making and can influence the type and amount of health care that is provided to patients."[25]

---

1 "United States Files False Claims Act Complaint Against Erlanger Health System" Office of Public Affairs, U.S. Department of Justice, July 26, 2024, https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-erlanger-health-system (Accessed 7/30/24).
2 *Ibid.*
3 "CRS Report for Congress: Medicare: Physician Self-Referral ("Stark I and II")" By Jennifer O'Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, available at: http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf (Accessed 1/3/24); "Limitation on certain physician referrals" 42 U.S.C. § 1395nn.
4 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a)(1)(B); "Definitions" 42 C.F.R. § 411.351 (2015). Note the distinction in 42 C.F.R. § 411.351 regarding what services are included as DHS: "Except as otherwise noted in this subpart, the term 'designated health services' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)."
5 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn(g).
6 "The False Claims Act" U.S. Department of Justice, February 2, 2022, https://www.justice.gov/civil/false-claims-act (Accessed 1/3/24).
7 *Ibid.*
8 *Ibid.*
9 Office of Public Affairs, U.S. Department of Justice, July 26, 2024.
10 *Ibid.*
11 *Ibid.*
12 *Ibid.*
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
16 *Ibid.*
17 *Ibid.*
18 *Ibid.*
19 "Ex-Erlanger executives allege kickbacks in whistleblower lawsuit" By Kelly Gooch, Becker's Hospital Review, May 28, 2024, https://www.beckershospitalreview.com/legal-regulatory-issues/ex-erlanger-executives-allege-kickbacks-in-whistleblower-lawsuit.html (Accessed 7/31/24).
20 Office of Public Affairs, U.S. Department of Justice, July 26, 2024.
21 "The United States of America et al., v. Murphy Medical Center Inc. et al." 1:21-CV-219-MR-WCM, The United States' Notice of Election to Intervene in Part and to Decline to Intervene in Part (W.D. NC April 26, 2024).
22 "The United States of America et al., v. Murphy Medical Center Inc. et al." No. 1:21-cv-00219-MR-WCM, p. 1-4 (NC, 2024).
23 *Ibid.*
24 Gooch, Becker's Hospital Review, May 28, 2024.
25 Office of Public Affairs, U.S. Department of Justice, July 26, 2024.

California Passes Bill Regulating Private Equity Deals

[Excerpted from the article published in September 2024.]

On August 31, 2024, the California legislature passed a bill that may curb private equity (PE) healthcare transactions in the state.[1] The legislation is now on Governor Gavin Newsom's desk for signature, who must sign or veto the bill by September 30, 2024. If signed into law, California will have the strictest regulation of PE deals of any state in the country. This Health Capital Topics article discusses the new law and reviews the status of both state and federal regulation of PE.

While PE is not altogether new to healthcare, its involvement in the sector has increased significantly over the last decade. This renewed interest has been attributed to a number of factors, including low interest rates, the "increasing commercialization" of healthcare, and the healthcare industry's failure to deliver high quality care (with Americans experiencing worse health outcomes than all other industrialized nations, despite higher spending).[2] From 2010 to 2019, there were approximately $750 billion in PE healthcare deals, and in 2023 alone, over 780 PE healthcare deals were announced or closed.[3] In a ten-year period, PE acquisitions of just physician practices increased sixfold, from 75 deals in 2012 to 484 deals in 2021.[4]

The California State Assembly and State Senate passed Assembly Bill (AB) 3129 by a fairly wide margin (21-11 in the Senate and 49-14 in the Assembly).[5] The bill regulates transactions wherein a PE group or hedge fund "establishes a change in governance or sharing of control over health care services provided by a health care facility, provider group, or provider doing business in [California]," or "otherwise assumes direct or indirect control."[6] In general, the bill requires that, starting January 1, 2025, transactions involving most types of healthcare organizations generating $25 million or more in gross annual revenue receive approval from the California Attorney General.[7] The Attorney General is to review the transaction "to determine if the transaction may have a substantial likelihood of anticompetitive effects and what mitigation measures could be adopted to avoid this result," and approve, conditionally approve, or deny the transaction.[8]

Notably, the following transactions are exempt from review:

(1) Transactions between a PE group/hedge fund and a nonphysician provider or a provider (defined as "a group of two to nine licensed health professionals") with gross annual revenue of $4 million or less; and
(2) Transactions involving for-profit hospitals.[9]

AB 3129 is not the first California law to require oversight of PE deals. In 2022, California enacted a requirement that healthcare investments be reviewed by the newly-created Office of Health Care Affordability.[10] With the passage of AB 3129, California now has the strictest regulation of healthcare PE investment in the U.S.[11] However, the passage of this bill is part of a wider trend across states, and within the federal government, to increase transparency and control costs, particularly where PE is involved, in the healthcare industry. As illustrated in the below map, 11 states have laws on the books that require some level of review over certain healthcare transactions.[12] For example, Oregon enacted a law similar to AB 3129 in 2022. While the legislation has not yet resulted in any blocked transactions, over a quarter of reviewed transactions were conditionally approved, such as requiring the organization to stay in-network for Medicaid post-transaction.[13]

In July 2024, the *Health Over Wealth Act* was introduced in the U.S. Senate, which would require PE and other for-profit health services providers to disclose certain financial and operational data and to create an escrow account to cover essential health services costs for five years in the event that its facility closes.[14] The Act would also give the U.S. Department of Health and Human Services (HHS) significantly more power to regulate and block PE deals across the U.S. However, as of the publication of this article, that bill has not yet advanced.[15] Additionally, the Senate Homeland Security Committee announced in April 2024 that it was launching an inquiry into whether expanding PE control over hospital emergency departments is endangering patient care and emergency preparedness.[16] In December 2023, the Senate initiated a bipartisan investigation into PE involvement in the healthcare industry, reaching out to a number of healthcare providers and PE groups to request information.[17] In addition to congressional action, the executive branch has taken a number of steps over the past few years to garner more information regarding, and increase transparency related to, PE moves in the healthcare space, especially as relates to competition in healthcare. For example, in March 2024, the Department of Justice's (DOJ's) Antitrust Division, the Federal Trade Commission (FTC), and HHS announced the launch of a multi-agency inquiry – in the form of a request for information (RFI) and public workshop – focusing on the increasing control of PE and other corporations over the healthcare industry.[18]

Detractors of AB 3129, and similar legislation in other states, argue that the increased complexity and scrutiny may result in reduced healthcare investment in the state, while proponents assert that such regulation is necessary to ensure the provision of high-quality, lower-cost medical care, given PE's increasing role in the U.S. healthcare delivery system.[19] A number of studies have found that PE acquisition of healthcare service providers have resulted in higher healthcare costs, lower quality of care, and poorer financial outcomes for those acquired entities.[20] Whether California's new law will be a harbinger of future state action, or incentivizes Congress to pass a law empowering the federal government to regulate PE deals at a national level, remains to be seen.

1 "Update: AB 3129 Passes in California Senate and Nears Finish Line" By Julia D'Errico, et al., Sheppard Mullin Richter & Hamilton LLP, September 9, 2024, available at: https://www.jdsupra.com/legalnews/update-ab-3129-passes-in-california-6487576/ (Accessed 9/23/24).

2 "Private Equity's Role in Health Care" The Commonwealth Fund, November 17, 2023, https://www.commonwealthfund.org/publications/explainer/2023/nov/private-equity-role-health-care (Accessed 9/5/24); "U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes" By Munira Z. Gunja, Evan D. Gumas, and Reginald D. Williams II, The Commonwealth Fund, January 31, 2023, https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022 (Accessed 9/5/24).

3 "California Takes Lead on Regulating Private Equity Health Deals" By Celine Castronuovo, Bloomberg Law, July 9, 2024, https://news.bloomberglaw.com/health-law-and-business/california-takes-lead-on-regulating-private-equity-health-deals (Accessed 9/5/24); "Soaring Private Equity Investment in the Healthcare Sector: Consolidation Accelerated, Competition Undermined, and Patients at Risk" By Richard M. Scheffler, Laura M. Alexander, and James R. Godwin, May 18, 2021, available at: https://bph-storage.s3.us-west-1.amazonaws.com/wp-content/uploads/2021/05/Private-Equity-I-Healthcare-Report-FINAL.pdf (Accessed 9/5/24), p. 2; "PE braces healthcare services deals as add-ons fall" By Jessica Hamlin, PitchBook, February 13, 2024, https://pitchbook.com/news/articles/pe-braces-healthcare-services-deals-as-add-ons-fall (Accessed 9/5/24).

4 The Commonwealth Fund, November 17, 2023.

5 "AB-3129 Health care system consolidation (2023-2024)" Section 1190(a)(1), California Legislative Information, available at: https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill_id=202320240AB3129&showamends=false (Accessed 9/5/24).

6 *Ibid*.

7 "California Senate Passes Bill to Clamp Down on Private-Equity Healthcare Deals" By Chris Cumming, Wall Street Journal, September 4, 2024, https://www.wsj.com/articles/california-senate-passes-bill-to-clamp-down-on-private-equity-healthcare-deals-118a2134 (Accessed 9/5/24).

8 Section 1190.10(h)(7)(B), California Legislative Information.

9 *Ibid*.

10 "California Senate Passes Bill to Clamp Down on Private-Equity Healthcare Deals" By Chris Cumming, Wall Street Journal, September 4, 2024, https://www.wsj.com/articles/california-senate-passes-bill-to-clamp-down-on-private-equity-healthcare-deals-118a2134 (Accessed 9/5/24).

11 *Ibid.*

12 Castronuovo, Bloomberg Law, July 9, 2024; "Health Care Transactions Laws – An Interactive Map" Ropes & Gray, https://www.ropesgray.com/en/sites/health-care-transactions-laws (Accessed 9/5/24).

13 "California weighs blocking private equity health deals" By Maya Goldman, Axios, August 22, 2024, https://www.axios.com/2024/08/22/california-private-equity-health-deals (Accessed 9/5/24).

14 "Sen. Markey offers bill to block private equity deals in health care" By Dan Primack, Axios, April 4, 2024, https://www.axios.com/2024/04/04/sen-markey-offers-bill-to-block-private-equity-deals-in-health-care (Accessed 9/5/24).

15 The bill has been referred to the Committee on Finance. S.4804 - Health Over Wealth Act, Congress.Gov, https://www.congress.gov/bill/118th-congress/senate-bill/4804/all-actions (Accessed 9/5/24).

16 "Senate to examine private equity's growing role in ER care" By Peter Sullivan, Axios, April 3, 2024, https://www.axios.com/2024/04/03/senate-private-equity-health-care (Accessed 9/5/24).

17 "Senators launch bipartisan probe of private equity's growing role in U.S. health care" By Gretchen Morgenson, NBC News, December 6, 2023, https://www.nbcnews.com/politics/congress/senators-grassley-whitehouse-probe-private-equity-us-health-care-rcna128070 (Accessed 9/5/24).

18 "Justice Department, Federal Trade Commission and Department of Health and Human Services Issue Request for Public Input as Part of Inquiry into Impacts of Corporate Ownership Trend in Health Care" Office of Public Affairs, Department of Justice, March 5, 2024, https://www.justice.gov/opa/pr/justice-department-federal-trade-commission-and-department-health-and-human-services-issue (Accessed 9/5/24); "Request for Information on Consolidation in Health Care Markets" Department of Justice, Department of Health and Human Services, Federal Trade Commission, February 29, 2024, https://content.govdelivery.com/attachments/USDOJOPA/2024/03/05/file_attachments/2803589/DOJ-FTC-HHS%20HCC%20RFI%20-%2003.04.24%20-%20FINAL.pdf (Accessed 9/5/24).

19 Cumming, Wall Street Journal, September 4, 2024.

20 Castronuovo, Bloomberg Law, July 9, 2024.

The Surgeon's Guide to Buying and Selling a Practice

HCC's Jessica Bailey-Wheaton, Esq. and Dr. Bhagwan Satiani of The Ohio State University College of Medicine provide tips and considerations when selling and buying a healthcare practice. These modules are free and include a whitepaper!

Module 1: The Surgeon's Guide to Buying a Practice

Module 2: The Surgeon's Guide to Selling a Practice

Competition Topics

FTC Lawsuit Targets Private Equity

[Excerpted from the article published in October 2023.]

On September 21, 2023, the Federal Trade Commission (FTC) sued U.S. Anesthesia Partners (USAP), a Texas-based anesthesia provider, and Welsh, Carson, Anderson & Stowe (Welch Carson), a private equity firm.[1] The FTC alleged that the two companies executed an anticompetitive scheme for multiple years to consolidate anesthesiology practices in Texas, boost their profits, and drive up the price of anesthesia services rendered to patients.[2] This Health Capital Topics article will discuss the lawsuit and how it appears to fit in with the FTC's recent moves to crack down on anticompetitive actions in healthcare.

According to the FTC, Welsh Carson created USAP in 2012 after they had noticed a fragmented anesthesiology market which consisted of multiple small physician practices.[3] Since USAP's inception, they have acquired over twelve anesthesiology practices across Texas, comprising over 750 nurses and 1,000 physicians.[4] After acquiring these anesthesiology practices, USAP raised pricing within these anesthesiology practices to reflect USAP's higher pricing.[5] Following the acquisitions, USAP then entered into arrangements with other independent anesthesiology groups to charge higher pricing for services rendered, and split any additional revenue with the independent groups.[6]

The FTC's complaint alleges that the scheme between USAP and Welsh Carson "cost Texans tens of millions of dollars more each year in anesthesia services than before USAP was created."[7] The FTC asserts that Welsh Carson: (1) entered into price-setting agreements with other practices; (2) executed a roll-up scheme, acquiring, merging, and consolidating multiple smaller companies into its portfolio; and (3) entered into a market allocation arrangement with a competitor.[8] According to the FTC, these actions met the bar for unlawful restraints of trade, unfair methods of competition, conspiracy to monopolize, unlawful monopolization, and unlawful acquisitions, in violation of the Sherman Act, the Clayton Act, and the FTC Act.[9]

The FTC lawsuit against USAP and Welsh Carson represents the latest in a series of federal government actions to increase scrutiny of private equity deals.[10] The lawsuit is notable for multiple reasons, as it: (1) is the first litigated serial acquisition challenge; (2) represents a pattern of heightened regulatory concern over private equity roll-up strategies; and (3) targets a minority stakeholder, a private equity firm.[11] Previously, both the FTC and the Department of Justice (DOJ) have been vocal about their need to scrutinize private equity transactions, with Assistant Attorney General Jonathan Kanter arguing in May 2022 that the roll-up model is "often very much at odds with the law and very much at odds with the competition we're trying to protect."[12]

In response to the suit, Welsh Carson expressed disappointment with the FTC and stated that the decision to pursue the case was "unprecedented and disregards well-settled principles of law."[13] Welsh Carson also mentioned that USAP's commercial reimbursement rates did not climb higher than the cost of medical inflation for nearly a decade.[14] USAP also released a statement shortly after the suit was announced, stating that it would "vigorously defend itself against the FTC's misguided allegations."[15] A member of USAP's board, Derek Schoppa, M.D., stated that "the FTC's intended outcome threatens to disrupt and restrict patients' equitable access to quality anesthesia care in Texas and will negatively impact the Texas hospitals and health systems that provide care in underserved communities."[16] Schoppa also stated that "the FTC's civil complaint is based on flawed legal theories and a lack of medical understanding about anesthesia, our patient-oriented business model, and our level of care for patients in Texas."[17]

In the FTC statement, Commissioner Lina Khan said that "private equity firm Welsh Carson spearheaded a roll-up strategy and created USAP to buy out nearly every large anesthesiology practice in Texas. Along with a set of unlawful agreements to set prices and allocate markets, these tactics enabled USAP and Welsh Carson to raise prices for anesthesia services—raking in tens of millions of extra dollars for these executives at the expense of Texas patients and businesses."[18] Khan also stated that "the FTC will continue to scrutinize and challenge serial acquisitions, roll-ups, and other stealth consolidation schemes that unlawfully undermine fair competition and harm the American public."[19]

The federal government has made a number of different, and increasingly emboldened, moves in the healthcare antitrust space over the past few years. As discussed in previous Health Capital Topics articles:

- In December 2018, the U.S. Departments of Health and Human Services (HHS), Treasury, and Labor, issued a report entitled, "Reforming America's Healthcare System Through Choice and Competition," exploring how to improve the U.S. healthcare delivery system by increasing competition in the healthcare industry;[20]
- The FTC challenged a number of hospital mergers and acquisitions in 2022 , indicating heightened regulatory scrutiny of hospital transactions;[21]
- In August 2022, the 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 asserted that COPAs negatively impact healthcare costs, quality of care, and hospital staff wages;[22]
- On January 5, 2023, the Federal Trade Commission (FTC) published a proposed rule that would ban employers from imposing non-competes clauses on their employees.[23]

It seems that the FTC's lawsuit against USAP and Welsh Carson is yet another indication of the administration's focus on enhancing competition in the healthcare industry.

---

1 "FTC Challenges Private Equity Firm's Scheme to Suppress Competition in Anesthesiology Practices Across Texas" Federal Trade Commission, September 21, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-challenges-private-equity-firms-scheme-suppress-competition-anesthesiology-practices-across (Accessed 10/4/23).
2 *Ibid.*
3 "FTC sues PE-backed anesthesia provider for monopolistic roll-ups, price setting" By Dave Muoio, Fierce Healthcare, September 21, 2023, https://www.fiercehealthcare.com/providers/ftc-sues-pe-backed-anesthesia-provider-monopolistic-roll-ups-price-setting (Accessed 10/4/23).
4 *Ibid.*
5 *Ibid.*
6 *Ibid.*
7 *Ibid*; Federal Trade Commission, September 21, 2023.
8 Muoio, Fierce Healthcare, September 21, 2023; "Roll Up Strategy" By CFI Team, Corporate Finance Institute, December 18, 2022, https://corporatefinanceinstitute.com/resources/valuation/roll-up-strategy/ (Accessed 10/4/23).
9 Muoio, Fierce Healthcare, September 21, 2023.
10 "Walking the Walk: FTC Lawsuit Targets Private Equity Roll-Up Strategy" Schulte Roth & Zabel LLP, October 2, 2023, https://www.lexology.com/library/detail.aspx?g=a426af1e-90db-4807-bce4-f579c4c764b1 (Accessed 10/4/23).
11 *Ibid.*
12 *Ibid.*
13 "FTC lawsuit targets serial acquisitions by private equity" By Stefania Palma, Financial Times, September 21, 2023, https://www.ft.com/content/cf24c968-3bf0-49f7-a63f-2c912dabc5ae (Accessed 10/4/23).
14 *Ibid.*
15 Muoio, Fierce Healthcare, September 21, 2023.
16 *Ibid.*
17 *Ibid.*
18 Federal Trade Commission, September 21, 2023.
19 "FTC Challenges Private Equity Firm's Scheme to Suppress Competition in Anesthesiology Practices Across Texas" Federal Trade Commission, September 21, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-challenges-private-equity-firms-scheme-suppress-competition-anesthesiology-practices-across (Accessed 10/4/23).
20 "Federal Agencies Recommend Policies to Increase Healthcare Competition" Health Capital Topics, Vol. 11, Issue 12 (December 2018), https://www.healthcapital.com/hcc/newsletter/12_18/HTML/POLICY/convert_policy_recommendations_cite_chked_cataloged_12.20.18_hba.php (Accessed 10/25/23).
21 "FTC Scrutiny Results in Several Scrapped Hospital Deals" Health Capital Topics, Vol. 15, Issue 6 (June 2022), https://www.healthcapital.com/hcc/newsletter/06_22/HTML/FTC/convert_ftc-health-capital-topics.php (Accessed 10/25/23).
22 "FTC Discourages Certificates of Public Advantage Laws" Health Capital Topics, Vol. 15, Issue 8 (August 2022), https://www.healthcapital.com/hcc/newsletter/08_22/HTML/FTC/convert_ftc-policy-against-copas-8.26.22.php (Accessed 10/25/23).
23 "FTC Proposes Banning Non-Compete Clauses" Health Capital Topics, Vol. 16, Issue 1 (January 2023), https://www.healthcapital.com/hcc/newsletter/01_23/HTML/NONCOMPETE/convert_noncompete-proposed-rule-topics-article.php (Accessed 10/25/23).

ACO Participation Increases in 2024

[Excerpted from the article published in February 2024.]

On January 29, 2024, the Centers for Medicare and Medicaid Services (CMS) announced that Performance Year 2024 participation increased in their various accountable care organization (ACO) initiatives.[1] Specifically, 50 new ACOs joined the Medicare Shared Savings Program (MSSP), and 71 ACOs renewed their contracts, bringing the total participation in the MSSP to 480 ACOs.[2] Additionally, 245 organizations chose to continue participation in two other CMS models – the ACO Realizing Equity, Access, and Community Health (REACH) Model and the Kidney Care Choice (KCC) Model.[3] This Health Capital Topics article reviews the CMS report and implications for CMS's ACO initiatives.

In general, the ACO model holds groups of healthcare providers responsible for the quality and cost of healthcare delivery provided to an ACO's patient population.[4] ACOs are controlled by the provider members who work together to control costs, improve quality, and coordinate care. Those ACOs that achieve payor-designated spending and quality targets receive a share of the cost savings.[5] Most ACOs adhere to one of three primary structures: (1) hospital-led; (2) physician-led; and (3) jointly-led.[6] ACOs vary significantly in the services delivered to patients, the types of providers included in an ACO group, and their range of capabilities, which may include care management, advanced analytics, and shared interdisciplinary decision making.[7] In general, ACOs are associated with improved patient satisfaction and other patient-reported measures,[8] many of which improvements are concentrated in high-need, high-cost populations.[9] However, there is significant variance in ACO performance, with some ACOs achieving savings and others spending far more after formation.[10]

Most ACOs participate in the federal accountable care models offered by CMS.[11] MSSP ACOs are comprised of hospitals, physicians, and other healthcare providers that collaborate to provide coordinated, high quality care to Medicare beneficiaries, while focusing on delivering the appropriate care at the correct time and avoiding unnecessary medical errors and services.[12] When an ACO succeeds in delivering high quality care and spending healthcare dollars wisely, the ACO could be eligible to share in the savings it achieves for Medicare.[13] A 2020 study of 513 ACOs participating in the MSSP showed that 67% of participating ACOs generated a positive shared savings of $2.3 billion.[14] Between 2016 and 2020, the percentage of ACOs with positive shared savings grew 21% annually.[15] Of the 482 ACOs in 2022, 84% achieved savings for Medicare, with 63% of ACOs earning shared savings.[16]

The ACO REACH Model provides resources and tools for healthcare providers to work together in an ACO to improve the quality of care for Medicare beneficiaries.[17] REACH ACOs are comprised of both primary and specialty care physicians.[18] To advance health equity, the model requires all participating ACOs to establish a plan describing how they will meet the needs of Medicare beneficiaries in underserved communities, and how they will make changes to address health disparities.[19]

In the KCC Model, dialysis facilities, nephrologists, and other healthcare providers form ACOs focused on managing care for Medicare beneficiaries with end-stage renal disease (ESRD) or chronic kidney disease (CKD) stages 4 and 5.[20] The model includes strong financial incentives for providers to manage this care, with the goal of delaying the onset of dialysis and incentivizing kidney transplants.[21]

As noted above, CMS announced that the MSSP currently has 480 participating ACOs comprising 634,657 providers and organizations with the ability to provide care to over 10.8 million traditional Medicare beneficiaries.[22] The agency also noted that participating ACOs are expected to deliver care to traditional Medicare beneficiaries in 9,032 federally qualified health centers (FQHCs), rural health clinics (RHCs), and critical access hospitals (CAHs), representing a 27% increase in participants from 2023.[23] For 2024, the ACO REACH Model has 122 ACOs with 173,004 healthcare organizations and providers furnishing care to an estimated 2.6 million traditional Medicare beneficiaries.[24] This model includes 1,042 FQHCs, RHCs, and CAHs, representing more than a 25% increase in participants from 2023.[25] The KCC Model is comprised of more than 9,227 participating healthcare organizations and providers, representing a 10%

increase in participants from 2023.[26] This year, 282,335 Medicare beneficiaries suffering from ESRD and CKD are expected to be served.[27]

These three aforementioned ACO programs are expected to increase access to high-quality care, with the ACO REACH Model targeting underserved populations (i.e., located in rural areas) and the KCC Model focusing on Medicare beneficiaries with ESRD and CKD.[28] CMS expects 13.7 million Medicare beneficiaries to be aligned with an ACO, which means nearly half of all traditional Medicare beneficiaries are (or will be) assigned to an ACO in 2024.[29]

President and CEO of the National Association of ACOs (NAACOS), Clif Gaus, stated that NAACOS "is happy to see growth in these important CMS programs, which was helped by changes put in place this year to help more provider organizations join value-based care models."[30] The group recommended that CMS modify the current models by revamping how benchmarks are set, altering patient engagement rules, and relaxing reporting requirements,[31] in order to encourage and increase participation in value-based programs (i.e., Medicare ACO programs).[32]

CMS Administrator Chiquita Brooks-LaSure stated that "one of CMS' top priorities is to expand access to quality, affordable health coverage and care."[33] Brooks-LaSure also said that "accountable care initiatives – which give more tools to health care providers to deliver better care and help people receive more coordinated care – through programs like the [MSSP] and the Innovation Center accountable care initiatives are critical to achieving this vision."[34] The Biden-Harris Administration has set a goal of bringing all Medicare beneficiaries into value-based care models by 2030, and ACOs will be essential in reaching that goal.[35]

---

1 "Participation Continues to Grow in CMS' Accountable Care Organization Initiatives in 2024" Centers for Medicare and Medicaid Services, January 29, 2024, https://www.cms.gov/newsroom/press-releases/participation-continues-grow-cms-accountable-care-organization-initiatives-2024 (Accessed 2/14/24).
2 *Ibid.*
3 *Ibid.*
4 "Accountable Care Organizations — The Risk of Failure and the Risks of Success" By Lawrence P. Casalino, The New England Journal of Medicine, Vol. 371, Issue 18, October 2014, p. 1750; "Moving Forward with Accountable Care Organizations: Some Answers, More Questions" By Carrie H. Colla, JAMA Internal Medicine, Vol. 177, No. 4, April 2017, p. 527.
5 "Shared Savings Program" Centers for Medicare & Medicaid Services, 2023, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram (Accessed 2/14/24).
6 "A taxonomy of accountable care organizations for policy and practice" By Stephen M. Shortell, et al., Health Services Research, Vol. 49, Issue 6, December 2014, p. 1883-1895; "Assessing Differences between Early and Later Adopters of Accountable Care Organizations Using Taxonomic Analysis" By Frances M. Wu, Stephen M. Shortell, Valerie A. Lewis, Carrie H. Colla, and Elliott S. Fisher, Health Services Research, Vol. 51, Issue 6, p. 2318-2329.
7 "First National Survey Of ACOs Finds That Physicians Are Playing Strong Leadership And Ownership Roles" By Carrie H. Colla, Valerie A. Lewis, Stephen M. Shortell, and Elliott S. Fisher, Health Affairs, Vol. 33, No. 6, June 2014, p. 967-970.
8 "Changes in Patients' Experiences in Medicare Accountable Care Organizations" By J. Michael McWilliams, Bruce E. Landon, Michael E. Chernew, and Alan M. Zaslavsky, The New England Journal of Medicine, Vol. 371, Issue 18, October 2014, p. 1715.
9 "Association Between Medicare Accountable Care Organization Implementation and Spending Among Clinically Vulnerable Beneficiaries" By Carrie H. Colla, Valerie A. Lewis, Lee-Sien Kao, et al, JAMA Internal Medicine, Vol. 176, Issue 8, August 2016, p. 1168; "Changes in Patients' Experiences in Medicare Accountable Care Organizations" By J. Michael McWilliams, Bruce E. Landon, Michael E. Chernew, and Alan M. Zaslavsky, The New England Journal of Medicine, Vol. 371, Issue 18, October 2014, p. 1715.
10 "Association of Pioneer Accountable Care Organizations vs Traditional Medicare Fee for Service With Spending, Utilization, and Patient Experience" By David J. Nyweide, Woolton Lee, Timothy T. Cuerdon, et al, JAMA, Vol. 313, Issue 21, June 2015, p. 2152-2161; "Association Between Medicare Accountable Care Organization Implementation and Spending Among Clinically Vulnerable Beneficiaries" By Carrie H. Colla, Valerie A. Lewis, Lee-Sien Kao, et al, JAMA Internal Medicine, Vol. 176, Issue 8, August 2016, p. 1167-1175.
11 "Moving Forward with Accountable Care Organizations: Some Answers, More Questions" By Carrie H. Colla, JAMA Internal Medicine, Vol. 177, No. 4 (April 2017), p. 527.
12 "Shared Savings Program" Centers for Medicare and Medicaid Services, February 5, 2024, https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos (Accessed 2/22/24).
13 *Ibid.*
14 "Financial Performance of Accountable Care Organizations: A 5-Year National Empirical Analysis" By Joseph Coyne et al., Journal of Healthcare Management, Foundation of the American College of Healthcare Executives, February 2024, https://pubmed.ncbi.nlm.nih.gov/38175536/ (Accessed 2/21/24).
15 *Ibid.*
16 "Medicare ACOs Saved $4.2 Billion in 2022 Shared Savings ACOs Continue to Deliver Savings, Improve Health" National Association of ACOs, August 24, 2023, https://www.naacos.com/press-release--medicare-acos-saved--4-2-billion-in-2022 (Accessed 2/22/24).
17 "ACO REACH" Centers for Medicare and Medicaid Services, 2024, https://www.cms.gov/priorities/innovation/innovation-models/aco-reach (Accessed 2/22/24).
18 *Ibid.*
19 *Ibid.*
20 "Kidney Care Choices (KCC) Model" Centers for Medicare and Medicaid Services, 2024, https://www.cms.gov/priorities/innovation/innovation-models/kidney-care-choices-kcc-model (Accessed 2/22/24).
21 *Ibid.*
22 Centers for Medicare and Medicaid Services, January 29, 2024.
23 *Ibid.*
24 *Ibid.*
25 *Ibid.*
26 *Ibid.*
27 *Ibid.*
28 "After Slowdown, ACO Participation in Shared Savings Program Grows" By Jacqueline LaPointe, RevCycleIntelligence, January 30, 2024, https://revcycleintelligence.com/news/after-slowdown-aco-participation-in-shared-savings-program-grows (Accessed 2/14/24).
29 *Ibid.*
30 "Medicare ACO participation spiked in 2024, CMS says" By Alison Bennett, Modern Healthcare, January 29, 2024, https://www.modernhealthcare.com/accountable-care/cms-aco-2024-reach-shared-savings-kidney-care (Accessed 2/14/24).
31 *Ibid.*
32 LaPointe, RevCycleIntelligence, January 30, 2024.
33 "Participation Continues to Grow in CMS' Accountable Care Organization Initiatives in 2024" Centers for Medicare and Medicaid Services, January 29, 2024, https://www.cms.gov/newsroom/press-releases/participation-continues-grow-cms-accountable-care-organization-initiatives-2024 (Accessed 2/14/24).
34 *Ibid.*
35 "Accountable care participation grows in 2024" By Maya Goldman, Axios, January 30, 2024, https://www.axios.com/2024/01/30/accountable-care-participation-grows-in-2024 (Accessed 2/14/23).

2023 M&A in Review: Indications for 2024

[Excerpted from the article published in February 2024.]

Overview

After healthcare mergers and acquisitions (M&A) activity began to regain momentum in 2022, following the slowing of deals in the wake of the COVID-19 pandemic, transactional activity continued to accelerate in 2023.[1] While the healthcare sector continued to be impacted by factors such as valuation gaps, higher-for-longer interest rates, general macroeconomic risks, and increased state and federal regulatory concerns in 2023, the outlook for 2024 remains cautiously optimistic.[2] This Health Capital Topics article reviews the U.S. healthcare industry's 2023 M&A activity and discusses what these trends may mean for 2024.

Healthcare Services

Although the health services deal volumes through November 15, 2023, experienced a decline of 13% compared to 2022 levels, the trailing 12-month volumes are nearly twice the average annual levels seen between 2018 and 2020.[3] Since the end of 2021, industry-wide enterprise value (EV) to earnings before interest, tax, income, depreciation, and amortization (EBITDA) multiples have declined steadily.[4] As of November 15, 2023, the average health services EBITDA multiple was 13.0x, comparatively lower than both 2022 (13.8x) and 2021 (15.9x) multiples.[5]

There were a number of major healthcare services acquisitions within 2023, by companies such as Amazon, CVS Health, and Village MD. Some of the largest (by deal size) are summarized below:

- Village MD, in which Walgreens Boots Alliance has majority ownership, completed an acquisition of Summit Health-City MD for $8.9 billion, adding 2,800 providers to their ranks.
- Amazon acquired One Medical, a virtual and in-person primary care company, for $3.9 billion.
- CVS Health added 10,000 providers to their network after acquiring Signify Health for $8 billion. CVS Health also completed a $10.6 billion acquisition of Oak Street Health, a primary care company.

Hospitals & Health Systems

Sixty-five hospital and health system transactions were announced in 2023, compared to 53 in 2022.[6] While M&A activity continued to increase in 2023, there was also an increase in the percent of financially distressed organizations that sought partners.[7] The financial pressures faced by hospitals and health systems were a key driver in 2023 M&A activity, with financial distress cited as a factor in 28% of transactions, compared to only 15% in 2022.[8]

Hospital and health system M&A activity is expected to remain robust – and potentially intensify – in 2024.[9] This expectation is informed by the following factors. First, health systems are focusing more on the development of regional markets. While cross-market mergers gained attention in 2023, health systems are expected to expand this focus and develop markets regionally, and larger health systems are expected to concentrate on developing key regions from their portfolios. An essential consideration will be balancing advantages of scale with the ability to respond to opportunities and regional issues with agility. Second, hospitals and health systems are examining new models of alignment. Factors such as regulatory challenges, retaining independence, and the desire to pursue less capital-intensive alignment structures are driving new waves of creative alignment models. Third, while hospital and health system financial performance is stabilizing, this stability may not be sustainable in the long-term. This may be especially true for smaller hospitals and health systems; as balance sheets across the country have been impacted by economic uncertainty, smaller hospitals have less margin for error. Organizations facing financial pressures, even those that maintained financial health during market headwinds, are expected to continue seeking partnerships with larger and more stable organizations.[10]

Physician Groups

In the physician services sector, consolidation continues to be a growing trend, even though activity in 2023 was comprised of a greater number of smaller "roll-up" deals (in contrast to larger "platform" transactions).[11] While very few private equity (PE) platforms exited the market in 2023, there is still a strong pipeline, and several platform sales are

expected in 2024.[12] Primary care continued to be the most active subsector with physician services (with 15 deals in the fourth quarter of 2023), followed by dermatology (6), plastic surgery and medical spas (4), and urology (4). A variety of other physician group specialties were acquired, including orthopedics, allergy, oncology, eye care, cardiology, podiatry, and fertility.[13]

Home Health

2023 saw two large transactions in the home health and hospice sector. UnitedHealth Group closed on a $5.4 billion acquisition of LHC Group, a home health company. Optum, a UnitedHealth Group subsidiary, announced plans to merge with Amedisys, a home and hospice care provider, in an all-cash deal valued at $101 per share, pending regulatory and shareholder approval.[14]

Demand for home health services is expected to continue in 2024, due to the rising costs of healthcare, patient preference for personalized care, and an aging population.[15] The increased demand for home health services is creating a buyer pool eagerly seeking acquisitions, resulting in escalating competition.[16] Home health agencies that invest in integration, technology, and data analytics are expected to stand out as ideal targets.[17] Despite concerns in proposed reimbursement cuts, favorable conditions in the home health market and increasing competition among buyers will increase the volume of sales and strategic alliances.[18]

Digital Health

Digital health deal volumes slumped toward the end of 2023; however, the sector still had the second highest deal volume in 2023.[19] Digital health deal activity is expected to continue growing through 2024, as investors show interest in healthcare AI applications, among other innovative technologies, and in increasing the use of consumer-focused and cloud applications to improve the care experience for patients.[20]

Conclusion

Overall, 2023 deal making volume in the healthcare industry slowed to pre-pandemic levels, and M&A activity is expected to hold steady in 2024.[21] Dealmakers are expected to be on the lookout for opportunities in physician practices, digital health, and payor markets.[22] In 2024, physician groups across a number of specialties are expected to remain prime acquisition targets, particularly for PE investors.[23] The digital health sector is expected to continue to develop, with the addition of new diagnostics, therapies, and treatments, as well as innovative approaches to the provision of cost-effective and quality healthcare.[24] Despite M&A activity slowing down in 2023, consolidation in healthcare is expected to drive an increase in deal activity.[25]

---

1 "Hospital and Health System M&A in Review: Financial Pressures Emerge as Key Driver in 2023" By Anu Singh, Kaufman Hall, January 18, 2024, https://www.kaufmanhall.com/insights/research-report/2023-hospital-and-health-system-ma-review (Accessed 2/1/24).
2 "Health services: US Deals 2024 outlook" PwC, https://www.pwc.com/us/en/industries/health-industries/library/health-services-deals-outlook.html (Accessed 2/1/23).
3 *Ibid.*
4 *Ibid.*
5 *Ibid.*
6 Singh, Kaufman Hall, January 18, 2024.
7 *Ibid.*
8 *Ibid.*
9 *Ibid.*
10 *Ibid.*
11 "Health Care M&A Insights: Q4 2023 & Outlook for 2024 Deal Activity" By Epstein Becker, KPMG, and Ziegler, Modern Healthcare, February 1, 2024, https://www.modernhealthcare.com/mergers-acquisitions/health-care-ma-insights-q4-2023-outlook-2024-deal-activity (Accessed 2/22/24).
12 *Ibid.*
13 *Ibid.*
14 "The major healthcare deals of 2023" By Naomi Diaz, Becker's Hospital Review, December 21, 2023, https://www.beckershospitalreview.com/disruptors/the-major-healthcare-deals-of-2023.html#:~:text=In%20February%2C%20UnitedHealth%20Group%20closed,deal%20was%20worth%20%248.9%20billion. (Accessed 2/2/24).
15 "Home Health M+A Expectations Going Into 2024" By Anna Elliott, VertessPress, September 12, 2023, https://vertesspress.com/home-health-ma-expectations-going-into-2024/ (Accessed 2/22/24).
16 *Ibid.*
17 *Ibid.*
18 *Ibid.*
19 "Health Care M&A Insights: Q4 2023 & Outlook for 2024 Deal Activity" By Epstein Becker, KPMG, and Ziegler, Modern Healthcare, February 1, 2024, https://www.modernhealthcare.com/mergers-acquisitions/health-care-ma-insights-q4-2023-outlook-2024-deal-activity (Accessed 2/22/24).
20 Becker, KPMG, and Ziegler, Modern Healthcare, February 1, 2024.
21 "Operating pressures, rising demand ensure dealmaking will hold steady in 2024, KPMG says" By Dave Muoio, Fierce Healthcare, January 5, 2024, https://www.fiercehealthcare.com/finance/operating-pressures-rising-demand-ensure-dealmaking-will-hold-steady-2024-kpmg-says#:~:text=Though%20dealmaking%20volume%20slowed%20to,payer%20and%20health%20IT%20markets. (Accessed 2/2/24).
22 *Ibid.*
23 Becker, KPMG, and Ziegler, Modern Healthcare, February 1, 2024.
24 *Ibid.*
25 "DC Discusses: Healthcare M&A Outlook for 2024" By Hector Torres, Rich Blann, and Manish Gupta, DC Advisory, January 31, 2024, https://www.dcadvisory.com/news-deals-insights/insights/dc-discusses-healthcare-m-a-outlook-for-2024/#gref (Accessed 2/22/24).

FTC Finalizes Ban on Noncompete Agreements

[Excerpted from the article published in May 2024.]

On April 23, 2024, the Federal Trade Commission (FTC) issued a final rule that would ban employers from imposing non-competes on their employees. The FTC asserts that this exploitative practice keeps wages low, and suppresses new ideas.[1] Notably, while the final rule will affect all industries, not just healthcare, this proposal comes at a time when healthcare employers across the U.S. are struggling with staffing shortages.[2] This Health Capital Topics article will discuss the final rule, reactions from healthcare industry stakeholders, and potential implications for healthcare valuations (both business and compensation valuations).

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

Under the final rule, existing noncompetes for the majority of workers will not be enforceable after the rule goes into effect.[7] Noncompetes for senior executives can remain in force under the new ruling, but employers may not enter in or attempt to enforce any new noncompetes, even if that includes a senior executive.[8] Notably, the Commission also recognizes that they have no jurisdiction over not-for-profit entities, however they reserve the right to evaluate any entity's non-profit status.[9] The agency noted that some "entities that claim tax-exempt nonprofit status may in fact fall under the Commission's jurisdiction."[10] The FTC specifically stated that "some portion of the 58% of hospitals that claim tax-exempt status as nonprofits and the 19% of hospitals that are identified as State or local government hospitals in the data cited by AHA likely fall under the Commission's jurisdiction and the final rule's purview."[11]

In healthcare, the medical profession has grown from small practices comprised of just a few physicians to mega-practices totaling a few hundred physicians, especially in urban settings. Non-competes in healthcare have traditionally been utilized as a tool to limit the harm that a physician may inflict upon departing a practice. While these large practices need to protect their investments, non-compete clauses may make it hard for a departing physician to seek employment within the same geographic area.[12] Non-compete clauses in specialty practices further complicate the ability for physicians to seek employment, as specialists only serve a subset of the population (i.e., there may be fewer outside opportunities for specialists).[13]

Multiple states have provisions that flat out ban or place a limit on an employer seeking to restrict the activity of a physician or other healthcare professional post-employment.[14] States that ban such clauses include Alabama, Arkansas, Colorado, Delaware, Massachusetts, New Hampshire, New Mexico, Rhode Island, and South Dakota.[15] Some states, such as Arkansas, allow non-competes, but have exceptions carved out for medical professionals.[16] Other states, such as Florida, impose limitations on healthcare non-competes, banning agreements for physicians specialists in a county when all those within the specialty are employed by a single entity.[17]

This final rule is the latest step in the federal government's push (across two presidential administrations) to increase competition in the healthcare industry. In 2018, the Department of Health and Human Services (HHS), the Department of the Treasury, and the Department of Labor issued a 119-page report comprising over 50 recommendations to increase quality, decrease cost, and promote competition in healthcare.[18] In 2021, President Biden issued an executive order to promote competition in the American economy.[19] The executive order was designed to address issues the administration identified as contributing to harmful trends associated with decreased competition and corporate consolidation, which are ultimately harming American consumers.[20] The executive order, which set forth 72 initiatives for multiple federal agencies, did not immediately establish requirements, but rather directed federal agencies to review issues and implement policies to reflect the administration's goals.[21] Pursuant to the executive order, federal agencies have taken action over

the past couple of years to lower healthcare and prescription drug costs for consumers as well as increase competition and safety in healthcare facilities.[22] Some of these actions include:

- HHS and the Centers for Medicare & Medicaid Services (CMS) is currently collecting feedback on how the agencies can promote competition, increase transparency, and identify the effects of vertical integration in Medicare Advantage (MA) markets.
- The FTC, Department of Justice (DOJ), and HHS published a Request for Information (RFI) to receive feedback and examine the role of corporate influence and private equity in the healthcare industry.
- CMS released ownership data for Federally Qualified Health Centers (FQHCs) in an effort to promote competition and increase transparency.
- HHS published Medicare-certified nursing home ownership data, increasing transparency of and the ability to identify common owners and those that had a history of poor performance.
- HHS announced steps to crack down on nursing homes that put resident safety at risk, including a proposed rule that set minimum staffing levels to ensure a higher quality of life for residents.
- The Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office (USPTO) announced increased scrutiny of pharmaceutical patents that resulted in higher prescription drug costs. The FDA and USPTO also began collaborating on ways to improve the patent system in order to increase access to affordable and safe prescription drugs.
- HHS enacted a rule cracking down on hospitals that failed to disclose their prices pursuant to Hospital Price Transparency requirements, including increasing nearly twentyfold the fine for hospitals that failed to report their prices.[23]

In response to the final rule, Chad Golder, general counsel for the American Hospital Association (AHA), stated that the "FTC's final rule banning non-compete agreements for all employees across all sectors of the economy is bad law, bad policy, and a clear sign of an agency run amok.[24] The agency's stubborn insistence on issuing this sweeping rule — despite mountains of contrary legal precedent and evidence about its adverse impacts on the health care markets — is further proof that the agency has little regard for its place in our constitutional order."[25] Golder also said that "Three unelected officials should not be permitted to regulate the entire United States economy and stretch their authority far beyond what Congress granted it--including by claiming the power to regulate certain tax-exempt, non-profit organizations."[26] In addition, the Federation of American Hospitals' (FAH) Chief Executive Officer Chip Kahn stated that "this final rule is a double whammy.[27] The ban makes it more difficult to recruit and retain caregivers to care for patients, while at the same time creating an anti-competitive, unlevel playing field between tax-paying and tax-exempt hospitals – a result the FTC rule precisely intended to prevent."[28] Kahn also said that "in a time of constant health care workforce shortages, the FTC's vote today threatens access to high-quality care for millions of patients."[29]

While many trade groups have criticized this ruling, most healthcare employees and workers, including physicians, believe that the noncompete ruling is long overdue and that noncompetes "impede patient access to care, limit physicians' ability to choose their employer, contribute to burnout and stifle competition."[30] The American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), and the American Medical Association (AMA) all have policies that oppose restrictive covenants for physicians as they could reduce the access to care for patients.[31]

FTC Chair Lina Khan stated that "noncompete clauses keep wages low, suppress new ideas, and rob the American economy of dynamism, including from the more than 8,500 new startups that would be created a year once noncompetes are banned."[32] Khan also stated that "the FTC's final rule to ban noncompetes will ensure Americans have the freedom to pursue a new job, start a new business, or bring a new idea to market."[33] By halting the practice of imposing non-competes, the FTC aims to lower healthcare costs by upwards of $194 billion over the next decade and expand career opportunities for approximately 30 million Americans.[34]

The presence, or absence, of noncompete agreements can impact the value of a business by:

(1) Restricting the ability of owners or workers to leave and start a competing business or work for a competitor;
(2) Impeding a potential buyer's ability to employ key personnel or enter specific markets; and/or,
(3) Providing the business a competitive advantage and prevents essential employees from leaving.

If noncompete agreements are too restrictive, it could also lower the value of a business by limiting their ability to retain and attract new employees, and by reducing the ability for the business to develop and expand.[35] It is important to note that the rule does not apply to noncompetes entered into by a person pursuant to a "bona fide" sale of a business entity, of the person's ownership interest in a business entity, or of all or substantially all of a business entity's operating assets. Further, the FTC also found evidence that noncompetes increase consumer prices for medical care, and estimates that banning noncompetes will result in $74-$194 billion in reduced spending on physician services over the next decade.[36]

Not only does the final rule have implications on the revenue stream of healthcare services, by banning noncompetes, physicians would be able to move between jobs with more freedom, and compensation could potentially increase.[37] This may impact the expense structure of healthcare entities and necessitate further contemplation by compensation valuation professionals when considering historical market compensation data that were subject to noncompetes for the purposes of analyzing prospective arrangements that are not subject to noncompetes.

Less than a day after the noncompete final rule was issued, the Business Roundtable and the US Chamber of Commerce filed a lawsuit against the FTC in federal court.[38] Two other businesses filed separate legal challenges, seeking to block the rule.[39] The business trade groups requested that courts issue a preliminary injunction to prohibit FTC enforcement of this rule, and that they issue a stay that would stop the rule from going into effect.[40] While the FTC rule is set to go into effect on September 4, 2024, the effective date may be delayed due to ongoing litigation.[41] If the rule is put on a hold until litigation is finished, the rule's effective date may be pushed out if it isn't struck down completely.[42]

1 "FTC Announces Rule Banning Noncompetes" Federal Trade Commission, April 23, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-announces-rule-banning-noncompetes (Accessed 4/24/24).
2 ""Healthcare Closely Watching FTC's Proposed Ban on Non-Competes" Jennifer Henderson, MedPage Today, January 12, 2023, https://www.medpagetoday.com/special-reports/exclusives/102618 (Accessed 4/24/24).
3 "Noncompete Agreements" By Alexander Colvin and Heidi Shierholz, Economic Policy Institute, December 10, 2019, https://www.epi.org/publication/noncompete-agreements/ (Accessed 4/24/24).
4 Federal Trade Commission, April 23, 2024.
5 "Noncompetes in the U.S. Labor Force" By Evan Starr, J.J. Prescott, and Norman Bishara, Journal of Law and Economics, July 3, 2015, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2625714 (Accessed 4/24/24).
6 *Ibid.*
7 Federal Trade Commission, April 23, 2024.
8 *Ibid.*
9 "16 CFR Part 910" Federal Trade Commission, April 23, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/noncompete-rule.pdf (Accessed 4/24/24).
10 *Ibid.*
11 *Ibid.*
12 "The Current State of the Enforceability of Restrictive Covenants in the Medical Profession" By Robert H. Schwartz, Phil Korovesis, and Mostafa Shanta, American Bar Association, December 28, 2022, https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2022-2023/december-2022/the-current-state-of-the-enforceablility-of-restrictive-covenants-in-the-medical-profession/ (Accessed 4/24/24).
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
16 *Ibid.*
17 *Ibid.*
18 "HHS Unveils Plans to Increase Healthcare Competition, Choice" By Jacqueline LaPointe, RevCycle Intelligence, December 5, 2018, https://revcycleintelligence.com/news/hhs-unveils-plans-to-increase-healthcare-competition-choice (Accessed 4/24/24).
19 "Executive Order on Promoting Competition in the American Economy" White House Press Release, July 9, 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/ (Accessed 4/24/24).
20 "Unprecedented Executive Order 14036 "Promoting Competition in the American Economy" – a call to action" By Christopher Brennan, Selina Coleman, Brad Funari, and Michelle Mantine, July 15, 2021, https://www.reedsmith.com/en/perspectives/2021/07/unprecedented-executive-order-14036 (Accessed 4/24/24).
21 *Ibid.*
22 "White House Competition Council" White House, 2024, https://www.whitehouse.gov/competition/ (Accessed 4/24/24).
23 *Ibid.*
24 "FTC issues final rule banning most noncompete clauses in employer agreements" American Hospital Association, April 23, 2024, https://www.aha.org/news/headline/2024-04-23-ftc-issues-final-rule-banning-most-noncompete-clauses-employer-agreements (Accessed 4/24/24).
25 *Ibid.*
26 *Ibid.*
27 ""Double Whammy" – FAH Leader Reacts to FTC's Final Noncompete Rule" FAH Hospital Policy Blog, Federation of American Hospitals, April 23, 2024, https://www.fah.org/blog/double-whammy-fah-leader-reacts-to-ftcs-final-noncompete-rule/ (Accessed 4/24/24).
28 *Ibid.*
29 *Ibid.*
30 "Noncompete clauses for physicians are hurting health care, AAFP says" Richard Payerchin, Medical Economics, April 11, 2023, https://www.medicaleconomics.com/view/noncompete-clauses-for-physicians-are-hurting-health-care-aafp-says (Accessed 4/24/24).
31 *Ibid.*
32 Federal Trade Commission, April 23, 2024.
33 *Ibid.*
34 *Ibid.*
35 "FTC's Proposed Ban on Non-Compete Agreements - Impact on Business Valuation" By Achille Ekeu, The Washington Valuation Group, March 20, 2023, https://www.washingtonvaluation.com/post/ftc-s-proposed-ban-on-non-compete-agreements-impact-on-business-valuation (Accessed 5/14/24).
36 "Noncompete Rule" Federal Trade Commission, https://www.ftc.gov/legal-library/browse/rules/noncompete-rule (Accessed 5/20/24).
37 "FTC votes to ban noncompetes, with far-reaching effects on doctors" By Rebecca Pifer, Healthcare Dive, April 23, 2024, https://www.healthcaredive.com/news/ftc-noncompete-ban-healthcare-doctor-effects/713846/#:~:text=The%20latest%20labor%20trends%20in%20healthcare,-Disputes%20between%20hospitals&-text=Zeroing%20out%20noncompetes%20equalizes%20the,also%20cause%20wages%20to%20rise. (Accessed 5/14/24).
38 "FTC is sued by business groups over its ban on noncompete agreements, which may delay enforcement" By Jeanne Sahadi, CNN Business, April 26, 2024, https://www.cnn.com/2024/04/25/success/ftc-noncompete-ban-lawsuit/index.html (Accessed 5/20/24).
39 "FTC Ban on Noncompetes Now Slated To Take Effect on September 4" By Matthew Collin et al., Skadden, Arps, Slate, Meagher & Flom LLP & Affiliates, May 8, 2024, https://www.skadden.com/insights/publications/2024/05/ftc-ban-on-noncompetes-now-slated (Accessed 5/20/24).
40 Sahadi, CNN Business, April 26, 2024.
41 *Ibid*; Collin et al., Skadden, Arps, Slate, Meagher & Flom LLP & Affiliates, May 8, 2024.
42 Sahadi, CNN Business, April 26, 2024.

Corporate Entrants in Healthcare Struggle

[Excerpted from the article published in June 2024.]

On April 30, 2024, retail giant Walmart announced their closure of Walmart Health, a network of 51 health centers that provided "primary and urgent care, labs, x-ray and diagnostics, behavioral health, dental, optometry and hearing services."[1] Walmart cited the lack of profitability, escalating costs of operation, and challenging environment for reimbursement as the reasons behind Walmart Health's unsustainability.[2] This Health Capital Topics article discusses Walmart's closures, the other corporate entrants struggling in the healthcare market, and what these challenges indicate for the primary care space.

Due to political impasses and systemic problems, the federal government is often incapable of making quick, meaningful improvements to the healthcare industry. Increasingly high costs, large deductibles, healthcare workforce shortages, and delays in treatment and obtaining medication plague the U.S. healthcare delivery system.[3] Instead of waiting on regulatory reform, large corporate entities such as Walmart have aimed to disrupt the healthcare industry through streamlining healthcare delivery (and associated costs) and capitalizing on technological advancements. While this "corporatization of medicine" has grown significantly over the last two decades,[4] these newer entrants to the primary care market have been forced to realize that traditional business strategies may not be successful given the various nuances unique to healthcare.

In November 2011, it was leaked to the press that Walmart intended to become the "largest provider of primary healthcare services in the nation."[5] While Walmart recanted parts of its claim as "overwritten and incorrect," the number of clinics owned by retailers such as Walmart has increased significantly over the past 15 years.[6] Walmart has been a long-time player in the healthcare market, with footholds most notably in pharmacies and retail clinics.[7] In 2014, Walmart implemented its "Healthcare Begins Here" initiative, which provided consumers with free health screenings, access to immunizations, and assistance with the (then new) Affordable Care Act (ACA) health insurance exchanges.[8] At that time, Walmart seemingly doubled down on its 2011 claim by announcing its ambitious intentions "to be the number one healthcare provider in the industry."[9]

The next iteration of Walmart's healthcare delivery quest – Walmart Health – launched in 2019. The retail giant opened more than 25 Walmart Health centers across the South and announced in early 2023 its plans to open an additional 75 centers by the end of 2024.[10] Walmart also made a number of complementary acquisitions during this timeframe, including: (1) FloCare (a health-technology business) in July 2019; (2) CareZone (a prescription management startup) in June 2020; and (3) MeMD (a telehealth provider) in May 2021.[11] Through this transactional activity, Walmart sought to increase healthcare access and promote better health outcomes by rendering healthcare services to patients where they are – in Walmart stores – and by providing transparent and affordable pricing for healthcare services.[12]

However, nearly five years later, Walmart did an about-face, announcing in April 2024 that it would shut down Walmart Health, closing all clinics by June 28, 2024.[13] While Walmart ambitiously grew their presence in the healthcare industry, issues of profitability, escalating costs, and a challenging reimbursement ultimately led to the company shifting their strategy.[14] Going forward, Walmart's focus will be on their 4,600 pharmacies and 3,000 vision centers that are already located in-store, and not on primary care.[15] Walmart aims to expand the clinical capabilities of the services their pharmacies provide; their pharmacies already largely offer the clinical services that Walmart Health clinics provided, such as treatment and testing for respiratory illnesses.[16]

The surprising closure of Walmart Health's clinics comes as other corporate healthcare disrupters are similarly struggling to sustainably operate in the primary care space.[17] Walgreens, a chain of retail pharmacy stores, entered the primary care space over a decade ago with plans to expand healthcare services to include patient treatment and diagnosis, and capitalize on concerns at the time about cost and a physician shortage.[18] Through its 2021 acquisition of primary care network VillageMD for $5.2 billion, Walgreens aimed to transform its pharmacies into healthcare destinations, providing patients a one-stop-shop for checkups and filling prescriptions.[19] Walgreens also made a number of additional

strategic acquisitions to bolster its healthcare offerings, including: (1) Shields Health Solutions (specialty pharmacy company) in September 2021 for $2.3 billion; (2) CareCentrix (a home care company) in October 2021 for $722 million; and (3) Summit Health-CityMD (an urgent care clinic group) in November 2022 for $8.9 billion.[20] However, less than three years after these acquisitions, Walgreens reported a loss of nearly $6 billion, which was largely attributed to the loss in value in VillageMD.[21] Instead of continuing to expand, Walgreens is in the midst of scaling back their VillageMD clinic footprint, shutting nearly 160 of the 200 clinics that were adjacent to the pharmacy chain's stores.[22] In fact, the Wall Street Journal reported on June 27, 2024 that Walgreens plans to reduce its majority ownership stake in VillageMD; Walgreens was also reportedly considering a sale of Shields Health Solutions, although it has since backed off that statement.[23] The retail pharmacy has been criticized for failing to capitalize on its significant investments and has attributed its struggles in part to "slower-than-expected trends in patient panel growth and multi-specialty productivity and recent changes in Medicare reimbursement models."[24]

Amazon, which has widely publicized its intention to disrupt the healthcare industry, has also not been immune to these difficulties in the healthcare market.[25] Amazon acquired PillPack (an online pharmacy) in June 2018 for $753 million,[26] and subsequently expanded its pharmaceutical footprint through its November 2020 launch of Amazon Pharmacy, providing transparent drug pricing and free, unlimited deliveries of medications to customers in 45 states.[27] The service has since expanded to all 50 states, and in 2023, Amazon commenced RxPass, a low-cost, generic drug subscription service targeting those with common, chronic conditions.[28] Beyond the pharmaceutical sector, in what has been characterized as its "potentially most significant move" in the healthcare space, Amazon acquired primary care network One Medical – and its 836,000 associated members and 221 medical offices across 27 markets – in July 2022 for $3.9 billion.[29] However, less than two years post-acquisition, One Medical reported operating losses of nearly $500 million, worse than the losses reported by the company prior to Amazon's acquisition.[30] In an effort to cut nearly $100 million in costs, Amazon (similar to the other corporate entities discussed above) is closing corporate offices and laying off One Medical staff.[31] Additionally seniors receiving care from One Medical have reportedly expressed frustration since the company's acquisition, citing shorter appointments and disappearing offerings.[32] One Medical is not Amazon's only struggling healthcare venture: Haven, a healthcare-specific joint venture with JPMorgan Chase and Berkshire Hathaway, was disbanded less than three years after its 2018 launch; Amazon Care, an Amazon-launched virtual health clinic, lasted only a couple of years; and, most recently, Amazon Clinic's telehealth market placed was nixed after only 19 months in operation (and consolidated into One Medical).[33] Despite recent difficulties, Amazon asserts that it "continues to see strong growth and positive feedback from One Medical members, and will continue investing to provide high-quality care to more people."[34]

Despite big plans and hubristic promises, the large corporate entities that have sought to disrupt U.S. healthcare generally, and the primary care space specifically, have been largely unable to deliver. One industry analyst noted that "primary care is often a loss leader for larger health systems but serves a critical role as a feeder of patients and customers for specialty care and procedures. Without those higher revenue opportunities, retailers must achieve high levels of adoption and volume to unlock profitability."[35] Another analyst summarized that "the news [regarding Walmart Health] is a significant setback for retail health players, some of whom are now realizing that delivering retail-driven primary care may not be economically viable and certainly isn't causing the disruption in local healthcare markets that many predicted."[36] The President and Chief Executive Officer of the Primary Care Collaborative stated that "Wal-Mart's recent announcement only confirms what every primary care clinician across the country already knows: we have a system that doesn't support the ongoing trusted primary care relationships that deliver better outcomes, create better patient experiences and enhance affordability."[37]

1 "Walmart Health Is Closing" Walmart, April 30, 2024, https://corporate.walmart.com/news/2024/04/30/walmart-health-is-closing (Accessed 6/25/24); "Walmart Health" OneWalmart, https://web.archive.org/web/20230328220149/https://one.walmart.com/content/usone/en_us/company/walmart-health.html (Accessed 6/25/24).
2 *Ibid.*
3 "Corporate Solutions in Healthcare" Health Capital Topics, Vol. 13, Issue 1 (January 2020), https://www.healthcapital.com/hcc/newsletter/01_20/HTML/CORP/convert_corporate-solutions-healthcare_hc_topics_12.19.19.php (Accessed 6/25/24).
4 "Healthcare Valuation: The Four Pillars of Healthcare Value" By Robert James Cimasi, Volume 1, Hoboken, NJ: Wiley, 2014, p. 442.
5 *Ibid*; "Walmart Wants To Be Nation's Biggest Primary Care Provider" By Sarah Varney and Julie Appleby, KFF Health News, November 9, 2011, https://kffhealthnews.org/news/walmart-primary-care-medical-services/ (Accessed 6/26/24).
6 Cimasi, Volume 1, Hoboken, NJ: Wiley, 2014, p. 442.
7 "Walmart Announces Ambitious Goal: To Be the Number One Healthcare Provider in the Industry" By Dan Diamond, Forbes, October 6, 2014, https://www.forbes.com/sites/dandiamond/2014/10/06/walmart-announces-ambitious-goal-to-be-the-number-one-healthcare-provider/#1c3159f75be1 (Accessed 6/26/24).
8 "Making a Difference through Health: How PwC is Helping to Change Lives" Pricewaterhouse Coopers, December 2015, https://www.pwc.com/gx/en/healthcare/case-studies/making-a-difference-global-health-usa-case-study.pdf (Accessed 4/5/18), p. 15.
9 By Dan Diamond, Forbes, October 6, 2014, https://www.forbes.com/sites/dandiamond/2014/10/06/walmart-announces-ambitious-goal-to-be-the-number-one-healthcare-provider/#1c3159f75be1 (Accessed 6/26/24).
10 "Walmart Health" OneWalmart; "Walmart Health's shutdown underscores major challenges for retail health 'disruptors'" By Heather Landi, Fierce Healthcare, April 30, 2024, https://www.fiercehealthcare.com/providers/walmart-shuttering-all-51-health-centers-virtual-care (Accessed 6/25/24).
11 "How Amazon, CVS and others have grown into healthcare powerhouses" By Caroline Hudson and Tim Broderick, Modern Healthcare, February 9, 2023, https://www.modernhealthcare.com/mergers-acquisitions/healthcare-deals-cvs-amazon-walmart-walgreens-one-medical-aetna (Accessed 6/25/24).
12 "How Walmart Became a Major Player in the Healthcare Industry" By Victoria Bailey, Revcycle Intelligence, March 14, 2023, https://revcycleintelligence.com/features/how-walmart-became-a-major-player-in-the-healthcare-industry (Accessed 6/25/24).
13 Walmart Health employees will be transferred to other Walmart or Sam's Club stores. "Walmart to shut all health clinics in US over lack of profitability" By Granth Vanaik and Siddharth Cavale, Reuters, May 1, 2024, https://www.reuters.com/business/healthcare-pharmaceuticals/walmart-close-51-us-health-centers-2024-04-30/ (Accessed 6/25/24); "Walmart Health to close all clinics Friday" By Caroline Hudson, Modern Healthcare, June 26, 2024, https://www.modernhealthcare.com/providers/walmart-health-clinics-closing-june-28 (Accessed 6/27/24).
14 Walmart, April 30, 2024.
15 Vanaik and Cavale, Reuters, May 1, 2024.
16 *Ibid.*
17 "Walmart Health's shutdown underscores major challenges for retail health 'disruptors'" By Heather Landi, Fierce Healthcare, April 30, 2024, https://www.fiercehealthcare.com/providers/walmart-shuttering-all-51-health-centers-virtual-care (Accessed 6/25/24).
18 "Walgreens Becomes 1st Retail Chain To Diagnose, Treat Chronic Conditions" By Julie Appleby,
19 "Walgreens boosts stake in primary-care company VillageMD with a $5.2 billion investment" By Melissa Repko, CNBC, October 14, 2021, https://www.cnbc.com/2021/10/14/walgreens-buys-majority-stake-in-primary-care-company-villagemd.html (Accessed 6/27/24).
20 Hudson and Broderick, Modern Healthcare, February 9, 2023.
21 Reported for the second quarter of 2024. "Walgreens Shutters 160 VillageMD Clinics after $6 Billion Loss" American Hospital Association, https://www.aha.org/aha-center-health-innovation-market-scan/2024-04-09-walgreens-shutters-160-villagemd-clinics-after-6-billion-loss (Accessed 6/25/24).
22 Landi, Fierce Healthcare, April 30, 2024; "Walgreens Has 200 VillageMD Clinics Attached To Stores As Doctor Network Takes Off" By Bruce Japsen, Forbes, January 5, 2023, https://www.forbes.com/sites/brucejapsen/2023/01/05/walgreens-has-200-villagemd-clinics-attached-to-stores-as-doctor-network-takes-off/ (Accessed 6/25/24); "Walgreens considers sale of Shields Health Solutions: Bloomberg" By Caroline Hudson, Modern Healthcare, January 24, 2024, https://www.modernhealthcare.com/mergers-acquisitions/walgreens-shields-health-solutions-sale-specialty-pharmacy (Accessed 6/27/24).
23 "Walgreens to cut stake in primary care provider VillageMD: WSJ" By Caroline Hudson, Modern Healthcare, June 27, 2024, https://www.modernhealthcare.com/providers/walgreens-villagemd-ownership-majority-stake?utm_source=modern-healthcare-daily-finance-thursday&utm_medium=email&utm_campaign=20240627&utm_content=article2-headline (Accessed 6/27/24); "Walgreens considers sale of Shields Health Solutions: Bloomberg" By Caroline Hudson, Modern Healthcare, January 24, 2024, https://www.modernhealthcare.com/mergers-acquisitions/walgreens-shields-health-solutions-sale-specialty-pharmacy (Accessed 6/27/24).
24 "Walgreens narrows profit outlook for 2024, takes $6B hit in Q2 from VillageMD investment" By Heather Landi, Fierce Healthcare, March 28, 2024, https://www.fiercehealthcare.com/retail/walgreens-takes-6b-hit-q2-villagemd-investment (Accessed 6/25/24).
25 "How Amazon built its healthcare strategy from Haven to One Medical" By Brock Turner and Caroline Hudson, Modern Healthcare, February 23, 2023, https://www.modernhealthcare.com/digital-health/amazon-healthcare-strategy-one-medical-rxpass-andy-jassy-neil-lindsay (Accessed 6/24/24).
26 Hudson and Broderick, Modern Healthcare, February 9, 2023; "Amazon acquires start-up Health Navigator, its first health-related purchase since PillPack" By Christina Farr, NBC, October 23, 2019, https://www.cnbc.com/2019/10/23/amazon-acquires-digital-health-start-up-health-navigator.html (Accessed 6/24/24).
27 Turner and Hudson, Modern Healthcare, February 23, 2023.
28 *Ibid.*
29 *Ibid.*
30 "Amazon, CVS, and Walgreens went all in on primary care. Their bets are bleeding money." By Shelby Livingston, Business Insider, March 6, 2024, https://www.businessinsider.com/cvs-walgreens-amazon-primary-care-acquisition-strategy-2024-3 (Accessed 6/25/24).
31 *Ibid.*
32 *Ibid.*
33 Turner and Hudson, Modern Healthcare, February 23, 2023; "Amazon folds telehealth clinic into One Medical" By Brock E.W. Turner, Modern Healthcare, June 27, 2024, https://www.modernhealthcare.com/digital-health/amazon-clinic-one-medical-combined?utm_source=modern-healthcare-daily-finance-thursday&utm_medium=email&utm_campaign=20240627&utm_content=article6-headline (Accessed 6/28/24).
34 "Amazon, CVS, and Walgreens went all in on primary care. Their bets are bleeding money." By Shelby Livingston, Business Insider, March 6, 2024, https://www.businessinsider.com/cvs-walgreens-amazon-primary-care-acquisition-strategy-2024-3 (Accessed 6/25/24).
35 Landi, Fierce Healthcare, April 30, 2024.
36 *Ibid.*
37 *Ibid.*

Novant/CHS Deal Scrapped after FTC Intervenes

[Excerpted from the article published in June 2024.]

In February 2023, Novant Health, a 19-hospital, non-profit health system operating throughout the Carolinas,[1] agreed to acquire two North Carolina hospitals – Davis Regional Medical Center and Lake Norman Regional Medical Center – from Community Health System (CHS), a publicly-traded mega-system operating in 15 states.[2] After the $320 million deal was announced, the Federal Trade Commission (FTC) began an extensive review of the acquisition, and concluded that: (1) the transaction may substantially reduce competition; (2) create a monopoly; and (3) constitute an unfair method of competition.[3] Consequently, on January 25, 2024, the agency filed a complaint to initiate an administrative proceeding (to determine the legality of the transaction) and filed suit in the Western District of North Carolina, requesting a temporary retaining order and preliminary injunction so that Novant and CHS could not complete their transaction while the FTC's proceedings were ongoing.[4] In its complaint, the FTC claimed the transaction was illegal because it would:

(1) "[S]ignificantly increase concentration in the already highly concentrated market," as "Novant would control a significant percentage of the Eastern Lake Norman Area market";
(2) "[E]liminate price competition between CHS and Novant that constrains reimbursement rates for hospital services in the market"; and
(3) Result in insurers having "fewer competing alternatives for inpatient [general acute care] services in the [market]."[5]

The district court, in considering whether the Novant/CHS deal could proceed during the FTC's administrative process, weighed the "public equities" associated with the transaction and the injunction (i.e., "whether it is in the public interest to allow Novant to buy [the hospitals]" and whether "the public [will] be better off and/or worse off if an injunction is entered").[6] In doing so, the court considered the FTC's allegations that:

(1) "[I]nsurance companies and ultimately their customers will be charged Novant's higher prices";
(2) "[S]tate and local governments will receive millions less in tax revenues as soon as [the hospitals] are owned by a 'non-profit' hospital system"; and
(3) "CHS could make additional investments or enter into partnerships with other healthcare companies if the transaction is not enjoined."[7]

The court also considered Novant and CHS's assertions that:

(1) Davis Regional Medical Center, a behavioral health hospital, would quickly close without the transaction, "depriving the community of important mental health services";
(2) Certain medical service lines that had been lost at Lake Norman Regional Medical Center would be immediately added back if the transaction went through; and
(3) "Novant has committed not to raise prices at LNR for three years, to support LNR's doctors and nurses with additional staff and higher pay, and to add numerous capital improvements (which CHS will either be unwilling or unable to provide)."[8]

After weighing the parties' arguments, the district court denied the FTC's request for a preliminary injunction,[9] concluding that the merger appeared to carry an equal amount of competitive benefit as it did competitive harm, and that an immediate closure of Davis Regional Medical Center and the addition of medical service lines at Lake Norman Regional Medical Center outweighed the loss of tax revenue.[10]

The FTC subsequently appealed the decision to the U.S. Court of Appeals for the Fourth Circuit and filed a motion in the district court to enjoin the transaction until the Fourth Circuit heard the appeal.[11] While the district court denied the FTC's motion, it extended a temporary restraining order until June 21, 2024, giving the FTC time to seek an injunction from the Fourth Circuit.[12]

Three days before the temporary retaining order expired, the Fourth Circuit granted the FTC's motion for an injunction, which would keep Novant and CHS from consummating the transaction until the appeals process was complete.[13] With any appeal of the injunction potentially taking up to two years, Novant ultimately decided to call off the CHS hospital acquisition.[14]

Novant's spokesperson said that Novant had "worked tirelessly for more than a year to create a path forward for Lake Norman Regional Medical Center and Davis Regional Medical Center."[15] The spokesperson also asserted that Novant is:

> "steadfast in our belief that these facilities and their patients would have greatly benefited from joining Novant Health, but with the FTC's continued roadblocks we do not see a way to finalize this transaction. The communities served by these facilities deserve better than the fate they've been dealt by the FTC so we will look for other ways to support patients and clinicians in these communities."[16]

This latest scrapped hospital deal underscores the federal government's push to increase competition in the healthcare industry. Over the past couple of years, the FTC has filed a number of lawsuits seeking to halt transactions, including:

(1) Suing to block a merger of two New Jersey-based health systems, RWJ Barnabas Health and Saint Peter's Healthcare System, which caused the systems to scrap their merger plans;[17]
(2) Suing to block HCA Healthcare's acquisition of five Utah hospitals from Steward Health, which caused HCA to abandon the acquisition;[18]
(3) Suing to block a merger of two Rhode Island health systems, Lifespan and Care New England, which caused the systems to abandon their merger plans;[19] and
(4) Suing to block New Jersey's biggest hospital system, Hackensack Meridian Health, from acquiring competitor Englewood Healthcare, which caused Hackensack to scrap the acquisition.[20]

While the scrapped Novant/CHS deal represents yet another win for the FTC, this case is different from the FTC's past successes. In this circumstance, Novant may have been able to successfully appeal the Fourth Circuit decision, but decided against it. The dissenting judge in the Fourth Circuit's order highlighted the fact that:

> "sending this [case] back to the FTC and the administrative law judge is a process that ordinarily takes over two years…Given the evidence I am not sure any financially hard-pressed healthcare facility would have that amount of time. Hospitals such as [the two CHS hospitals] may not provide a full menu of advanced procedures, but they do tend to increase access to vital healthcare for underserved populations."[21]

The dissenting judge also called out the FTC, stating that the agency "is acting too aggressively in this case, forgetting there is such a thing as a vibrant private sector."[22] The Novant case highlights not only the emboldened actions of the FTC in hospital mergers and acquisitions, but hospitals not wanting to engage in years of litigation (particularly when one or more of the hospitals at issue are financially distressed), and simply scrapping hospital mergers and acquisitions, which may have the undesirable effect of those un-acquired, financially distressed hospitals ultimately closing.

1 "Company" Novant Health, https://www.novanthealth.org/about/company/ (Accessed 6/27/24).
2 "Company Overview" Community Health Systems, https://www.chs.net/company-overview/ (Accessed 6/27/24); "Investor Relations" Community Health Systems, https://www.chs.net/investor-relations/ (Accessed 6/27/24); "District Court Denies FTC Request to Block Novant's Purchase of Hospitals from CHS — Purchase Can Go Forward" Stevens & Lee, June 6, 2024, https://www.stevenslee.com/health-law-observer-blog/district-court-denies-ftc-request-to-block-novants-purchase-of-hospitals-from-chs-purchase-can-go-forward/ (Accessed 6/26/24).
3 "District Court Denies FTC Request to Block Novant's Purchase of Hospitals from CHS — Purchase Can Go Forward" Stevens & Lee, June 6, 2024, https://www.stevenslee.com/health-law-observer-blog/district-court-denies-ftc-request-to-block-novants-purchase-of-hospitals-from-chs-purchase-can-go-forward/ (Accessed 6/26/24).
4 *Ibid.*
5 "In the Matter of Novant Health, Inc., and Community Health Systems, Inc." Docket No. 9425, Federal Trade Commission Office of Administrative Law Judges, Complaint (January 25, 2024), p. 2-3.
6 "Federal Trade Commission v. Community Health Systems, Inc. and Novant Health, Inc." Case No. 5:24-CV-00028, Order (June 5, 2024), p. 5, 52.
7 *Ibid*, p. 5.
8 *Ibid.*
9 Stevens & Lee, June 6, 2024.
10 Case No. 5:24-CV-00028, Order (June 5, 2024), p. 55.
11 "Judge denies latest FTC attempt to halt Novant Health-CHS deal" By Andrew Cass, Becker's Hospital Review, June 11, 2024, https://www.beckershospitalreview.com/legal-regulatory-issues/judge-denies-latest-ftc-attempt-to-halt-Novant Health-chs-deal.html (Accessed 6/13/24).
12 The extension of the temporary restraining order was an alternate request from the FTC, an order which typically precedes an injunction "Judge denies another FTC request to block Novant Health-CHS deal" By Caroline Hudson, Modern Healthcare, June 11, 2024, https://www.modernhealthcare.com/legal/Novant Health-health-chs-ftc-injunction-north-carolina (Accessed 6/13/24).
13 "Novant Health gives up $320M hospital deal after FTC secures appeals court injunction" By Dave Muoio, Fierce Healthcare, June 18, 2024, https://www.fiercehealthcare.com/providers/novant-health-gives-320m-hospital-deal-after-ftc-secures-appeals-court-injunction (Accessed 6/19/24).
14 "Novant Health calls off North Carolina hospital deal, giving a win to the FTC" By Bob Herman, Stat News, June 19, 2024, https://www.statnews.com/2024/06/19/Novant Health-health-ends-north-carolina-hospital-deal-chs-ftc/ (Accessed 6/19/24).
15 "Judge denies FTC's preliminary bid to block Novant Health, CHS' $320M hospital deal" By Dave Muoio, Fierce Healthcare, June 5, 2024, https://www.fiercehealthcare.com/providers/judge-denies-ftcs-preliminary-bid-block-Novant Health-chs-320m-hospital-deal (Accessed 6/7/24).
16 "Novant Health gives up $320M hospital deal after FTC secures appeals court injunction" By Dave Muoio, Fierce Healthcare, June 18, 2024, https://www.fiercehealthcare.com/providers/novant-health-gives-320m-hospital-deal-after-ftc-secures-appeals-court-injunction (Accessed 6/19/24).
17 "2 N.J. health systems call off merger after federal lawsuit" By Spencer Kent, NewJersey.com, June 15, 2022, https://www.nj.com/healthfit/2022/06/2-nj-health-systems-call-off-merger-after-federal-lawsuit.html (Accessed 6/7/24).
18 "Following FTC Action, HCA, Steward Call Off Utah Deal" By David Raths, Healthcare Innovation, June 17, 2022, https://www.hcinnovationgroup.com/finance-revenue-cycle/mergers-acquisitions/news/21271444/following-ftc-action-hca-steward-call-off-utah-deal (Accessed 6/7/24).
19 "Lifespan and Care New England officially pull the plug on merger" By Patrick Anderson, The Providence Journal, February 23, 2022, https://www.providencejournal.com/story/news/politics/2022/02/23/ri-lifespan-and-care-new-england-pull-plug-on-merger/6914674001/ (Accessed 6/7/24).
20 "FTC's lawsuit can put the brakes on N.J. hospital merger - 3rd Circ" By Barbara Grzincic, Reuters, March 23, 2022, https://www.reuters.com/legal/litigation/ftcs-lawsuit-can-put-brakes-nj-hospital-merger-3rd-circ-2022-03-23/ (Accessed 6/7/24).
21 "Federal Trade Commission v. Community Health Systems, Inc. and Novant Health, Inc." Case No. 24-1526, Order (June 18, 2024), p. 2-3.
22 *Ibid*, p. 4.

Federal Judge Strikes Down Noncompete Ban

[Excerpted from the article published in August 2024.]

Introduction

On August 20, 2024, a Texas federal judge stopped the FTC's ban on noncompete agreements from going into effect on September 4, 2024. This decision comes after the FTC issued a final rule on April 23, 2024, that bans employers from imposing noncompetes on their employees. The FTC asserted that this exploitative practice kept wages low and suppressed new ideas.[1] While the FTC's ban will affect all industries – not just healthcare – it comes at a time when healthcare employers across the U.S. are struggling with staffing shortages.[2] This Health Capital Topics article reviews the court's ruling and discusses the FTC's ban on noncompete agreements.

Noncompete Background

Noncompete agreements are defined as "employment provisions that ban workers at one company from going to work for, or starting, a competing business within a certain period of time after leaving a job."[3] Approximately 30 million Americans are bound by noncompete clauses, which restrict them from pursuing other employment opportunities.[4] Further, workers in states where noncompete enforcement is easier typically experience lower wages.[5] Specific to healthcare, the FTC reports that noncompetes increase healthcare costs, and estimates that banning noncompetes would result in upwards of $194 billion in reduced healthcare spending over a ten-year period.[6]

The presence, or absence, of noncompete agreements can impact the value of a business by:

(1) Restricting the ability of owners or workers to leave and start a competing business or work for a competitor;
(2) Impeding a potential buyer's ability to employ key personnel or enter specific markets; and/or,
(3) Providing the business a competitive advantage.

If a noncompete agreement is too restrictive, it could also lower the value of a business by limiting its ability to retain and attract new employees, and by reducing the business's ability to develop and expand.[7] It is important to note that the FTC's ban does not apply to noncompetes entered into by a person pursuant to a "bona fide" sale of a business entity, of the person's ownership interest in a business entity, or of all or substantially all of a business entity's operating assets.

Under the final rule, existing noncompetes for the majority of workers would have been unenforceable beginning September 4, 2024.[8] Notably, noncompetes for senior executives would have remained in force, but employers could not have entered into, or attempted to enforce, any new noncompetes, even for senior executives.[9] Notably, the rule does not apply to non-profit entities, as the FTC acknowledged that it has no jurisdiction over these entities.[10] Nevertheless, the agency reserves the right to evaluate any entity's non-profit status, noting that some "entities that claim tax-exempt nonprofit status may in fact fall under the Commission's jurisdiction."[11] The FTC specifically stated that "some portion of the 58% of hospitals that claim tax-exempt status as nonprofits and the 19% of hospitals that are identified as State or local government hospitals… likely fall under the Commission's jurisdiction and the final rule's purview."[12]

Cases Addressing the FTC's Ban

In *Ryan LLC v. FTC*, the plaintiff, a tax company, as well as the U.S. Chamber of Commerce, Business Roundtable, Texas Association of Business, and Longview Chamber of Commerce (which parties intervened in the lawsuit), filed a lawsuit in the U.S. District Court for the Northern District of Texas to block the FTC from implementing its ban on noncompete agreements. On July 3, 2024, the court granted a limited preliminary injunction in the case, staying the FTC's ban only for the plaintiffs involved in the case (i.e., the ruling did not extend to other businesses in the U.S.).[13] In that decision, the court stated that the FTC "lacked substantive rule-making authority with respect to unfair methods of competition" and noted that "the plaintiffs were likely to succeed on the merits of their challenge."[14]

Then, in its August 20, 2024 ruling on the plaintiffs' motion for summary judgment, the court struck down the FTC ban in its entirety, and applied its ruling nationwide, finding that the FTC exceeded its statutory authority in promulgating its final rule banning noncompetes.[15] The court also found the rule to be arbitrary and capricious, stating that the FTC's

ban is "unreasonably overbroad without a reasonable explanation."[16] The court stated that "[t]he Rule imposes a one-size-fits-all approach with no end date, which fails to establish a 'rational connection between the facts found and the choice made.'"[17] Notably, the court cited multiple times to the recent *Loper Bright* case, wherein the U.S. Supreme Court overturned *Chevron* deference.[18] As a result of the court's order, the FTC's ban can no longer take effect starting September 4th, or be enforced.[19]

Notably, this decision from the Northern District of Texas has created a federal circuit split with the Eastern District of Pennsylvania that may ultimately need to be resolved by the U.S. Supreme Court.[20] The Pennsylvania federal district court previously declined to block the FTC's ban in July 2024. In *ATS Tree Services, LLC v. FTC*, the plaintiff filed a motion for a preliminary injunction, requesting that the court stay the FTC ban's effective date.[21] In their complaint, ATS argued (similar to Ryan LLC) that the FTC did not have the authority to impose such a ban, claiming it violates the Administrative Procedure Act (APA) and the U.S. Constitution.[22] ATS also alleged that the FTC overstepped their statutory authority under the FTC Act, arguing that the agency could only make such decisions on a case-by-case basis rather than by implementing a broad ban.[23] However, the court declined to stop the ban from taking effect, ruling that the employer plaintiff failed to demonstrate that the FTC ban would cause irreparable harm or that the Plaintiff was likely to win the case.[24]

Healthcare Implications of the FTC's Ban

In the event that the FTC's ban is later allowed to become effective, not only will it have implications on the revenue stream of healthcare services, by banning noncompetes, but physicians would be able to move between jobs with more freedom, and compensation could potentially increase.[25] This may impact the expense structure of healthcare entities and necessitate further contemplation by compensation valuation professionals when considering historical market compensation data that were subject to noncompetes for the purposes of analyzing prospective arrangements that are not subject to noncompetes.

In healthcare, the medical profession has grown from small practices comprised of just a few physicians to mega-practices totaling a few hundred physicians, especially in urban settings. Noncompetes in healthcare have traditionally been utilized as a tool to limit the harm that a physician may inflict upon departing a practice. While these large practices need to protect their investments, noncompete clauses may make it difficult for a departing physician to seek employment within the same geographic area.[26] Noncompete clauses in specialty practices further complicate the ability for physicians to seek employment, as specialists only serve a subset of the population (i.e., there may be fewer outside opportunities for specialists).[27]

Conclusion

For now, the FTC's noncompete ban is blocked and will not take effect for the foreseeable future. However, multiple states have provisions that wholesale ban, or place a limit on, non-compete agreements, some of which are specific to physicians or other healthcare professionals.[28] States that ban such clauses include Alabama, Arkansas, California, Colorado, Delaware, Massachusetts, New Hampshire, New Mexico, Rhode Island, and South Dakota.[29] Some states, such as Arkansas, allow noncompetes, but have exceptions carved out for medical professionals.[30] Other states, such as Florida, impose limitations on healthcare noncompetes, banning agreements for physician specialists in a county when all those within the specialty are employed by a single entity.[31]

Employers would be well-served to keep up to date on future developments related to the FTC's ban. The FTC has stated that the agency is "seriously considering" an appeal,[32] and may be able to leverage the Pennsylvania district court's ruling in any responses in the Texas case. In other words, the fight over noncompete agreements is not over.

1 "FTC Announces Rule Banning Noncompetes" Federal Trade Commission, April 23, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-announces-rule-banning-noncompetes (Accessed 7/26/24).
2 ""Healthcare Closely Watching FTC's Proposed Ban on Non-Competes" Jennifer Henderson, MedPage Today, January 12, 2023, https://www.medpagetoday.com/special-reports/exclusives/102618 (Accessed 7/26/24).
3 "Noncompete Agreements" By Alexander Colvin and Heidi Shierholz, Economic Policy Institute, December 10, 2019, https://www.epi.org/publication/noncompete-agreements/ (Accessed 7/26/24).
4 *Ibid.*
5 "Noncompetes in the U.S. Labor Force" By Evan Starr, J.J. Prescott, and Norman Bishara, Journal of Law and Economics, Revised April 5, 2023, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2625714 (Accessed 7/26/24).
6 "Noncompete Rule" Federal Trade Commission, https://www.ftc.gov/legal-library/browse/rules/noncompete-rule (Accessed 5/20/24).
7 "FTC's Proposed Ban on Non-Compete Agreements - Impact on Business Valuation" By Achille Ekeu, The Washington Valuation Group, March 20, 2023, https://www.washingtonvaluation.com/post/ftc-s-proposed-ban-on-non-compete-agreements-impact-on-business-valuation (Accessed 5/14/24).
8 Federal Trade Commission, April 23, 2024.
9 *Ibid.*
10 "16 CFR Part 910" Federal Trade Commission, April 23, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/noncompete-rule.pdf (Accessed 7/26/24).
11 *Ibid.*
12 *Ibid.*
13 "Ryan LLC et al. v. FTC" No. 3:24-CV-00986-E, Memorandum Opinion & Order (N.D. Tex., July 3, 2024), p. 10, 32.
14 *Ibid.*
15 *Ibid.*
16 *Ibid*, p. 23-24.
17 *Ibid*, p. 24.
18 For more information on the Loper Bright case, see "SCOTUS Rejects Chevron Deference: Healthcare Industry Implications" Health Capital Topics, Vol. 17, Issue 7 (July 2024), https://www.healthcapital.com/hcc/newsletter/07_24/HTML/CHEVRON/convert_chevron_deference_overruled.php (Accessed 8/23/24).
19 Memorandum Opinion & Order (N.D. Tex., August 20, 2024), p. 27.
20 "Federal Court In Pennsylvania Creates District Split On Enforceability of FTC Non-Compete Ban" By Jesse Coleman et al., Mondaq, July 29, 2024, https://www.mondaq.com/unitedstates/contract-of-employment/1497722/federal-court-in-pennsylvania-creates-district-split-on-enforceability-of-ftc-non-compete-ban#:~:text=This%20puts%20this%20court's%20ruling,up%20a%20potential%20circuit%20split%20 (Accessed 7/30/24).
21 "ATS TREE SERVICES, LLC V. FTC – BASIS FOR LEGAL CHALLENGE" By Vasilios Kalogredis and Sonal Parekh, Lamb Mcerlane, July 9, 2024, https://www.lambmcerlane.com/articles/ats-tree-services-llc-v-ftc-basis-for-legal-challenge/ (Accessed 7/26/24).
22 "ATS Tree Services v. Federal Trade Commission et al." No. 24-1743, Memorandum (E.D. Pa., July 23, 2024), p. 1-3.
23 *Ibid.*
24 *Ibid.*
25 "FTC votes to ban noncompetes, with far-reaching effects on doctors" By Rebecca Pifer, Healthcare Dive, April 23, 2024, https://www.healthcaredive.com/news/ftc-noncompete-ban-healthcare-doctor-effects/713846/#:~:text=The%20latest%20labor%20trends%20in%20healthcare,-Disputes%20between%20hospitals&text=Zeroing%20out%20noncompetes%20equalizes%20the,also%20cause%20wages%20to%20rise. (Accessed 5/14/24).
26 "The Current State of the Enforceability of Restrictive Covenants in the Medical Profession" By Robert H. Schwartz, Phil Korovesis, and Mostafa Shanta, American Bar Association, December 28, 2022, https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2022-2023/december-2022/the-current-state-of-the-enforceablility-of-restrictive-covenants-in-the-medical-profession/ (Accessed 7/26/24).
27 *Ibid.*
28 *Ibid.*
29 *Ibid.*
30 *Ibid.*
31 *Ibid.*
32 "Federal judge blocks FTC noncompete ban" By Caroline Hudson, Modern Healthcare, August 20, 2024, https://www.modernhealthcare.com/legal/ftc-noncompete-ban-blocked-texas?utm_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm_medium=email&_hsenc=p2ANqtz-80RnhwvLqRCvTVpsk8oobaMfAarF-gtnXMjxwzKk_HTk7gNNSnGzTvV2R9ieVQqfqeiIKr_rzoiWptXsLXaNoWbDFDMw&_hsmi=321060144&utm_content=321060144&utm_source=hs_email (Accessed 8/23/24).

Medicare Advantage Plans Face Headwinds

[Excerpted from the article published in September 2024.]

With the annual enrollment period for Medicare Advantage (MA) plans slated to open in less than two months, many MA plans are cutting benefits and provider payments, while approving fewer claims. Further, after a decade of accelerated growth in the MA market, several MA plan executives have announced MA market exits and decreases in membership for the upcoming plan year.[1] This Health Capital Topics article discusses recently announced MA market exits, the reasons for those exits, and the current environment in which MA plans are operating.

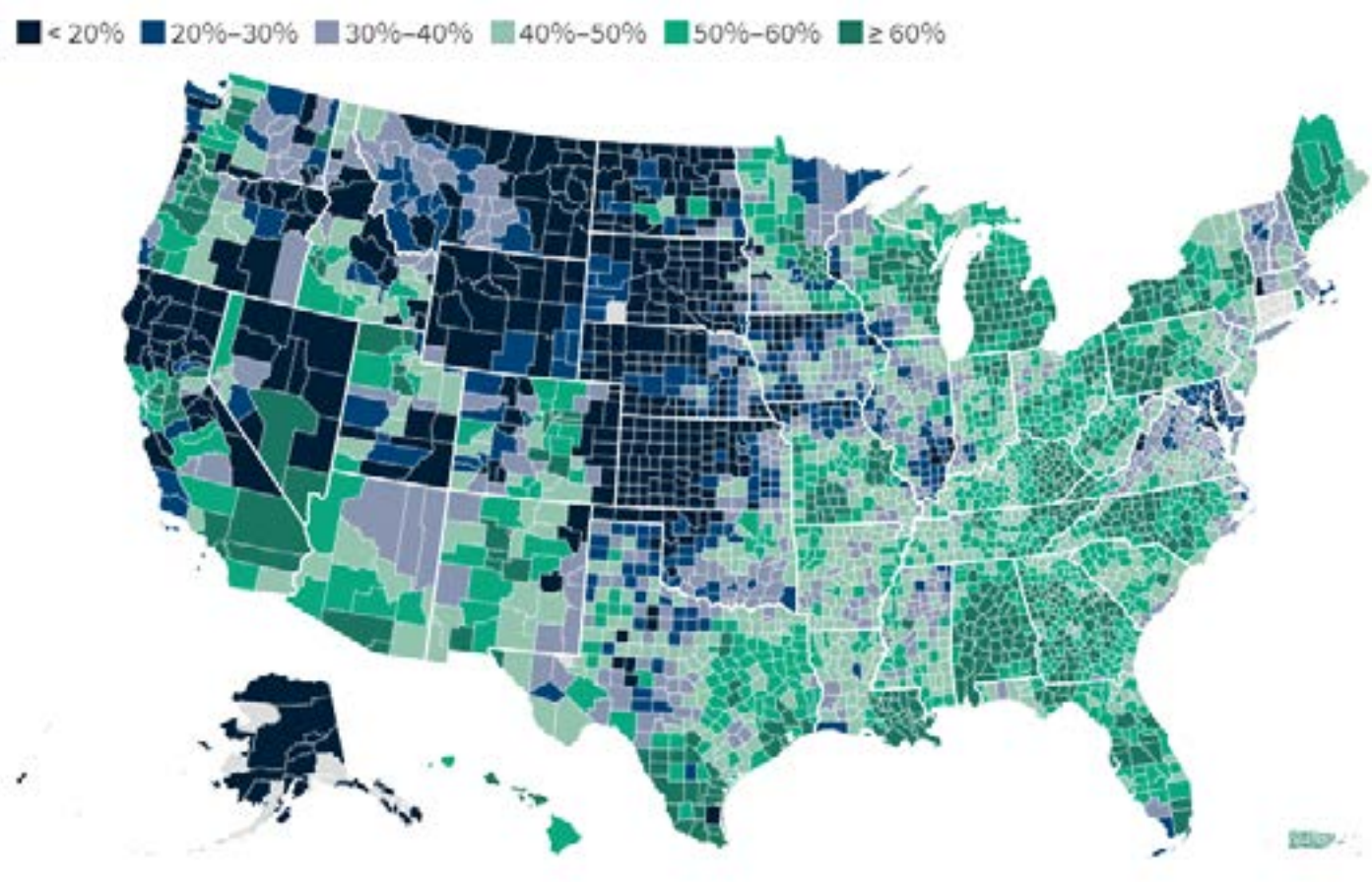
MA plans, also known as Part C plans, serve as a supplement or an alternative to Traditional fee-for-service (FFS) Medicare Part A and Part B coverage, but they are still part of the Medicare program.[2] MA was created to offer seniors an alternative to Traditional Medicare – with an emphasis on treating and managing the health of the whole patient. MA plans are offered to Medicare beneficiaries by Medicare-approved private companies that must follow rules set by Medicare.[3] Under the MA program, Medicare purchases insurance coverage for Medicare beneficiaries from private MA plans. These plans can be advantageous for beneficiaries because they limit patient out-of-pocket costs for covered services (although out-of-pocket costs vary by plan) and may cover additional healthcare services (e.g., fitness programs, vision, dental, hearing) as well as other benefits (e.g., transportation to appointments, drugs/services that promote wellness).[4] However, in order to manage costs, MA organizations may require beneficiaries to utilize providers in the plan's network.

As illustrated in Exhibit 1 below, enrollment in MA plans has grown much faster than in Traditional Medicare. As of 2024, 32.8 million Americans are enrolled in an MA plan,[5] comprising 54% of total Medicare enrollment, which proportion is expected to increase to 64% by 2033.[6]

Exhibit 1: Medicare Advantage Enrollment, 2008-2024[7]

While nearly all Medicare beneficiaries have access to an MA plan,[8] MA enrollment is not well-distributed geographically, with the percent of Medicare beneficiaries enrolled in MA highest in the Eastern U.S.

Exhibit 2: Medicare Advantage Penetration by County, 2024[9]



Due to the growing popularity of MA plans, and the number of Americans becoming Medicare eligible every year, MA enrollment has steadily increased over the past two decades.[10] However, over the past year, there has been speculation as to whether the MA "gold rush" has reached its apex.[11] UnitedHealth (the largest MA plan in the U.S.) forecasted its 2024 enrollment to slow from 11% growth to approximately 5%.[12] Further, Aetna, Centene, and Humana have all announced MA market exits and/or membership declines for the upcoming enrollment year, and many plans have threatened to reduce benefits, tighten prior authorization policies, and reassess provider networks and markets.[13] For the 2024 enrollment year, twelve MA plans exited the MA market, replaced by only three new entrants.[14] In September 2024, Humana announced that it would exit 13 counties where its performance has been substandard, resulting in an expected loss of hundreds of thousands of members; Humana also announced it would reduce certain benefits and increase premiums.[15] Additionally, Cigna announced that it would fully exit at least three counties in 2025 and reduce service areas in eight states (Colorado, Florida, Illinois, Missouri, North Carolina, Tennessee, Texas and Utah), affecting over 5,300 beneficiaries.[16] A month prior, Centene announced the upcoming exit of its WellCare MA subsidiary from MA markets in six states (Alabama, Massachusetts, New Hampshire, New Mexico, Rhode Island and Vermont), affecting approximately 37,300 members (3% of Centene's total MA enrollment).[17] In June 2024, Blue Cross and Blue Shield of Kansas City, a relatively small MA plan, announced it would exit the MA market entirely by the end of 2024, due to "heightened regulatory demands and rising market and financial pressures."[18]

The reasons for the seemingly abrupt turn in MA expectations stem from a number of reimbursement and regulatory changes over the past year. In April 2024, the Centers for Medicare & Medicaid Services (CMS) announced a 0.16% reduction in the MA benchmark rate, the second consecutive year of rate cuts.[19] Moreover, MA plans will receive approximately 8% less in Medicare bonuses in 2024 compared to the prior year (the first decrease since before 2015).[20] Compounding this problem, MA plan expenditures have risen, due largely to increased member utilization post-pandemic.[21] In addition, the government has increased its scrutiny over MA prior authorization, marketing, and brokers, and made changes to the Star Ratings quality program, making high scores – and resulting bonus payments – more difficult to obtain.[22] Aside from reimbursement and regulatory pressures, competition among MA plans has increased, with a more than 100% increase in the number of offered MA plans between 2018 and 2023, as commercial insurers seek to "tap into a rapidly expanding market segment."[23]

For the most part, MA plans are no longer able to counter the risk presented by these various stressors with surges in enrollment (and, consequently, profitability), as the last of the Baby Boomers will age into Medicare in 2030, capping a significant influx of Americans into the age 65+ cohort over the past two decades. Going forward, the Congressional Budget Office (CBO) predicts MA plan enrollment growth of 1% per year, the lowest rate in ten-plus years.[24] MA plans are therefore attempting to turn the tide on their profitability by not just reducing their geographic footprints and reducing their beneficiary offerings, as discussed above, but also by squeezing hospitals through increased claim denials and additional prior authorization policies, negatively affecting both hospitals and patients.[25] In return, hospitals are increasingly disputing MA plan coverage determinations, or altogether opting out of MA plan in-network agreements.[26] This could commence a vicious circle between hospitals and MA plans in which everyone – most importantly patients – loses.

Despite the various headwinds faced by MA plans, they are anticipated to still be the most profitable payor business segment in 2026.[27] However, previously bullish analyses on the future of MA may be overstated. In order to right-size, MA plans seem to be getting back to basics in order to weather the storm of increased costs and utilization combined with decelerating enrollment.

1 "Will 2025 Mark a Turning Point for Medicare Advantage?" By Laura Beerman, HealthLeaders, September 4, 2024, https://www.healthleadersmedia.com/payer/will-2025-mark-turning-point-medicare-advantage (Accessed 9/6/24).
2 "Your health plan options" Medicare.gov, https://www.medicare.gov/health-drug-plans/health-plans/your-health-plan-options (Accessed 9/6/24).
3 *Ibid.*
4 *Ibid.*
5 "Medicare Advantage in 2024: Enrollment Update and Key Trends" By Meredith Freed, et al., Kaiser Family Foundation, August 8, 2024, https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2024-enrollment-update-and-key-trends/ (Accessed 9/6/24).
6 Beerman, HealthLeaders, September 4, 2024.
7 Freed, et al., Kaiser Family Foundation, August 8, 2024.
8 *Ibid.*
9 *Ibid.*
10 *Ibid.*
11 "The Medicare Gold Rush Is Slowing Down" By David Wainer, The Wall Street Journal, December 6, 2023, https://www.wsj.com/health/healthcare/the-medicare-gold-rush-is-slowing-down-ebc5a4af (Accessed 9/6/24).
12 *Ibid.*
13 Beerman, HealthLeaders, September 4, 2024; "Humana, Aetna likely to lose Medicare Advantage members" By Nona Tepper and Lauren Berryman, Modern Healthcare, May 14, 2024, https://www.modernhealthcare.com/insurance/aetna-humana-expect-medicare-advantage-membership-losses-2025 (Accessed 9/6/24).
14 Freed, et al., Kaiser Family Foundation, November 15, 2023.
15 "Humana to depart 13 Medicare Advantage markets" By Lauren Berryman, Modern Healthcare, September 4, 2024, https://www.modernhealthcare.com/insurance/humana-medicare-advantage-markets-2025 (Accessed 9/6/24).
16 "Cigna to cut Medicare Advantage plans in several states" By Lauren Berryman, Modern Healthcare, September 19, 2024, https://www.modernhealthcare.com/insurance/cigna-medicare-advantage-plans-2025 (Accessed 9/20/24).
17 "Centene Medicare Advantage subsidiary WellCare to retreat from 6 states in 2025" By Noah Tong, FierceHealthcare, August 7, 2024, https://www.fiercehealthcare.com/payers/centene-subsidiary-wellcare-retreats-six-states-2025 (Accessed 9/6/24).
18 "Blue KC exiting Medicare Advantage market by 2025 due to 'regulatory demands'" By Noah Tong, FierceHealthcare, June 3, 2024, https://www.fiercehealthcare.com/payers/blue-kc-exiting-medicare-advantage-market-2025-due-regulatory-demands (Accessed 9/6/24).
19 "CMS finalizes Medicare Advantage rate cut" By Lauren Berryman and Nona Tepper, Modern Healthcare, April 1, 2024, https://www.modernhealthcare.com/policy/medicare-advantage-rate-cut-cms-2025 (Accessed 9/6/24).
20 "Kaiser, Humana, UnitedHealth reap big Medicare Advantage bonuses" By Lauren Berryman, Modern Healthcare, September 12, 2024, https://www.modernhealthcare.com/insurance/kaiser-humana-unitedhealth-medicare-advantage-star-bonuses-cms (Accessed 9/13/24).
21 "Rising Medicare Advantage costs squeeze providers, insurers, tech" By Nona Tepper, Modern Healthcare, February 1, 2024, https://www.modernhealthcare.com/medicare/medicare-advantage-costs-humana-aetna-cano-health-caremax (Accessed 9/6/24); Beerman, HealthLeaders, September 4, 2024.
22 "Medicare Advantage provider, benefit cuts may follow rate reduction" By Nona Tepper, Modern Healthcare, February 6, 2024, https://www.modernhealthcare.com/insurance/medicare-advantage-rate-cut-2025-reimbursements-benefits-united-health-humana (Accessed 9/6/24).
23 "How do Medicare Advantage plans compete in a crowded market?" By Nate Jacoby, et al., PWC, September 25, 2023, https://www.pwc.com/us/en/industries/health-industries/library/how-medicare-advantage-plans-compete.html (Accessed 9/11/24).
24 Beerman, HealthLeaders, September 4, 2024.
25 "Why Medicare Advantage plans are losing more providers" By Alex Kacik, Modern Healthcare, September 10, 2024, https://www.modernhealthcare.com/providers/medicare-advantage-plans-provider-insurer-contracts-humana-unitedhealthcare (Accessed 9/11/24).
26 *Ibid.*
27 "Sweeping changes to Medicare Advantage: How payers could respond" By Gabe Isaacson, et al., McKinsey, July 11, 2023, https://www.mckinsey.com/industries/healthcare/our-insights/the-future-of-medicare-advantage (Accessed 9/6/24).

Technology Topics

Generative AI in Healthcare: Valuation Considerations

[Excerpted from the article published in October 2023.]

Introduction

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

Advantages & Disadvantages

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

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

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

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

Regulatory

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

In addition to regulatory agencies, the rapid implementation of AI will require healthcare organizations to monitor any risks (e.g., reputational, legal, and ethical) emanating from AI use and determine how to address those risks, particularly given the current lack of regulatory framework and oversight.[28] In June 2023, the American Medical Association (AMA) voted to adopt a proposal to protect patients against misleading or false medical information from AI tools.[29] The AMA aims to work with agencies such as the Federal Trade Commission (FTC) and the FDA to mitigate any misinformation, and anticipates the establishment of federal and state regulations in the near future.[30]

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

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

Advancements & Entrants

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

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

In April 2023, Epic, a healthcare software company, announced a collaboration with Microsoft to combine Microsoft's Azure OpenAI and Epic's EHR software to respond to patient messages, alleviating provider workload.[45] The initial rollout will begin at UNC Health with five to ten clinicians and eventually expand to other health systems.[46] The first iteration of this technology will draft suggested responses to the most common patient questions and messages for physicians to review and send.[47]

Effect of AI in Healthcare M&A

Healthcare merger and acquisition (M&A) activity reached record-breaking levels in 2021 and 2022, and volumes have remained high during the first half of 2023, despite factors that typically would dampen the appetite for such transactions, e.g., increased regulatory scrutiny, higher interest rates, and concerns over a potential recession.

Many of these transactions included companies that featured AI technologies, a trend likely to become more prevalent going forward. The global artificial intelligence in healthcare market size was estimated at $15.1 billion (USD) in 2022 and it is expected to surpass around $187.95 billion (USD) by 2030, growing at a compound annual growth rate (CAGR) of 37% during the forecast period 2022 to 2030.[48]

Not only are established companies attractive targets, startup companies are also taking advantage of the industry's fascination with the potential of AI. In particular, AI technologies can drive a healthcare company's value by:

(1) Adding new or complementary patient services, such as capacity management and referral management;[49]
(2) Augmenting physician services, by automating administrative services, or by providing easy access to clinical knowledge,[50] for example, saving the physician valuable time that he or she can instead use to perform clinical services;
(3) Increasing patient utilization, by automating scheduling or discharge processes;[51]
(4) Enabling healthcare companies to more easily analyze and extract new insights from patient data;[52]
(5) Increasing quality and cost effectiveness, through continuous internal provider benchmarking, utilization management, and patient risk scoring;[53] and
(6) Allowing access to new data sources, such as the ability to extract, aggregate, and make searchable data from different types of medical records that are stored in different formats across various platforms.[54]

Conclusion

While generative AI will continue to disrupt the healthcare industry, it aims to ultimately increase the efficacy of the healthcare system. By streamlining clerical work, performing literature searches, and even reducing error and bias within medicine, generative AI has the potential to revolutionize the way healthcare is delivered.[55] While generative AI has nearly unlimited potential, there are also risks associated with the technology, particularly in healthcare. Patient data could result in bias by the bot and even be susceptible to hacking or stealing. Generative AI has the potential to revolutionize the healthcare industry, but industry stakeholders will need to remain up-to-date on the risks and ongoing regulatory changes that affect the usage of generative AI.

1 "What is Generative AI" McKinsey & Company, January 19, 2023, https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-generative-ai (Accessed 7/21/23); "What is generative AI? Everything you need to know" By George Lawton, TechTarget, https://www.techtarget.com/searchenterpriseai/definition/generative-AI?Offer=abt_pubpro_AI-Insider (Accessed 7/26/23).
2 McKinsey & Company, January 19, 2023.
3 "ChatGPT's Use In Medicine Raises Questions Of Security, Privacy, Bias" By Robert Pearl, Forbes, April 24, 2023, https://www.forbes.com/sites/robertpearl/2023/04/24/chatgpts-use-in-medicine-raises-questions-of-security-privacy-bias/?sh=267cb97d5373 (Accessed 5/23/23).
4 "Top Three Reasons Why AI is Critical for Value-Based Care" By Jay Ackerman, Managed Healthcare Executive, June 27, 2023, https://www.managedhealthcareexecutive.com/view/top-three-reasons-why-ai-is-critical-for-value-based-care (Accessed 7/7/23).
5 *Ibid.*
6 *Ibid.*
7 *Ibid.*
8 *Ibid*; "The State of the Nation's Nursing Shortage" By Julia Haines, U.S. News & World Report, November 1, 2022, https://www.usnews.com/news/health-news/articles/2022-11-01/the-state-of-the-nations-nursing-shortage (Accessed 7/26/23).
9 Pearl, Forbes, April 24, 2023.
10 *Ibid.*
11 *Ibid.*
12 "How will generative AI impact healthcare?" World Economic Forum, May 12, 2023, https://www.weforum.org/agenda/2023/05/how-will-generative-ai-impact-healthcare/ (Accessed 6/14/23).
13 *Ibid.*
14 *Ibid.*
15 Pearl, Forbes, April 24, 2023.
16 *Ibid.*
17 *Ibid.*
18 *Ibid.*
19 "Opportunities and risks of ChatGPT in medicine, science, and academic publishing: a modern Promethean dilemma" By Jan Homolak, Croatian Medical Journal, National Institute of Health, February 2023, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10028563/ (Accessed 5/24/23).
20 *Ibid.*
21 *Ibid.*
22 *Ibid.*
23 "Generative AI could augment 40% of healthcare working hours" By Bill Siwicki, Healthcare IT News, May 11, 2023, https://www.healthcareitnews.com/news/generative-ai-could-augment-40-healthcare-working-hours (Accessed 6/14/23); "A new era of generative AI for everyone" Accenture, March 22, 2023, https://www.accenture.com/us-en/insights/technology/generative-ai?c=acn_glb_largelanguagemomediarelations_13427684&n=mrl_0323 (Accessed 6/14/23).
24 Siwicki, Healthcare IT News, May 11, 2023.
25 "US FTC opens investigation into OpenAI over misleading statements –document" Reuters, July 13, 2023, https://www.reuters.com/technology/us-ftc-opens-investigation-into-openai-washington-post-2023-07-13/ (Accessed 7/13/23).
26 "Artificial Intelligence/Machine Learning (AI/ML)-Based Software As a Medical Device (SaMD) Action Plan" U.S. Food and Drug Administration, January 2021, https://www.fda.gov/media/145022/download (Accessed 7/7/23).
27 *Ibid.*
28 Siwicki, Healthcare IT News, May 11, 2023.
29 "AMA adopts proposal to protect patients from false and misleading AI-generated medical advice" By Kristine White, Healthcare Brew, https://www.healthcare-brew.com/stories/2023/06/14/ama-adopts-proposal-to-protect-patients-from-false-and-misleading-ai-generated-medical-advice (Accessed 7/6/23).
30 *Ibid.*
31 "US FTC opens investigation into OpenAI over misleading statements –document" Reuters, July 13, 2023, https://www.reuters.com/technology/us-ftc-opens-investigation-into-openai-washington-post-2023-07-13/ (Accessed 7/13/23).
32 "FTC is investigating ChatGPT-maker OpenAI for potential harm to consumers" By Brian Fung, CNN, July 13, 2023, https://www.cnn.com/2023/07/13/tech/ftc-openai-investigation/index.html (Accessed 7/13/23).
33 *Ibid.*
34 "Dr. Watson, A.I.: The Current Approach to Artificial Intelligence Training in the Medical Field and Legal Considerations for AI Diagnosis Dependence" By Allison Newsome and Jasmeet Singh, American Health Law Association, July 6, 2023, https://www.americanhealthlaw.org/content-library/publications/briefings/d88632df-8f1e-48ce-b5f4-066d19b12aa6/Dr-Watson-A-I-The-Current-Approach-to-Artificial-I?Token=60909932-7f8c-4a43-97b9-8bcb7e610f4e (Accessed 7/18/23).
35 *Ibid.*
36 "What Is Chat GPT? – Everything You Need to Know" Enterprise DNA, https://blog.enterprisedna.co/what-is-chat-gpt-everything-you-need-to-know/#:~:text=The%20history%20of%20ChatGPT%20starts,promising%20but%20limited%20language%20model (Accessed 5/23/23).
37 "Revolutionizing Healthcare: The Top 14 Uses Of ChatGPT In Medicine And Wellness" By Bernard Marr, Forbes, March 2, 2023, https://www.forbes.com/sites/bernardmarr/2023/03/02/revolutionizing-healthcare-the-top-14-uses-of-chatgpt-in-medicine-and-wellness/?sh=ba393de6e547 (Accessed 7/26/23).
38 "What Is Chat GPT? – Everything You Need to Know" Enterprise DNA, https://blog.enterprisedna.co/what-is-chat-gpt-everything-you-need-to-know/#:~:text=The%20history%20of%20ChatGPT%20starts,promising%20but%20limited%20language%20model (Accessed 5/23/23).
39 "Bing, Bard, and ChatGPT: AI chatbots are rewriting the internet" By Umar Shakir, The Verge, June 14, 2023, https://www.theverge.com/23610427/chatbots-chatgpt-new-bing-google-bard-conversational-ai (Accessed 6/14/23).
40 "The latest generative AI efforts in healthcare: Carbon Health, Tempus launch tools for docs" By Heather Landi, Fierce Healthcare, June 6, 2023, https://www.fiercehealthcare.com/health-tech/latest-generative-ai-efforts-healthcare-carbon-health-tempus-launch-tools-docs (Accessed 6/14/23).
41 *Ibid.*
42 *Ibid.*
43 *Ibid.*
44 "Epic is going all in on generative AI in healthcare. Here's why a handful of health systems is eager to test-drive it" By Heather Landi, Fierce Healthcare, May 25, 2023, https://www.fiercehealthcare.com/health-tech/epic-moves-forward-bring-generative-ai-healthcare-heres-why-handful-health-systems-are (Accessed 6/14/23).
45 *Ibid.*
46 *Ibid.*
47 *Ibid.*
48 *Ibid.*
49 "The Potential Impact of Artificial Intelligence on Healthcare Spending" By Nikhil Sahni, et al., National Bureau of Economic Research, Working Paper 30857, January 2023, https://www.nber.org/papers/w30857 (Accessed 10/20/23).
50 *Ibid.*
51 Healthcare May Be The Ultimate Proving Ground For Artificial Intelligence" By Joe McKendrick, Forbes, February 22, 2023, https://www.forbes.com/sites/joemckendrick/2023/02/22/healthcare-may-be-the-ultimate-proving-ground-for-artificial-intelligence/?sh=75f8442e2b55 (Accessed 10/20/23); "The Potential Impact of Artificial Intelligence on Healthcare Spending" By Nikhil Sahni, et al., National Bureau of Economic Research, Working Paper 30857, January 2023, https://www.nber.org/papers/w30857 (Accessed 10/20/23).
52 *Ibid.*
53 Sahni, et al., National Bureau of Economic Research, Working Paper 30857, January 2023.
54 "The Role of AI in Health Care M&A: Driving Value in a Difficult Market" By Laura Burlot and Nikhil Pradhan, Foley & Lardner LLP, May 10, 2023, available at: https://www.jdsupra.com/legalnews/the-role-of-ai-in-health-care-m-a-8975425/ (Accessed 10/20/23); "Google announces new generative AI search capabilities for doctors" By Ashley Capoot, CNBC, October 9, 2023, https://www.cnbc.com/2023/10/09/google-announces-new-generative-ai-search-capabilities-for-doctors-.html (Accessed 10/20/23).
55 "Opportunities and risks of ChatGPT in medicine, science, and academic publishing: a modern Promethean dilemma" By Jan Homolak, Croatian Medical Journal, National Institute of Health, February 2023, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10028563/ (Accessed 5/24/23).

Biden Issues Executive Order on Artificial Intelligence

[Excerpted from the article published in November 2023.]

On October 30, 2023, President Joseph Biden signed an executive order to establish new standards for artificial intelligence (AI) in the U.S.[1] The executive order focuses on protecting the privacy of Americans and establishes new standards for security and safety in AI.[2] While the executive order is not specific to healthcare, the order contains some healthcare-specific provisions. This Health Capital Topics article will discuss the executive rule, subsequent agency actions, and industry implications.

The executive order is guided by eight priorities and principles:

(1) "AI must be safe and secure by requiring robust, reliable, repeatable and standardized evaluations of AI systems, as well as policies, institutions, and, as appropriate, mechanisms to test, understand, and mitigate risks from these systems before they are put to use";
(2) "The US should promote responsible innovation, competition and collaboration via investments in education, training, [research & development] and capacity while addressing intellectual property rights questions and stopping unlawful collusion and monopoly over key assets and technologies";
(3) "The responsible development and use of AI require a commitment to supporting American workers though education and job training and understanding the impact of AI on the labor force and workers' rights";
(4) "AI policies must be consistent with the advancement of equity and civil rights";
(5) "The interests of Americans who increasingly use, or purchase AI and AI-enabled products in their daily lives must be protected";
(6) "Americans' privacy and civil liberties must be protected by ensuring that the collection, use and retention of data is lawful, secure and promotes privacy";
(7) "It is important to manage the risks from the federal government's own use of AI and increase its internal capacity to regulate, govern and support responsible use of AI to deliver better results for Americans"; and
(8) "The federal government should lead the way to global societal, economic and technological progress including by engaging with international partners to develop a framework to manage AI risks, unlock AI's potential for good and promote a common approach to shared challenges."[3]

While the executive order impacts a variety of industries, there are many implications for the healthcare industry specifically. The order directs the Department of Health and Human Services (HHS) to develop a task force focused on AI within 90 days, which task force will be responsible for developing frameworks and policies on the responsible use and deployment of AI and AI-enabled technology.[4] Within 365 days of the task force's creation, new guidance must be created related to the monitoring of quality and safety of technology enabled by AI and the incorporation of equity in new AI models.[5]

Additionally, HHS is tasked with establishing a safety program that is capable of receiving reports, which will ultimately guide the agency in remedying unsafe practices in healthcare settings that involve the use of AI.[6] HHS is also expected to take appropriate actions to ensure compliance with federal nondiscrimination law.[7] The agency will be given 180 days to decide if the current AI applications are sufficiently accurate for use in the healthcare industry.[8] HHS will also work alongside the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop and establish frameworks that can capture and identify clinical errors in all healthcare settings that may result from AI use.[9] The administration is also expected to increase funding for grants in AI research.[10]

In addition to the federal government's push to monitor and regulate AI, the rapid implementation of the technology requires healthcare organizations to monitor any risks (e.g., reputational, legal, and ethical) emanating from AI use and determine how to address those risks, particularly given the current lack of regulatory framework and oversight.[11] Toward that end, and in the absence (to date) of governmental the American Medical Association (AMA) voted in June 2023 to adopt a proposal to protect patients against misleading or false medical information from AI tools.[12] The AMA aims to work with agencies such as the Federal Trade Commission (FTC) and the Food & Drug Administration (FDA) to mitigate any misinformation, and anticipates the establishment of federal and state regulations in the near future.[13]

Even before the issuance of the executive order, AI companies had already started to face government scrutiny. In July 2023, the FTC opened an investigation and sent a records request to OpenAI, the company behind ChatGPT, a free-to-use generative AI bot.[14] In its investigation as to whether OpenAI engaged in practices that resulted in consumer harm, the FTC requested information regarding how OpenAI obtained data used to train their models and descriptions of ChatGPT's abilities.[15] The agency also requested descriptions of OpenAI's testing, algorithms, responses, and the company's false information policies.[16]

The level of development and the pace of clinical AI implementation may be directly influenced by the liability faced by practitioners, designers, and health systems, as more liability could discourage the use of AI in healthcare.[17] As the technology continues to be developed and utilized, new legal pathways will need to be established, especially as increased liability would likely repel practitioners, designers, and health systems from implementing and developing clinical AI models.[18]

While the executive order directs federal agencies to coordinate efforts around the regulation of AI, the agencies can only act within their budget and authority.[19] Another impediment to AI regulation may include any change in presidential administration, where different priorities may result in the executive order being revoked.[20] While many of the executive order's provisions have bipartisan support, the implementation of the policies may not be completed before the 2024 Presidential Election, leaving the ultimate outcome of these policies vulnerable to changing political forces.[21]

1 "FACT SHEET: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence" The White House, October 30, 2023, https://www.whitehouse.gov/briefing-room/statements-releases/2023/10/30/fact-sheet-president-biden-issues-executive-order-on-safe-secure-and-trustworthy-artificial-intelligence/ (Accessed 11/6/23).
2 *Ibid.*
3 "Key takeaways from the Biden administration executive order on AI" By Bridget Neill, John Hallmark, Richard Jackson, and Dan Diasio, Ernst & Young, October 31, 2023, https://www.ey.com/en_us/public-policy/key-takeaways-from-the-biden-administration-executive-order-on-ai (Accessed 11/15/23).
4 "Biden focuses on healthcare with AI executive order, industry reacts" By Gabriel Perna, Modern Healthcare, October 30, 2023, https://www.modernhealthcare.com/digital-health/biden-ai-executive-order-healthcare?utm_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm_medium=email&_hsmi=280576001&_hsenc=p2ANqtz-_ebqSF0TiEm7rxosKPqfQZBTvrUEl8tn7-ulTkdRYSpYX07SxjKol6plm_oSrnlXZAwwT-ZzcEc0lagQ9itrECjHkngg&utm_content=280576001&utm_source=hs_email (Accessed 11/6/23).
5 *Ibid.*
6 "Biden to sign sweeping executive order pursuing 'safe, secure and trustworthy' AI development" By Dave Muoio, Fierce Healthcare, October 30, 2023, https://www.fiercehealthcare.com/ai-and-machine-learning/biden-sign-sweeping-executive-order-pursuing-safe-secure-and-trustworthy-ai (Accessed 11/6/23).
7 *Ibid*; "Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence" By Joseph Biden, The White House, October 30, 2023, https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/ (Accessed 11/22/23).
8 Muoio, Fierce Healthcare, October 30, 2023.
9 Perna and Brock Turner, Modern Healthcare, October 30, 2023.
10 Muoio, Fierce Healthcare, October 30, 2023.
11 "Generative AI could augment 40% of healthcare working hours" By Bill Siwicki, Healthcare IT News, May 11, 2023, https://www.healthcareitnews.com/news/generative-ai-could-augment-40-healthcare-working-hours (Accessed 11/15/23).
12 "AMA adopts proposal to protect patients from false and misleading AI-generated medical advice" By Kristine White, Healthcare Brew, https://www.healthcare-brew.com/stories/2023/06/14/ama-adopts-proposal-to-protect-patients-from-false-and-misleading-ai-generated-medical-advice (Accessed 11/15/23).
13 *Ibid.*
14 "US FTC opens investigation into OpenAI over misleading statements –document" Reuters, July 13, 2023, https://www.reuters.com/technology/us-ftc-opens-investigation-into-openai-washington-post-2023-07-13/ (Accessed 11/15/23).
15 "FTC is investigating ChatGPT-maker OpenAI for potential harm to consumers" By Brian Fung, CNN, July 13, 2023, https://www.cnn.com/2023/07/13/tech/ftc-openai-investigation/index.html (Accessed 11/15/23).
16 *Ibid.*
17 "Dr. Watson, A.I.: The Current Approach to Artificial Intelligence Training in the Medical Field and Legal Considerations for AI Diagnosis Dependence" By Allison Newsome and Jasmeet Singh, American Health Law Association, July 6, 2023, https://www.americanhealthlaw.org/content-library/publications/briefings/d88632df-8f1e-48ce-b5f4-066d19b12aa6/Dr-Watson-A-I-The-Current-Approach-to-Artificial-I?Token=60909932-7f8c-4a43-97b9-8bcb7e610f4e (Accessed 11/15/23).
18 *Ibid.*
19 "How Will The Executive Order On Artificial Intelligence Impact Health Care?" By Jodi Daniel and Harlan Krumholz, Health Affairs, November 17, 2023, https://www.healthaffairs.org/content/forefront/executive-order-artificial-intelligence-impact-health-care (Accessed 11/22/23).
20 *Ibid.*
21 *Ibid.*

About HCC

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.

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

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

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

LEADERSHIP

HCC Health Capital Consultants

Todd A. Zigrang, MBA, MHA, FACHE, CVA, ASA, ABV, is the President of HCC, where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 28 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 2,500 transactions and joint ventures involving acute care hospitals and health systems; physician practices; ambulatory surgery centers; diagnostic imaging centers; accountable care organizations, managed care organizations, and other third-party payors; dialysis centers; home health agencies; long-term care facilities; and, numerous other ancillary healthcare service businesses. Mr. Zigrang is also considered an expert in the field of healthcare compensation for physicians, executives and other professionals.

Mr. Zigrang is the co-author of "The Adviser's Guide to Healthcare - 2nd Edition" [AICPA - 2015], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: The Guide to Valuing Physician Compensation and Healthcare Service Arrangements (BVR/AHLA); The Accountant's Business Manual (AICPA); Valuing Professional Practices and Licenses (Aspen Publishers); Valuation Strategies; Business Appraisal Practice; and, NACVA QuickRead. Additionally, Mr. Zigrang has served as faculty before professional and trade associations such as the American Society of Appraisers (ASA); the National Association of Certified Valuators and Analysts (NACVA); the American Health Lawyers Association (AHLA); the American Bar Association (ABA); the Association of International Certified Professional Accountants (AICPA); the Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute. He also serves on the Editorial Board of The Value Examiner and QuickRead, both of which are published by NACVA.

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 in Business Valuation (ABV) designation from AICPA, and 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).

LEADERSHIP

HCC Health Capital Consultants

Jessica L. Bailey-Wheaton, Esq., serves as Senior Vice President and General Counsel of HCC. Her work focuses on the areas of Certificate of Need (CON) preparation and consulting, as well as project management and consulting services related to the impact of both federal and state regulations on healthcare transactions. In that role, Ms. Bailey-Wheaton provides 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.

Additionally, Ms. Bailey-Wheaton heads HCC's CON and regulatory consulting service line. In this role, she prepares CON applications, including providing services such as: health planning; researching, developing, documenting, and reporting the market utilization demand and "need" for the proposed services in the subject market service area(s); researching and assisting legal counsel in meeting regulatory requirements relating to licensing and CON application development; and, providing any requested support services required in litigation challenging rules or decisions promulgated by a state agency. Ms. Bailey-Wheaton has also been engaged by both state government agencies and CON applicants to conduct an independent review of one or more CON applications and provide opinions on a variety of areas related to healthcare planning. She has been certified as an expert in healthcare planning in the State of Alabama.

Ms. Bailey-Wheaton is the co-author of numerous peer-reviewed and industry articles in publications such as: The Health Lawyer (American Bar Association); Physician Leadership Journal (American Association for Physician Leadership); The Journal of Vascular Surgery; St. Louis Metropolitan Medicine; Chicago Medicine; The Value Examiner (NACVA); and QuickRead (NACVA). She has previously presented before the American Bar Association (ABA), the American Health Law Association (AHLA), the National Association of Certified Valuators & Analysts (NACVA), the National Society of Certified Healthcare Business Consultants (NSCHBC), and the American College of Surgeons (ACS).

She serves on the editorial board of NACVA's QuickRead and as Co-Chair of the ABA Health Law Section (HLS) Membership Committee; ABA Young Lawyers Division (YLD) Liaison to the ABA HLS Governing Council; and Young Lawyer Liaison to the ABA HLS Litigation & Risk Management Interest Group.

Ms. Bailey-Wheaton is a member of the Missouri and Illinois Bars and holds a Juris Doctorate, with a concentration in Health Law, from Saint Louis University School of Law, where she served as Fall Managing Editor for the Journal of Health Law & Policy. She received her Bachelor of Arts degrees in Political Science and Foreign Languages from West Virginia University. She currently serves as Adjunct Faculty in the Master's in Health Administration Program, Walker College of Health Professions, at Maryville University, where she teaches a course on Healthcare Law, Ethics and Risk Management.

LEADERSHIP

HCC HEALTH CAPITAL CONSULTANTS

Janvi R. Shah, MBA, MSF, CVA, serves as Senior Financial Analyst of HCC. Mrs. Shah holds a M.S. in Finance from Washington University Saint Louis and the Certified Valuation Analyst (CVA) designation from the National Association of Certified Valuators and Analysts (NACVA). She develops fair market value and commercial reasonableness opinions related to healthcare enterprises, assets, and services. In addition 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 (ASTC) revenue streams.

HCC
HEALTH CAPITAL CONSULTANTS

For more information
Please visit: www.healthcapital.com