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

DEDICATION

As we celebrate our twenty-seventh year in service, the entire team at **HEALTH CAPITAL CONSULTANTS** *dedicates this 10th edition of Health Capital Topics to the many clients nationwide whom we have had the privilege to serve; to their attorneys, accountants, consultants, and vendors with whom HCC has worked to serve the needs of the projects we undertake on their behalf; and, to our professional colleagues nationwide, who both inform and inspire us toward excellence.*

PREFACE

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

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

ACKNOWLEDGEMENTS

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

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

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

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

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

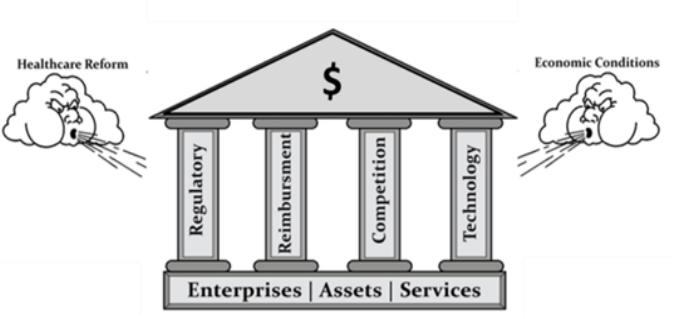
INTRODUCTION

After an unprecedented, tumultuous 2020, we thought 2021 would be less eventful for the U.S. and the American healthcare system – we were wrong. Although restrictions generally eased across the U.S. throughout the year, COVID-19 continued to play a large part in our society, with the news cycle consumed with updates about various pandemic sub-plots, from the race to vaccinate the world to persistently ominous updates about virus variants.

Beyond COVID-19, and the immense stress that this ongoing, (hopefully) once-in-lifetime pandemic has put on our clients, a number of other changes in the healthcare industry required the attention of providers. In January 2021, the Stark Law and Anti-Kickback Statute revisions came into effect, providing a pathway to more innovative, value-based arrangements that have the potential to increase quality while decreasing costs without running afoul of fraud and abuse laws. On the same day, the Hospital Price Transparency final rule became effective, with the goal of improving price and quality transparency and fostering competition. In June 2021, the U.S. Supreme Court rejected, for the third time, a legal challenge to the ACA, solidifying the landmark healthcare law's future. In the midst of these sea changes, healthcare M&A activity boomed, due to deal holdovers from 2020, COVID-19 challenges and opportunities that required providers to reconsider future operations, and the entry of more non-healthcare entities, such as private equity, into the healthcare transactional arena.

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

The Four Pillars of the Healthcare Industry



INTRODUCTION *(Continued)*

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

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

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

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

Sincerely,

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

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I. VALUATION TOPICS

Valuation of Telemedicine: Introduction

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

Telemedicine has rapidly advanced over the past couple of decades, and its advancement has been significantly accelerated since the COVID-19 pandemic struck the U.S. These virtual services have the potential to allow greater access to, and quality of, care, while also resulting in significant cost savings. However, the technology also has numerous challenges, such as infrastructure gaps, capital requirements, and knowledge barriers among patients. The first installment in this five-part series on the valuation of telemedicine provides a description of telemedicine, an overview of its role during the COVID-19 *public health emergency* (PHE), and the potential challenges and opportunities it may face in the future.

Defining Telemedicine and Telehealth

The *National Institutes of Health* (NIH) broadly defines telehealth as the "*use of communications technologies to provide health care at a distance*."[1] Telehealth can be used to describe the monitoring of medical devices; health status data collection and analysis via smart devices; or, virtual visits between physicians and patients.[2] The *World Health Organization* (WHO) defines telemedicine as "*the delivery of health care services, where distance is a critical factor…using information and communication technologies…for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers*."[3]

The terms "*telehealth*" and "*telemedicine*" are distinguished by some in the healthcare industry, including the WHO, which differentiates *telemedicine*, which only includes services administered by physicians, from *telehealth*, which describes services administered by nurses, pharmacists, or other healthcare professionals.[4] In contrast, the *American Telemedicine Association* (ATA) considers the terms to be synonymous and largely interchangeable.[5] For the purposes of this series, the terms will be considered to be synonymous, with the term "*telemedicine*" used for the sake of consistency.

The three main forms of telemedicine include:

(1) *Store-and-Forward* or "*asynchronous*" telemedicine, where information such as medical histories, reports, or other data is sent to a specialist for diagnosis and treatment;
(2) *Remote patient monitoring*, where a patient's clinical status is evaluated continuously through video monitoring, images, or remotely reviewing tests; and,
(3) *Real-time* or "*synchronous*" telemedicine, which consists of a live conversation between the patient and provider.[6]

The Rise of Telemedicine

Although utilization of telemedicine technology has been relatively low historically, provider use of telemedicine services has grown considerably in recent years as the technology becomes more readily available and affordable.[7] Advancements in telemedicine technology and its infrastructure have allowed otherwise unserved or underserved patients to receive healthcare services. Payors and providers (including physician practices and hospitals) alike have been adopting telemedicine technologies at a rapid pace in an attempt to reduce avoidable hospitalizations, improve in-facility care, and decrease costs.[8] As healthcare reimbursement has continued to shift from *volume-based* to *value-based*, healthcare providers have increasingly looked to telemedicine to expand their services and better support patients before and after their visit.[9] Telemedicine can also be a more appealing option for patients who face difficulty accessing care or leaving their residences. This technology means that healthcare services can be delivered either at a closer facility or in the comfort of the patient's home.[10] While telemedicine utilization has been on the rise over the past decade, it was not until the 2020 COVID-19 PHE that the technology became widely adopted and utilized by a variety of patients and providers.

Telemedicine and the COVID-19 PHE

Since the beginning of the COVID-19 PHE in March 2020, all states and medical specialties have seen unprecedented increases in telemedicine utilization.[11] Several policies and developments have jump-started this rapid expansion. Following the declaration of COVID-19 as a PHE, the *Centers for Medicare and Medicaid Services* (CMS) announced a number of relaxations and flexibilities for telemedicine reimbursement and coverage. This emergency declaration allowed beneficiaries to receive care wherever they were located – even from out-of-state providers – and did not penalize providers who, while acting in good faith, violated the *Health Insurance Portability and Accountability Act* (HIPAA) by using unencrypted video programs such as Skype or FaceTime to conduct telemedicine visits.[12] These measures represented dramatic changes from the previous policies, which only covered telemedicine for rural patients and had stringent restrictions on the originating site for the care and only allowed physicians to care for established patients in the same state in which they were licensed.

In addition to relaxing the originating site requirements, CMS also expanded the number of services that could be provided through telemedicine. An additional 135 services, including emergency department visits, were added to the list of covered (and thus reimbursable) services for Medicare beneficiaries.[13] While all of these flexibilities and expansions were originally only valid for the length of the PHE, CMS has been looking to extend some expansions in covered services and reimbursement semi-permanently or permanently. For example, CMS's 2021 *Medicare Physician Fee Schedule* (MPFS) proposed rule included expansions to reimbursement for telemedicine services.[14] This proposed rule suggested permanently implementing or temporarily expanding coverage for several telemedicine services.[15] Services

such as *evaluation and management* (E/M) and some visits for patients with cognitive impairment were proposed to be permanently covered for telemedicine.[16] CMS also proposed continued reimbursement for some telemedicine services, such as emergency department visits, only temporarily, until the end of the calendar year when the COVID-19 PHE officially ends.[17] Under this proposed rule, nine telemedicine service codes would remain covered permanently under this proposed rule, 13 would remain covered temporarily, and 74 would be removed immediately after the PHE ends.[18]

Rural providers, as evidenced by their lower rates of telemedicine usage, have not been able to take advantage of the opportunities provided by telemedicine to the same extent as urban providers.[19] However, an executive order issued by President Trump on August 3, 2020, calls for dramatic functional and reimbursement changes for these rural providers specifically.[20] The executive order also directs CMS to review the 135 services that it originally waived on a temporary basis in March 2020, and orders certain services to be permanently delivered via telemedicine technology going forward, although the specific codes have not yet been decided.[21]

Future Challenges to Implementation

Telemedicine's significant potential to increase quality and access to care and its exponentially-expanded popularity during the COVID-19 PHE is countered by a few major barriers experienced by providers seeking to implement and expand telemedicine into their practice. One of the greatest challenges for telemedicine is the limited reimbursement for its services. High upfront technology, administration, and set-up costs, without the guarantee of permanent reimbursement (comparable to in-person services), may deter some (and particularly small) providers. In fact, larger organizations of 100 or more clinicians were able to shift an average of 16% of their pre-pandemic visits to telemedicine, compared to only about 8% for smaller organizations.[22] From the abrupt spike in use through March and April 2020, volume has apparently begun decreasing, with the volume of telemedicine visits during the week of June 14, 2020 nearly a third less than in early April.[23] Additionally, there is a lack of integration and interoperability among healthcare organizations' various *electronic health record* (EHR) systems, which platforms also may not coordinate with the telemedicine platform. These issues facing the telemedicine industry may result in the provision of costly and inefficient care, and many providers seem to be wary of fully adopting the technology without plans in place for long-term viability.

Patient satisfaction with telemedicine services seems to be high, but research also indicates that certain patient populations may not be able to take full advantage of these virtual visits. On one hand, those who have been able to utilize telemedicine and virtual visits seem to be satisfied, with one survey indicating that 96% of patients found arranging virtual visits to be either extremely or somewhat easy, and 96% were satisfied with the virtual care they received (with 77% being completely or very satisfied).[24] Importantly, 86% of the surveyed patients were likely to recommend virtual care to others.[25] Another

survey found that 83% of patients were likely to use telemedicine after the COVID-19 PHE.[26] Other studies examining the ease of telemedicine use for older adults indicate less promising statistics. An August 2020 study found that, across more than 4,500 adults aged 65 or older, over 70% showed signs of unreadiness, including difficulty hearing or communicating or inexperience with the technology required.[27] Another study, using pre-COVID-19 data, similarly showed that older age was strongly associated with lower telemedicine utilization.[28] Because these older adults comprise approximately 25% of all physician office visits, their inability (and unwillingness) to utilize telemedicine could slow the technology's adoption rate in the near future.[29] However, the quick expansion of telemedicine over the past few years, even before COVID-19, indicates that this technology will continue to expand as usage and adoption rates by physicians and patients alike increase in the future. One way to accomplish this, it seems, is through expanded reimbursement past the COVID-19 PHE. The second installment of this five-part series will cover the past, current, and future state of telemedicine reimbursement.

Valuation of Telemedicine: Reimbursement

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

Introduction

The second installment in this five-part *Health Capital Topics* series on the valuation of telemedicine will focus on the reimbursement environment for telemedicine.[30] Telemedicine is reimbursed based on the services provided through this medium and includes many restrictions on where, how, and by whom services can be conducted. The first installment in this series introduced telemedicine and its increasing importance to, and popularity among, providers and patients. It also discussed the current and future challenges related to telemedicine, many of which hinge upon reimbursement restrictions and regulations.[31]

Pre-COVID-19

Traditionally, there have been many restrictions on telemedicine service coverage. Medicare has included geographical restrictions, provider restrictions, payment limitations, facility fee limitations, and limitations on covered services in their telemedicine reimbursement regulations. For example, Medicare beneficiaries had to be located in a rural *Health Professional Shortage Area* (HPSA) or in a county outside of a *Metropolitan Statistical Area* (MSA).[32] It was not until the *Creating Opportunities Now for Necessary and Effective Care Technologies* (CONNECT) *for Health Act of 2019* that the *Centers for Medicare & Medicaid Services* (CMS) was allowed to waive

certain geographic restrictions related to the patient's location.[33] A patient's location when receiving care, called the *originating site*, was, until the CONNECT Act, an important factor in determining reimbursement eligibility.[34] In 2019, whether an originating site (to which Medicare pays a facility fee – $26.65 in 2019[35]) was authorized depended on the facility's geographic area.[36] States also had differing rules on the patient setting, with 29 states not including patient setting as a condition for payment, and 12 states recognizing school, and 12 states recognizing the home, as originating sites.[37] Medicare also restricted which practitioners could receive payments for covered telemedicine services.[38] Covered services have also traditionally been limited, although CMS has added new services to this list every year through the *Medicare Physician Fee Schedule* (MPFS). At the beginning of 2020, 101 telemedicine services were reimbursed by Medicare.[39]

Telemedicine's greatest appeal and promise for many is not just the ability to reach underserved populations, but to save money for both payors and patients by giving the latter a less expensive option for care than in-person or emergency room visits. However, while adoption and utilization of telemedicine have been increasing over the years, telemedicine has remained a low percentage of all healthcare visits and spending, as government reimbursement remains uncertain. Because CMS has been slow to expand telemedicine benefits, reimbursement has been trailing behind a growing interest from providers and patients in these services. Additionally, as with most healthcare services, private payors followed Medicare's lead on telemedicine reimbursement; consequently, even as technological capabilities have grown, telemedicine services have remained on the margins of healthcare spending and investment. By 2016, however, most private insurance carriers and self-insured employers had included telemedicine benefits, such as for behavioral health, dermatology, radiology, infectious diseases, and stroke.[40] Around that same time, however, only 15% of family physician practices used telemedicine, with the majority of physicians citing a lack of reimbursement as their top reason for not integrating telemedicine into their practice.[41]

As public payors, as well as more private payors and providers, began to recognize the potential of telemedicine, adoption of this technology accelerated. As of the *American Telemedicine Association's* (ATA's) 2019 report on coverage and reimbursement, only ten states had not yet enacted substantive policies for telemedicine reimbursement.[42] Additionally, 21 and 28 states have coverage and payment parity policies related to Medicaid, respectively.[43] States more often regulate private payors, with 36 states having coverage parity and 16 states having payment parity related to private payments.[44] These parity policies may provide strong incentives for the adoption and viability of telemedicine technology for physician practices.[45] However, at the same time, equal payments undermine the cost-saving argument of telemedicine and create complications for technology adoption.[46]

In the 2019 report, the ATA further stated that 29 states do not include patient setting as a condition for payment.[47] Further, the majority of states also

recognize modalities of telemedicine delivery other than synchronous technology, with some states even allowing for audio-only visits; however, 16 states still limit telemedicine to just video, synchronous visits.[48] More than half of states did not have restrictions related to eligible provider types, with ten others allowing for six or more provider types.[49] The vast inconsistency of these regulations also created difficulties for providers to provide cost-effective telemedicine services across locations.

Expansion During the Pandemic

COVID-19 was declared a *public health emergency* (PHE) on January 31, 2020, and a national emergency on March 13, 2020.[50] Subsequent to this declaration, and the shutdowns and gathering restrictions that followed, telemedicine and remote care became vital for many who could not visit their provider in person or were reticent to visit the hospital due to exposure concerns. After the start of the PHE, telemedicine quickly became routine for Medicare beneficiaries. From March to early July 2020, over 10 million beneficiaries received care through telemedicine, compared with only 14,000 per week at the start of 2020.[51] Specifically, telemedicine utilization rates for Medicare primary visits soared from 0.1% prior to February 2020 to 43.5% by April.[52] All states, as well as both primary and specialty care physicians, have experienced increases in the number of telemedicine visits.[53]

Several reimbursement and regulation policy changes made this dramatic expansion possible. First, on March 17, 2020, CMS released waivers that:

(1) Reduced the barriers to providers by allowing beneficiaries to receive care wherever they were located, including in their home, and by allowing physicians to treat patients outside of the state wherein they are licensed;

(2) Exempted providers who had acted in good faith, but had nonetheless committed a privacy violation by using unencrypted video programs such as Skype or FaceTime, to conduct telemedicine visits free from *Health Insurance Portability and Accountability Act* (HIPAA) penalties;

(3) Expanded telemedicine reimbursement coverage to 135 new services, including emergency department visits; and,

(4) Increased the types of providers that can conduct telemedicine visits to: "*physicians, nurse practitioners, physician assistants, nurse midwives, certified nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians, and nutrition professionals*."[54]

Further legislation that played a role in expanding Medicare coverage included the *Coronavirus Aid, Relief, and Economic Security (CARES) Act*, which delegated $200 million to the *Federal Communications Commission* (FCC) to expand telemedicine services and infrastructure.[55] A March 30, 2020 release of regulatory changes from CMS established a pay parity rule for telemedicine visits, so that they would be reimbursed at the same rate as in-person visits, and extended coverage further to more than 80 added services, which included

emergency department visits, initial visits, discharges from nursing facilities, and home visits.[56] Because telemedicine is reimbursed on the basis of services conducted, CMS's expansion of covered services was vital for sustainable reimbursement. In fact, in CMS's 2021 final payment rule for *skilled nursing facilities* (SNFs), more provisions were included to help providers care for patients through telemedicine, including adding new codes to allow Medicare beneficiaries greater access to virtual care services.[57] The newest code additions, which include physician telephone *evaluation and management* (E/M) services, represent an ongoing expansion of telehealth codes by CMS that will continue at least over the course of the pandemic and possibly beyond it.[58]

Most private insurers have also expanded their telemedicine benefits since the start of the pandemic, allowing for greater coverage, and incentives for patients to utilize these services. Many waived out-of-pocket costs and co-payments for COVID and telemedicine patients, but began rolling back these benefits over the summer after only a few months of coverage.[59] Many insurers have changed rates throughout the pandemic and are covering telemedicine services much less generously than Medicare, which will generally cover most of its expanded telemedicine services until at least the end of the PHE period.[60] In fact, several private payors halted their telemedicine copay waivers beginning in October 2020 for certain non-COVID-19-related services, a move which may raise costs for some patients.[61] This recent trend of decreasing utilization for virtual visits (although these rates are still many times higher than in 2019), may be a sign of providers' frustrations with these quickly-withdrawn reimbursement allowances and rate changes.[62] The sustainability of telemedicine has been questioned by many, and those who had not already integrated this technology before or at the start of the pandemic may be weary of expanding these services while reimbursement policies continue to be inconsistent and uncertain. Current reimbursement amounts for many services, such as telephone visits, are small and may not be sustainable for providers who have yet to establish telemedicine services.[63] The initial capital investment in telemedicine can be intimidating and may not make financial sense for many providers. Telemedicine software can cost between $20 and $500 per user per month,[64] while the hardware (and training) can cost thousands of dollars each, meaning a medical practice may conservatively spend more than $50,000 just to launch their telemedicine program.[65] Especially for smaller providers, such an initial investment may not be feasible.

Potential Future Reimbursement Trends

While the future of telemedicine reimbursement post-COVID-19 seems uncertain, CMS has recently released payment legislation that seems to indicate that some telemedicine regulatory relaxations will remain in place, including the 2021 MPFS proposed rule and new payment models for rural providers and *accountable care organizations* (ACOs). In CMS's proposed rule, reimbursement coverage for several telemedicine services was permanently implemented or temporarily expanded. Nine telemedicine services such as E/M

services and some visits for patients with cognitive impairment are proposed to be permanently covered,[66] while payments for 13 other telemedicine services, such as emergency department visits, are proposed to be extended only temporarily, until the end of the *calendar year* (CY) in which the COVID-19 PHE officially ends.[67] Seventy-four codes that have been reimbursed during the COVID-19 PHE will be removed immediately after the end of this PHE.[68]

Further, to support rural providers, CMS has proposed a new *Community Health Access and Rural Transformation* (CHART) model. This model was created in response to an August 3, 2020, executive order, which highlighted opportunities for investment in technological infrastructure for rural areas and urged the *U.S. Department of Health and Human Services* (HHS) to develop a new payment model with increased flexibility, more predictable payments, and quality incentives for rural hospitals.[69] Rural patients struggle with access to healthcare, and telemedicine provides a unique challenge for rural patients because of a lack of infrastructure. Lower adoption and utilization rates in rural communities exemplify this idea, as do other reports which, for example, indicate internet issues for about one in five adults living in rural areas.[70] The CHART model will operate through two value-based reimbursement "*tracks*": (1) the *Community Transformation Track* and (2) the *ACO Transformation Track*.[71] Among other benefits, both of these tracks will continue telemedicine expansion post-COVID-19 for rural providers.[72]

Conclusion

Telemedicine's rapid expansion during COVID-19 now faces an uncertain future. A lack of reimbursement, as well as widely varied reimbursement policies among states and payors, has long been a major barrier to entry for many providers pre-COVID-19. Telemedicine utilization, however, has been increasing steadily over the past several years with a large, unprecedented rise in March and April 2020, at the start of the COVID-19 PHE. Utilization and adoption rates remain higher than ever before, but many providers seem hesitant to invest in telemedicine long-term as public and private payors begin to plan to pull back benefits and service coverage. Still, CMS is planning to make some of the 135 services under its expanded coverage in March 2020 permanent or available on a longer term basis until the end of the PHE. If these telemedicine services indeed continue to be reimbursed, and policy changes continue to be implemented, the future of telemedicine may be bright for patients and providers alike. Reimbursement will either provide an incentive or barrier to this future and will require cooperation and consistency across states and payors.

Valuation of Telemedicine: Regulatory

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

Introduction

The third installment in this five-part *Health Capital Topics* series on the valuation of telemedicine will focus on the regulatory environment for telemedicine, with a specific focus on fraud and abuse laws.[73] The first installment in this series introduced telemedicine and its increasing importance to, and popularity among, providers and patients. It also discussed the current and future challenges related to telemedicine, many of which hinge upon reimbursement restrictions and regulations.[74] The second installment took a deeper dive into the growth, new payment rules, and future uncertainties surrounding reimbursement for telemedicine services.[75]

Federal Fraud and Abuse Laws

Healthcare service organizations face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. Fraud and abuse laws, specifically those related to the federal *Anti-Kickback Statute* (AKS) and physician self-referral laws (the "*Stark Law*"), may have the most significant impact on the operations of those 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 receive funding from any federal healthcare program, the Stark Law specifically addresses the referrals from physicians to entities with which the physician has a financial relationship for the provision of defined services that are paid for by the Medicare program.[76] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[77]

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.[78] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[79] Additionally, interpretation and application of the AKS under case law have created a precedent for a regulatory hurdle known as the *one purpose* test. Under the *one purpose* test, healthcare providers violate the

AKS if even one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[80]

The *Patient Protection and Affordable Care Act* (ACA) made two noteworthy changes to the intent standards related to the AKS. First, the legislation amended the AKS by stating that a person need not have *actual knowledge* of the AKS or *specific intent* to violate the AKS for the government to prove a kickback violation.[81] However, the ACA did not remove the requirement that a person must "*knowingly and willfully*" offer or pay remuneration for referrals to violate the AKS.[82] Therefore, to prove a violation of the AKS, the government must show that the defendant was aware that the conduct in question was "*generally unlawful*," but not that the conduct specifically violated the AKS.[83] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the *False Claims Act* (FCA).[84] This means that in addition to *civil monetary penalties* paid under the AKS, violation of the AKS would create additional liability under the FCA, which itself carries *civil monetary penalties* of over $21,500 plus treble damages.[85]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[86] In response to these concerns, Congress promulgated several *safe harbors*,[87] which 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.[88] Failure to comply with all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[89] Some of the safe harbors most applicable to a telemedicine arrangement include the space and equipment rental safe harbors, for the purposes of leasing telemedicine equipment or space, and the personal services and management contracts safe harbor, for the arrangement for the provision of telemedicine services between an entity and a physician.[90]

Of note, in November 2020, the HHS *Office of Inspector General* (OIG) made several revisions to the AKS in a final rule, many of which are similar to those revisions to the Stark Law proposed by CMS. Among the more notable changes related to the AKS includes a new safe harbor related to *cybersecurity technology and services*. This safe harbor protects the nonmonetary donation of cybersecurity technology and services subject to several conditions, including that the agreement is in writing and that the donation (or receipt thereof) does not directly take into account the volume or value of referrals or other business between the parties.[91]

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).[92] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[93]

Under the Stark Law, DHS include, but are not limited to, the following:

(1) Certain therapy services, such as physical therapy;
(2) Inpatient and outpatient hospital services;
(3) Radiology and certain other imaging services;
(4) Radiation therapy services and supplies;
(5) Durable medical equipment; and,
(6) Outpatient prescription drugs.[94]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and compensation arrangements, which are defined as arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or "*in kind*."[95]

Similar to the AKS *safe harbors*, 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.[96] However, unlike the AKS safe harbors, an arrangement must entirely fall within one of the *exceptions* to shield from enforcement of the Stark Law.[97] Some of the exceptions most applicable to a telemedicine arrangement include the space and equipment leasing arrangement exception, for the purposes of leasing telemedicine equipment or space; the bona fide employment arrangement exception, for the employment of a physician who is providing services through telemedicine; fair market value (FMV) compensation arrangements, for compensation that is paid at fair market value; and, the personal services arrangements exception, for the arrangement for the provision of telemedicine services between an entity and a physician.[98] Note that, generally, these exceptions require that: the arrangement be memorialized in a signed, written agreement; the compensation not exceed FMV and be commercially reasonable; and the compensation not reflect the volume or value of referrals.[99]

In November 2020, CMS finalized revisions to the Stark Law, including:

(1) Revised definitions for Fair Market Value;
(2) A definition for Commercial Reasonableness (as this term was previously undefined);
(3) New permanent exceptions for value-based arrangements; and,
(4) A new exception for limited remuneration to a physician.[100]

These rule changes seek to make it easier for healthcare providers to provide value-based care without running afoul of the Stark Law.

Licensure

The growth in reimbursable telemedicine services varies widely across payor types, as well as across states.[101] Much of this geographic variance can be attributed to the current state of medical licensure rules for each state. While many state legislatures have debated increasing reimbursement for telemedicine services,[102] the *American Telemedicine Association's* (ATA's) 2019 report on coverage and reimbursement reported that ten states have not yet enacted substantive policies for telemedicine reimbursement.[103] Additionally, coverage, payment parity, geographic restrictions for both

patients and physicians, and restrictions on provider types all vary by state, and this inconsistency has made cost-effective telemedicine service offerings difficult to achieve across provider locations.

In 2014, the *Federation of State Medical Boards* (FSMB) issued a *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine* (Model Policy) requiring those practicing telemedicine to be licensed in the state where a patient is located.[104] FSMB cited overriding concerns for patient welfare as the reason for their conservative position on this issue.[105] As of July 2020, 49 states require physicians providing telemedicine to be licensed in the state in which the patient is located.[106] Additionally, 12 states allow for a special license or certificate for physicians to practice across state lines for the purpose of providing telemedicine services, and six states require registration for practicing telemedicine across state lines.[107]

As of November 2020, 29 states, as well as the District of Columbia, have signed the *Interstate Medical Licensure Compact* (IMLC), an "*expedited pathway to licensure for qualified physicians who wish to practice in multiple states*."[108] The IMLC expedites licensure, but only for physicians that meet certain eligibility requirements – approximately 80% of physicians meet this criteria sufficient for obtaining IMLC licensure.[109] Thirty-four states have signed onto a somewhat analogous agreement – the *Nurse Licensure Compact* (NLC).[110] The NLC was launched in 2015, and has effectively allowed for nurses to practice in other NLC states physically, telephonically, and electronically.[111]

Corporate Practice of Medicine (CPOM)

The CPOM doctrine prohibits unlicensed individuals or corporations from engaging in the practice of medicine by employing licensed physicians.[112] The CPOM is regulated on a state level, with regulations varying significantly by state.[113] Some states expressly prohibit the practice, including laws restricting unlicensed individuals from owning or operating a business in which medical services are provided to patients. Other restrictions include placing limitations on physicians and their ability to enter into professional relationships with unlicensed individuals or nonprofessional business entities. Further, some states except tax-exempt healthcare entities from liability under the CPOM,[114] with the rationale that the lack of a "profit incentive" eliminates the dangers associated with the CPOM.

As a result of changes in the delivery of healthcare, new practice areas have surfaced that may be prone to running afoul of current statutes restricting the CPOM, e.g., telemedicine companies. Telemedicine companies are often owned by non-providers and operate (and provide services) across state lines, both of which issues may implicate CPOM. Consequently, in order to refrain from CPOM violations, these companies may set up their corporate structure utilizing a "friendly PC" or "captive PC" model, wherein physicians own the legal entity, typically a professional corporation (PC) or professional limited liability company (PLLC), that provides healthcare services, and that "captive"

or "friendly" entity contracts with a management services organization (MSO), which provides the management services to the PC/PLLC.[115]

Regulations During and After the COVID-19 Pandemic

Many of the federal and state regulations and licensing requirements have been temporarily suspended during the COVID-19 *public health emergency* (PHE). For example, FSMB reports that, as of October 30, 2020, 41 states have enacted waivers for out-of-state physicians, preexisting relationships, and audio-only requirements in response to the COVID-19 PHE.[116] Further, the *Department of Health and Human Services* (HHS) and the *Office for Civil Rights* (OCR) have temporarily suspended regulations under the *Health Insurance Portability and Accountability Act of 1996* (HIPAA). HHS and OCR announced in early Spring 2020 that they would not enforce penalties on providers who violated HIPAA rules, but acted in good faith in providing telemedicine during the COVID-19 PHE.[117] Other telemedicine visit regulations that have been suspended during the PHE include requiring an initial in-person visit, geographic restrictions that required the telemedicine visit to take place at a clinical facility, and obtaining special training before conducting these visits.[118]

As providers speculate as to the future of healthcare post-COVID-19, many suggest that simplifying the complex regulatory system may be key to the continued success of telemedicine.[119] Post-pandemic regulations will be critical in determining the future of telemedicine, and many believe that permanently relaxing or eliminating regulations that were waived during the PHE and creating a single, federal regulatory framework (in contrast to a state-by-state approach) would be important steps toward making the investment into telemedicine feasible and cost effective for many providers, especially smaller providers who have not yet implemented this technology into their practice.[120]

Valuation of Telemedicine: Competition

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

Introduction

The fourth installment in this five-part *Health Capital Topics* series on the valuation of telemedicine will focus on the competitive environment in which telemedicine providers operate.[121] The first installment in this series introduced telemedicine and its increasing importance to, and popularity among, providers and patients, as well as the current and future challenges related to telemedicine.[122] The second installment took a deeper dive into the reimbursement environment in which telemedicine providers operate, including before and during the COVID-19 pandemic,[123] while the third installment examined telemedicine's regulatory environment, with a specific focus on fraud and abuse laws.[124]

The Rise of Telemedicine Supply and Demand

Although telemedicine utilization has been relatively low historically, in recent years, practitioners' use of telemedicine has grown considerably as the technology becomes more readily available and affordable.[125] The use of telemedicine has become increasingly popular among both payors and providers, who have been adopting the technology at a rapid pace in an attempt to reduce avoidable hospitalizations and improve in-facility care.[126] In fact, after slower growth in the early part of the decade, telemedicine utilization increased 53% between 2016 and 2017, but still only accounted for 0.11% of all national medical claim lines in 2017.[127] Urban use of telemedicine grew much faster than rural use during that time, with growth rates of 55% and 29%, respectively.[128] Further, 76% of hospitals had, by 2017, at least partially implemented a telemedicine system to connect with their patients through videoconferences, remote monitoring, online consultation, and other wireless communications.[129]

During this time, many health systems found that implementing telemedicine also provided them a competitive advantage. This technology allowed patients to receive ongoing care, particularly from specialists, and allowed those specialists to take on more patients and tap into new markets.[130] One main competitive advantage reported by providers was that telemedicine allowed them to have a stronger presence in underserved markets.[131]

This growing utilization of telemedicine among providers and patients in recent years is attributable to several factors. First, as healthcare reimbursement has shifted over the years from *volume-based* to *value-based* care, healthcare providers have increasingly looked to telemedicine to expand patient services and better support patients before and after their in-office visit.[132] This care may lead to better patient outcomes and reduce costly and unnecessary hospitalizations.[133] For patients who face multiple serious conditions, difficulty leaving their home, or other barriers to accessing traditional care, telemedicine can represent a more appealing option,[134] as these services can be delivered either at a closer facility or in the comfort of the patient's home.[135] Second, as mentioned briefly above, advancements in telemedicine technology itself, as well as in technology infrastructure such as broadband availability for patients, have allowed otherwise unserved or underserved patients to receive healthcare services.[136] In fact, other than barriers to in-person visits such as paid parking, the ability to access high-speed internet is a main factor of patients to choose telemedicine over in-person visits.[137] Third, using telemedicine as a healthcare service delivery method has great potential for cost savings, in large part by reducing unnecessary visits to emergency departments.[138] While telemedicine utilization has been on the rise over the past decade due to these various reasons, it was not until the 2020 COVID-19 *public health emergency* (PHE) that telemedicine became widely adopted and utilized by a variety of patients and providers.

Changes to Telemedicine Supply and Demand during the COVID-19 PHE

Telemedicine has quickly become routine for Medicare beneficiaries since the start of the PHE. Only 14,000 Medicare beneficiaries per week used telemedicine at the start of 2020, but from March to early July 2020, the total number of beneficiaries who received care through telemedicine soared to over 10 million.[139] Similarly, only 0.1% of Medicare primary care visits were conducted via telemedicine prior to February 2020, compared to 43.5% in April 2020.[140] Both primary and specialty care physicians have experienced increases in the number of telemedicine visits from the start of the PHE.[141] The growth and expansion of telemedicine has been slower in rural areas; however, even the state with the lowest rate of telemedicine use, Nebraska, saw increases in telemedicine primary care visits – up to 22% of all primary care visits.[142] Several policy changes from the *Centers for Medicare and Medicaid Services* (CMS), which included relaxations of previous rules and stipulations; added services; and, increased flexibility for providers and patients, launched this rapid expansion following the declaration of the COVID-19 national emergency.[143] Going forward, the continued success of telemedicine may again hinge on CMS and whether wider reimbursement is implemented.[144]

Despite the increased utilization of telemedicine during the COVID-19 PHE, there is also evidence that overall primary care visits decreased significantly. Primary care visits in the second quarter of 2020 were more than 20% lower than the average of the previous two years' second quarter visit numbers.[145] Researchers also found that the contents of the visits that did occur in Q2 2020 were different than for Q2 2018 and Q2 2019 – for example, the assessment of important risk factors such as blood pressure and cholesterol was significantly less common in 2020.[146] Further, the demand for telemedicine has begun to decrease since the summer of 2020, after the first few months of the pandemic. In July, nationwide telemedicine visits were down to 21% of all visits, from 69% in April.[147] These dramatic changes in demand from pre-COVID-19 to later in the pandemic have reportedly left hospitals and other providers having to provide training in virtual care to their staff, only to switch many of these staff back to in-person visits.[148] After the financial tolls of the pandemic, many providers are looking to balance the most cost effective combination of these two visit types, which now seems to mean scaling back their telemedicine operations from those levels early into the COVID-19 PHE.[149]

How Will Telemedicine Continue to Transform Competition?

Despite uncertainties, many experts continue to project growth over the next several years in the area of telemedicine. One market analysis projected that the global telemedicine market will be valued at nearly $186 billion by 2026, an increase of $152 billion from 2018.[150] The *compound annual growth rate* (CAGR) is projected to be approximately 25.3%, which highlighted the COVID-19 pandemic and investment in research and development as major reasons for this growth.[151]

Further, while telemedicine has undoubtedly already had an effect on competition and likely has been a useful tool for competing in the healthcare market for many years, some predict that it could have an even more profound effect in the future. One analysis likened telemedicine in healthcare to the rise of online shopping for other industries or online education in the higher education system.[152] Similarly, by releasing some constraints typically put on patient choice, telemedicine may also lead to lower prices and greater availability of services.[153] As discussed above, providers have found themselves able to serve more patients with telemedicine. Since the start of the COVID-19 PHE, they are also able to serve new patients to their practice (in contrast to only established patients), as well as patients in different states. A continued relaxation of these restrictions may serve to at least partially ameliorate geographic and availability limitations through the use of telemedicine. Where limited specialists and hospital consolidations have led to increased prices of care, telemedicine may be a powerful tool to foster competition and decrease those prices.[154]

In addition to ameliorating access, telemedicine also has the potential to lessen the effects of growing primary care physician shortages. The *Association of American Medical Colleges* (AAMC) has predicted that there will be a shortfall of 21,000 to over 55,000 primary care physicians by 2033.[155] Physicians retiring, the aging population in the U.S. (and particularly the "*Baby Boomer*" cohort), and improved access to healthcare services are likely to all be strong contributors to this shortage.[156] Because telemedicine makes visits more efficient,[157] the potential effects from this shortage may be lessened through telemedicine, which allows one physician to see and monitor a greater number of patients. By contrast, the entrant of a new competitor into the market – the telemedicine companies themselves – may create more competition for physician talent.[158] Because telemedicine does not need to be conducted through a traditional health system or healthcare provider, many patients may be able to access symptom monitoring, educational materials, and referrals directly from a telemedicine company.[159] Especially if telemedicine continues to be commonly utilized by patients in the future, and the technology continues to develop and expand the limits of telemedicine, health systems may find themselves competing with the telemedicine providers directly, for patients, physicians, and non-physician providers.

Barriers to Entry

In order to realize the full potential of telemedicine, providers will have to continue to supply telemedicine services in the long-term, not just during the current PHE, and patients will have to be willing to regularly utilize telemedicine in the course of their medical regimen. Recent decreases in both the supply and demand of telemedicine services may call both of these assumptions into question. On the demand side, rural patients, who have the greatest need for these services, still struggle to access telemedicine due to limited broadband availability, which may significantly affect their demand for these services.[160] On the supply side, the up-front costs of the hardware,

software, and human resources needed to begin offering telemedicine may also be a steep barrier for providers, and particularly for smaller practices.[161] These barriers will likely set limits on who can provide telemedicine, especially given the uncertainty of expanded reimbursement post-COVID-19.[162]

Despite these myriad issues, experts remain confident that telemedicine will continue to grow. Telemedicine's full effect on the healthcare industry may be yet unseen and will depend on the factors discussed in previous *Health Capital Topics* articles on telemedicine valuation as well as the subject of the final installment of this series – technology.

Valuation of Telemedicine: Technology

[This is the final article in a five-part series regarding Valuation of Telemedicine This installment was published in January 2021.]

Introduction

The final installment in this five-part *Health Capital Topics* series on the valuation of telemedicine will focus on the technology available to telemedicine providers, how that technology has evolved, and its anticipated development going forward.[163] The first installment in this series introduced telemedicine and its increasing importance to, and popularity among, providers and patients, as well as the current and future challenges related to telemedicine.[164] The second installment took a deeper dive into the reimbursement environment in which telemedicine providers operate, including before and during the COVID-19 pandemic;[165] the third installment examined telemedicine's regulatory environment, with a specific focus on fraud and abuse laws;[166] and, the fourth installment discussed supply and demand related to telemedicine, as well as how telemedicine may change healthcare competition generally.[167]

History and Development

Telemedicine in the modern sense began nearly 60 years ago, but remained out of reach for the general public until much more recently. The *U.S. National Aeronautics and Space Administration* (NASA) began using telemedicine out of necessity as a way to treat and conduct symptom management for its astronauts in space.[168] In the decades since this initial innovation, the uptake of telemedicine has been slow among the general population. Technological, financial, legal, and human resource barriers have all contributed to this slow adoption by providers and demand by patients.[169] Some of these barriers, including the lack of proper reimbursement; high upfront investment costs; geographic and provider limitations set by the *Centers for Medicare and Medicaid Services* (CMS); and other medical information protection and security issues have been addressed in previous *Health Capital Topics* articles.[170] Consequently, this article will focus on both the technological

barriers and advancements that slowed telemedicine's adoption rates by patients and providers in the past but have now thrust telemedicine into the foreground of the U.S. healthcare delivery system.

Over the past 15 years, targeted legislation, healthcare reform, and government funds have intersected with widening broadband availability; increased investment in developing new telemedicine technology, including the evolution of *Mobile Health* (mHealth); and, the ability for various technologies to become sufficiently secure so as to satisfy *Health Insurance Portability and Accountability Act of 1996* (HIPAA) requirements.[171] National legislation advancements include, for example, the *Health Information Technology for Economic and Clinical Health* (HITECH) *Act of 2009*, which was included as a part of the broader *American Recovery and Reinvestment Act of 2009* (ARRA). Through these acts, $32 billion was allocated to subsidies for modern *health information technology* (HIT) systems, health research, and facility construction.[172] As discussed in previous *Health Capital Topics* articles, various recent measures passed by CMS during the COVID-19 *public health emergency* (PHE) allowed providers greater flexibility in, and incentives for, offering telemedicine services.[173]

Many aspects of telemedicine are dependent on robust technological networks, and broadband in particular. When the *Federal Communications Commission* (FCC) released their National Broadband Plan in 2010, which included the goal of providing every American with "*access to broadband capability*," approximately one-third of the country – 100 million Americans – *did not* have broadband at home, despite unprecedented growth over the previous decade from 8 million to 200 million Americans with broadband access.[174] The plan focused on several areas of broadband improvements related to healthcare: *electronic health records* (EHRs), video consultation, and remote patient monitoring.[175] First, hosted EHRs, where one computer acts as a server for the patient record system database, require internal IT expertise and broadband availability, but cost less and provide tools to patients more quickly than traditional solutions.[176] Cloud-based EHR systems similarly require a strong and consistent internet connection for access to files.[177] Second, video consultations, with store-and-forward technology (discussed below), could lead to cost savings and increased access to care, especially to specialists.[178] Finally, remote patient monitoring for symptoms can aid in early detection and, consequently, better health outcomes.[179] According to the *American Telemedicine Association* (ATA), mobile applications generally fall into "*acute care telemedicine*," where clinicians diagnose and treat ill patients and "*chronic disease management telemedicine*," where a chronically sick patient is regularly monitored and managed for symptoms.[180]

In order to further the nation's technological networks, a number of recent legislative acts have allocated funds to the cause. In 2019, the FCC established a $20.4 billion Rural Digital Opportunity Fund to provide greater broadband access to currently underserved areas.[181] The FCC set aside $61.8 million of that total to expand rural broadband as a part of Phase II of the Connecting

America national plan, which will allocate nearly $1.5 billion in total to expanding broadband access to over 700,000 homes and small businesses over the next decade.[182] The 2020 *Coronavirus Aid, Relief, and Economic Security* (CARES) Act similarly allocated $500 million to increase broadband access for rural communities to help support telemedicine, distance learning, and social distncing.[183]

Technologies such as mHealth, mobile sensors and monitors (e.g., heart rhythms, vital sign indicators, and motion and fall detectors for older adults living independently), telemedicine kits, biosensor recliners, and remote medicine robots, all represent great potential in expanding remote patient care.[184] Similarly to the FCC, the ATA, in a 2006 report, identified 5 types of services that can be delivered through telehealth:

(1) Specialist referral services involving a specialist visit using video technology;
(2) Direct patient care using audio or video technology for diagnosis, treatment, prescriptions, advice, or patient monitoring;
(3) Remote patient monitoring using devices that collect medical data;
(4) Medical education and mentoring for health professionals and seminars; and,
(5) Consumer medical and health information, or using the internet to find health information, discussion groups, and peer support for specialized issues.[185]

However, utilization of the many technologies available to healthcare providers have not been adopted equally. In a 2013 survey:

(1) Video conferencing, wireless technologies, and data monitoring were used by approximately 50% of healthcare organizations;
(2) Internet-based technologies, smartphone apps, interactive voice response technology, and fax were used by at least 33% of organizations;
(3) Audio conferencing, mobile broadband, and fixed-line broadband were used by 25% or more of organizations; and,
(4) Mobile diagnostics and narrowband technologies were used by less than 20% of healthcare organizations surveyed.[186]

A more recent study from early 2020 similarly found that telemedicine applications and utilization are increasing. Communication through EHR almost doubled from 2018 to early 2020 (38% to 63%).[187] Remote monitoring (6% to 13%), video visits (14% to 19%), and physician-to-physician virtual consultations (17% to 22%) all increased from 2018.[188]

Current Applications of Telemedicine

Telemedicine technology grew rapidly over the past decade as well as during the COVID-19 PHE. As of mid-2020, patient portals for scheduling appointments, communicating with clinical staff, refilling prescriptions, and reviewing test results; virtual appointments through teleconferencing or phone calls; remote monitoring through mobile applications and monitoring devices;

virtual consultations between doctors, especially between specialists and primary care physicians; personal EHRs for emergency vital information; and personal health applications for tracking caloric intake, physical activity, and other measures were all included as telemedicine services.[189] As noted above, the four main types of telemedicine currently utilized by healthcare providers include:

(1) *Store-and-Forward* or "*asynchronous*" telemedicine, where information such as medical histories, reports, or other data are sent to a specialist for diagnosis and treatment;
(2) *Remote patient monitoring*, where a patient's clinical status is evaluated continuously through video monitoring, images, or remotely reviewing tests; and,
(3) *Real-time* or "*synchronous*" telemedicine, which consists of a live conversation between the patient and provider.
(4) *Mobile health* or *mHealth*, which involves health information being provided through mobile devices through educational information, targeted text messages, and notifications about disease outbreaks.[190]

Availability and affordability has allowed telemedicine technology to grow considerably in recent years. However, internet issues are still a problem for approximately one in five adults living in rural areas and have led to lower adoption and utilization rates for telemedicine.[191] While the main advantages of telemedicine include quality, accessibility, and efficiency, some remaining concerns include potential gaps in care and continued limitations in broadband internet access and the cost of mobile devices, which may disproportionately affect rural patients who may also be some of the most at-need patients.[192]

Software and Hardware Requirements

Modern telemedicine setups include equipment and program requirements. First, a computer, tablet, or smartphone with an appropriate operating system is required.[193] Second, a camera or microphone is also necessary; this technology may be built into the computer or mobile device or may be external.[194] Software for live video conferences, store-and-forward technology, and patient data collection and monitoring which software (which may be located physically on the desktop or mobile device or in the "*cloud*") may all be needed.[195] Because of this significant software requirement, especially for uploads, downloads, and live video streaming, an internet connection with sufficient speeds is also integral.[196] Other technology that aids in telemedicine includes mobile medical devices. Currently, these options include mobile *electrocardiogram* (ECG) devices, vital signs monitors, and scopes such as stethoscopes which can capture both visual and audio information.[197] For all of these technologies that deal with sensitive patient information, data security and HIPAA compliance are of the utmost concern.

Telemedicine Technology during the COVID-19 PHE and Future Prospects

Besides greater utilization of telemedicine visits,[198] the COVID-19 PHE has brought about several changes in the development of telemedicine technology. Recent developments include an *emergency medical service* (EMS) remote monitoring and defibrillator device; wearable biomedical electronics that can be drawn onto the skin using special inked pens to monitor vitals and other measurements; an ultrasound device that connects to a smartphone; and, a wireless, smart hospital bed with numerous monitoring features.[199]

Today, in order to provide telemedicine services, a healthcare organization must have a secure broadband connection with sufficient internet speed to handle intensive technologies, a video connection and platform, technical support staff, the ability to record virtual visits and interactions, and mobile telemedicine units or similar technology that can be used during a telemedicine visit to diagnose and treat ailments.[200] Broadband connections, a lack of staff training and licensure, and the cost of purchasing, setting up, troubleshooting, and maintaining this technology may all be deterrents.[201] More research is needed to develop effective best practices, and there are still some exams and procedures that must be conducted in person.[202] Whether that remains the case as technology continues to develop remains to be seen. If past patterns continue, however, it can be expected that telemedicine technology will only become more prevalent in our everyday care outside of the physician's office and that this technology will become more capable and accessible. Until then, it is vital that nationwide technological infrastructure rise to meet the demands of this new technology so that all patients (especially those in rural, underserved areas) can have wider access to remote care and so that new gaps and barriers in access to care do not emerge as a result of healthcare becoming increasingly reliant upon internet, mobile devices, and other technology.

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1 "Telehealth" National Institutes of Health, https://www.nibib.nih.gov/science-education/science-topics/telehealth (Accessed 8/31/20).

2 *Ibid.*

3 "Removing regulatory barriers to telehealth before and after COVID-19" By Nicol Turner Lee, Jack Karsten, and Jordan Roberts, Brookings Institute, May 6, 2020, https://www.brookings.edu/research/removing-regulatory-barriers-to-telehealth-before-and-after-covid-19/ (Accessed 9/15/20), p. 4-5.

4 *Ibid*, p. 5.

5 *Ibid.*

6 "Telehealth Systems" By Oren Mechanic, Yudy Persaud, and Alexa Kimball, StatPearls, July 26, 2020, https://www.ncbi.nlm.nih.gov/books/NBK459384/ (Accessed 9/11/20).

7 "Family Physicians and Telehealth: Findings from a National Survey" By Kathleen Klink et al., Robert Graham Center, October 30, 2015, http://www.graham-center.org/content/dam/rgc/documents/publications-reports/reports/RGC%202015%20Telehealth%20Report.pdf (Accessed 9/11/20), p. 3-4.

8 "What Are the Advantages of Telehealth Nursing" AMD Global Telemedicine, October 1, 2019, http://www.amdtelemedicine.com/blog/article/telemedicine-skilled-nursing-facilities-benefits (Accessed 9/11/20); "On-demand synchronous audio video telemedicine visits are cost effective" By Garrison Nord, Kristin Rising, Roger Band, Brendan Carr, and Judd

Hollander, The American Journal of Emergency Medicine, Vol. 37, No. 5 (August 2018), p. 890; "Telemedicine and prostate cancer survivorship: a narrative review" By Nnenaya Q. Agochukwu, Ted A. Skolarus, and Daniela Wittmann, Mhealth, Vol. 4, No. 45 (October 2018), p. 1, 7-8.

9 "Telehealth 2018: Vendor Assessment and Market Outlook" Chilmark Research, https://go.chilmarkresearch.com/hubfs/Telehealth%202018%20-%20Vendor%20Assessment%20and%20Market%20Outlook.pdf (Accessed: 9/11/20), p. 15-17.

10 "Telemedicine and prostate cancer survivorship: a narrative review" By Nnenaya Q. Agochukwu, Ted A. Skolarus, and Daniela Wittmann, Mhealth, Vol. 4, No. 45 (October 2018), p. 1, 7-8.

11 "HHS Issues New Report Highlighting Dramatic Trends in Medicare Beneficiary Telehealth Utilization amid COVID-19" Department of Health and Human Services, July 28, 2020, https://www.hhs.gov/about/news/2020/07/28/hhs-issues-new-report-highlighting-dramatic-trends-in-medicare-beneficiary-telehealth-utilization-amid-covid-19.html (Accessed 9/11/20).

12 *Ibid*; "Medicare Telemedicine Health Care Provider Fact Sheet" Centers for Medicare and Medicaid, March 17, 2020, https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet (Accessed 9/15/20).

13 "Early Impact Of CMS Expansion Of Medicare Telehealth During COVID-19" By Seema Verma, HealthAffairs, July 15, 2020, https://www.healthaffairs.org/do/10.1377/hblog20200715.454789/full/ (Accessed 9/11/20).

14 "Proposed Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2021" Centers for Medicare & Medicaid Services, August 3, 2020, https://www.cms.gov/newsroom/fact-sheets/proposed-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-4 (Accessed 9/11/20).

15 *Ibid.*

16 *Ibid.*

17 *Ibid.*

18 "COVID-19: Here's What CMS Will Do With the Temporary Telemedicine Codes When the PHE Ends" By Rachel B. Goodman and Nathanial M. Lacktman, Foley & Lardner LLP, August 12, 2020, https://www.foley.com/en/insights/publications/2020/08/covid-19-cms-temporary-telehealth-codes-phe-ends (Accessed 9/11/20).

19 Department of Health and Human Services, July 28, 2020.

20 "Executive Order on Improving Rural Health and Telehealth Access" By President Donald J. Trump, The White House, August 3, 2020, https://www.whitehouse.gov/presidential-actions/executive-order-improving-rural-health-telehealth-access/ (Accessed 9/11/20).

21 "President Trump Signs Executive Order to Permanently Expand Telehealth Benefits for Medicare Recipients" By Jack O'Brien, HealthLeaders, August 4, 2020, https://www.healthleadersmedia.com/innovation/president-trump-signs-executive-order-permanently-expand-telehealth-benefits-medicare (Accessed 9/11/20).

22 "This is supposed to be telemedicine's time to shine. Why are doctors abandoning it?" By Ateev Mehrotra, David Linetsky, and Hilary Hatch, STAT News, June 25, 2020, https://www.statnews.com/2020/06/25/telemedicine-time-to-shine-doctors-abandoning-it/ (Accessed 9/11/20).

23 *Ibid.*

24 "Survey: Most patients satisfied with virtual care" By Jeff Bendix, Medical Economics, September 14, 2020, https://www.medicaleconomics.com/view/survey-most-patients-satisfied-with-virtual-care (Accessed 9/15/20).

25 *Ibid.*

26 "Telemedicine Adoption in the Age of COVID-19 and Beyond" Doctor.com, https://cdn2.hubspot.net/hubfs/3053445/Doctor_Telemedicine_Survey_Infografic.pdf (Accessed 9/11/20).

27 "Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic" By Kenneth Lam, Amy Lu, Ying Shi, and Kenneth Covinsky, Journal of the American Medical Association, August 3, 2020, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2768772 (Accessed: 9/11/20).

28 "Patient Characteristics Associated With Choosing a Telemedicine Visit vs Office Visit With the Same Primary Care Clinicians" By Mary Reed, Jie Huang, Ilana Graetz, Catherine Lee, Emilie Muelly, Chris Kennedy, and Eileen Kim, Journal of the American Medical Association, June 17, 2020, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2767244 (Accessed 9/11/20).
29 Lam, Lu, Shi, and Covinsky, August 3, 2020.
30 For the purposes of this series, the terms "telemedicine" and "telehealth" will be considered to be synonymous, with the former used exclusively for the sake of consistency.
31 See the September 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Introduction" Vol. 13, Issue 9, https://www.healthcapital.com/hcc/newsletter/09_20/HTML/TELEMEDICINE/convert_introduction_to_telemedicine_9.22.20a.php (Accessed 10/12/20).
32 "Telehealth Services" Medicare Learning Network, ICN 901705, January 2019, https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/TelehealthSrvcsfctsht.pdf (Accessed 9/23/20), p. 4.
33 "Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2019" S. 2741, 116th Cong. (10/30/2019).
34 Medicare Learning Network, ICN 901705, January 2019, p. 4-5.
35 "Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule" Federal Register, Vol. 84, No. 221 (November 15, 2019), p. 62630.
36 Authorized originating sites at the end of 2019 included: physician and practitioner offices, hospitals, critical Access Hospitals (CAHs), Rural Health Clinics, Federally Qualified Health Centers, hospital-based or CAH-based Renal Dialysis Centers (including satellites), Skilled Nursing Facilities (SNFs), Community Mental Health Centers (CMHCs), Renal Dialysis Facilities, homes of beneficiaries with End-Stage Renal Disease (ESRD) getting home dialysis, and Mobile Stroke Units; Medicare Learning Network, ICN 901705, January 2019, p. 5.
37 "2019 State of the States: Coverage & Reimbursement" By Ann Mond Johnson, Libby Baney, Tricia Beckmann, and Sarah-Lloyd Stevenson, American Telemedicine Association, July 18, 2019 (Accessed 9/14/20), p. 4.
38 At the end of 2019, these practitioners included physicians, nurse practitioners (NPs), physician assistants (PAs), nurse-midwives, clinical nurse specialists (CNSs), nurse anesthetists, clinical psychologists and social workers, and registered dietitians; Medicare Learning Network, ICN 901705, January 2019, p. 6.
39 "Covered Telehealth Services CY 2019 and CY 2020 (Updated 11/01/19) (ZIP)" available at: "CMS-1612-FC" Center for Medicare and Medicaid Services, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1612-FC (Accessed 9/23/20).
40 "Virtual reality: More insurers are embracing telehealth" By Bob Herman, Modern Healthcare, February 20, 2016, https://www.modernhealthcare.com/article/20160220/MAGAZINE/302209980/virtual-reality-more-insurers-are-embracing-telehealth (Accessed 9/14/20).
41 *Ibid*.
42 Johnson, Baney, Beckmann, and Stevenson, July 18, 2019, p. 4.
43 *Ibid*, p. 17.
44 *Ibid*, p. 19.
45 "Removing regulatory barriers to telehealth before and after COVID-19" By Nicol Turner Lee, Jack Karsten, and Jordan Roberts, Brookings Institute, May 6, 2020,

https://www.brookings.edu/research/removing-regulatory-barriers-to-telehealth-before-and-after-covid-19/ (Accessed 9/15/20), p. 6.

46 *Ibid*.

47 Johnson, Baney, Beckmann, and Stevenson, July 18, 2019, p. 6.

48 *Ibid*, p. 9.

49 *Ibid*, p. 14.

50 "Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak" The White House, March 13, 2020, https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak (Accessed 9/14/20).

51 "Trump Administration Proposes to Expand Telehealth Benefits Permanently for Medicare Beneficiaries Beyond the COVID-19 Public Health Emergency and Advances Access to Care in Rural Areas" Centers for Medicare & Medicaid Services, August 3, 2020, https://www.cms.gov/newsroom/press-releases/trump-administration-proposes-expand-telehealth-benefits-permanently-medicare-beneficiaries-beyond (Accessed 8/5/20).

52 "HHS Issues New Report Highlighting Dramatic Trends in Medicare Beneficiary Telehealth Utilization amid COVID-19" Department of Health and Human Services, July 28, 2020, https://www.hhs.gov/about/news/2020/07/28/hhs-issues-new-report-highlighting-dramatic-trends-in-medicare-beneficiary-telehealth-utilization-amid-covid-19.html (Accessed 8/6/20).

53 *Ibid*.

54 *Ibid*; "Medicare Telemedicine Health Care Provider Fact Sheet" Centers for Medicare and Medicaid Services, March 17, 2020, https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet (Accessed 9/22/20).

55 Lee, Karsten, and Roberts, May 6, 2020, p. 14.

56 "Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge" Centers for Medicare and Medicaid Services, March 30, 2020, https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient (Accessed 9/22/20).

57 "COVID-19: Coverage of Physician Telehealth Services Provided to SNF Residents" Centers for Medicare & Medicaid Services, July 31, 2020, https://www.cms.gov/files/document/2020-07-31-mlnc-se.pdf (Accessed 8/3/20).

58 *Ibid.*

59 "Telehealth can be lifesaving amid COVID-19, yet as virus rages, insurance companies look to scale back" By Jayne O'Donnell and Ken Alltucker, USA Today, July 3, 2020, https://www.usatoday.com/story/news/2020/07/03/despite-covid-19-increase-insurance-companies-pull-back-telehealth/5352297002/ (Accessed 8/6/20).

60 *Ibid*.

61 "As insurers move this week to stop waiving telehealth copays, patients may have to pay more for virtual care" By Rebecca Robbins and Erin Brodwin, STAT News, September 29, 2020, https://www.statnews.com/2020/09/29/united-healthcare-anthem-telemedicine-coverage-insurers/ (Accessed 10/13/20).

62 O'Donnell and Alltucker, July 3, 2020.

63 *Ibid*.

64 "The State of Telemedicine" By Adam Uzialko, Business.com, November 11, 2019, https://www.business.com/articles/telemedicine-software-and-medical-practices/ (Accessed 9/22/20).

65 *Ibid*.

66 "Proposed Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2021" Centers for Medicare & Medicaid Services, August 3, 2020, https://www.cms.gov/newsroom/fact-sheets/proposed-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-4 (Accessed 8/5/20).

67 *Ibid*.

68 "COVID-19: Here's What CMS Will Do With the Temporary Telemedicine Codes When the PHE Ends" By Rachel B. Goodman and Nathanial M. Lacktman, Foley & Lardner LLP, August 12, 2020, https://www.foley.com/en/insights/publications/2020/08/covid-19-cms-temporary-telemedicine-codes-phe-ends (Accessed: 8/13/20).

69 "Executive Order on Improving Rural Health and Telehealth Access" By President Donald J. Trump, The White House, August 3, 2020, https://www.whitehouse.gov/presidential-actions/executive-order-improving-rural-health-telehealth-access/ (Accessed 8/13/20).
70 Department of Health and Human Services, July 28, 2020; "Life in Rural America: Part II" National Public Radio, May 2019, https://media.npr.org/documents/2019/may/NPR-RWJF-HARVARD_Rural_Poll_Part_2.pdf (Accessed 9/15/20), p. 10.
71 "Community Health Access and Rural Transformation (CHART) Model Fact Sheet" Centers for Medicare and Medicaid Services, August 11, 2020, https://www.cms.gov/newsroom/fact-sheets/community-health-access-and-rural-transformation-chart-model-fact-sheet (Accessed 8/13/20).
72 *Ibid.*
73 For the purposes of this series, the terms "telemedicine" and "telehealth" will be considered to be synonymous, with the former used exclusively for the sake of consistency.
74 See the September 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Introduction" Vol. 13, Issue 9, https://www.healthcapital.com/hcc/newsletter/09_20/HTML/TELEMEDICINE/convert_introduction_to_telemedicine_9.22.20a.php (Accessed 10/12/20).
75 See the October 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Reimbursement" Vol. 13, Issue 10, https://www.healthcapital.com/hcc/newsletter/10_20/HTML/TELE/convert_telemedicine_reimbursement_10.26.20.php (Accessed 11/2/20).
76 "Fundamentals of the Stark Law and Anti-Kickback Statute" By Asha B. Scielzo, American Health Lawyers Association, Fundamentals of Health Law: Washington, DC, November 2014, available at: https://docplayer.net/17313708-Ahla-fundamentals-of-the-stark-law-and-anti-kickback-statute-asha-b-scielzo-pillsbury-winthrop-shaw-pittman-llp-washington-dc.html (Accessed 11/2/20), p. 4-6, 17, 19, 42.
77 *Ibid*, p. 42.
78 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).
79 *Ibid.*
80 "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 11/25/19), p. 4-5; "U.S. v. Greber" 760 F.2d 68, 69 (3d. Cir. 1985).
81 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 6402, 10606, 124 Stat. 119, 759, 1008 (March 23, 2010).
82 "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 11/2/20), p. 5.
83 *Ibid.*
84 "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).
85 "False claims" 31 U.S.C. § 3729(a)(1).
86 Demske, July 28, 2015, p. 5.
87 *Ibid.*
88 "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.
89 "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 11/2/20), p. 1.
90 "Telemedicine: A review of the fraud and abuse landscape" By Douglas Grimm and Hillary Stemple, Arent Fox, https://www.arentfox.com/sites/default/files/2019-03/Telemedicine-A-review-of-the-fraud-and-abuse-landscape.pdf (Accessed 11/21/20).

91 "HHS Makes Stark Law and Anti-Kickback Statute Reforms to Support Coordinated, Value-Based Care" Centers for Medicare & Medicaid Services, November 20, 2020, https://www.hhs.gov/about/news/2020/11/20/hhs-makes-stark-law-and-anti-kickback-statute-reforms-support-coordinated-value-based-care.html (Accessed 11/21/20).
92 "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 11/2/20); "Limitation on certain physician referrals" 42 U.S.C. § 1395nn.
93 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn(a)(1)(A).
94 "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)."
95 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn.
96 *Ibid.*
97 "Health Care Fraud and Abuse: Practical Perspectives" By Linda A. Baumann, Health Law Section of the American Bar Association, Washington, DC: BNA Books, 2002, p. 106.
98 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn; "Telemedicine: A review of the fraud and abuse landscape" By Douglas Grimm and Hillary Stemple, Arent Fox, https://www.arentfox.com/sites/default/files/2019-03/Telemedicine-A-review-of-the-fraud-and-abuse-landscape.pdf (Accessed 11/21/20).
99 42 U.S.C. § 1395nn; "Telemedicine Fraud and Abuse Under the Microscope" By Douglas Grimm and Hillary Stemple, HCCA Louisville Regional Conference, November 1, 2019, slide 8.
100 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Centers for Medicare & Medicaid Services, HHS, Final Rule, RIN 0938-AT64, available at: https://public-inspection.federalregister.gov/2020-26140.pdf (Accessed 11/21/20).
101 For more information on the history, growth, and current state of the telemedicine reimbursement environment, see the October 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Reimbursement" Vol. 13, Issue 10, https://www.healthcapital.com/hcc/newsletter/10_20/HTML/TELE/convert_telemedicine_reimbursement_10.26.20.php (Accessed 11/2/20).
102 "2019 State of the States" American Telemedicine Association, July 18, 2019, https://cdn2.hubspot.net/hubfs/5096139/Files/Thought%20Leadership_ATA/2019%20State%20of%20the%20States%20summary_final.pdf (Accessed 11/2/20).
103 "2019 State of the States: Coverage & Reimbursement" Ann Mond Johnson, Libby Baney, Tricia Beckmann, and Sarah-Lloyd Stevenson, American Telemedicine Association, July 18, 2019 (Accessed 11/2/20).
104 "Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine" Federation of State Medical Boards, 2014, https://www.fsmb.org/siteassets/advocacy/policies/fsmb_telemedicine_policy.pdf (Accessed 11/2/20), p. 5.
105 *Ibid*, p. 3-4.
106 "Telemedicine Policies: Board by Board Overview" Federation of State Medical Boards, July 2020, https://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf (Accessed 11/2/20).
107 *Ibid.*
108 An additional three states have passed the ILMC (and it is in the process of implementation) and six states have introduced Compact legislation. "The IMLC" Interstate Medical Licensure Compact, https://imlcc.org/ (Accessed 11/2/20).
109 "The IMLC" Interstate Medical Licensure Compact, https://imlcc.org/ (Accessed 11/2/20).
110 "Nurse Licensure Compact: NurseCompact.com" Nurse Licensure Compact, https://www.nursecompact.com/Updated_Legislator_FAQ.pdf (Accessed 11/2/20).

111 *Ibid.*
112 "Issue brief: Corporate practice of medicine" American Medical Association, available at: https://www.ama-assn.org/media/7661/download (Accessed 11/21/20).
113 *Ibid.*
114 *Ibid.*
115 "Corporate Practice of Medicine: The Unseen Hurdle in Telehealth" By Daniel Gottlieb, Health Law Advisor, Epstein Becker Green, February 6, 2013, https://www.healthlawadvisor.com/2013/02/06/corporate-practice-of-medicine-the-unseen-hurdle-in-telehealth/ (Accessed 11/21/20)
116 "U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19" Federation of State Medical Boards, October 30, 2020, https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf (Accessed 11/2/20).
117 "Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency" Office for Civil Rights, March 30, 2020, https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html (Accessed 11/2/20).
118 "Telemedicine: What Should the Post-Pandemic Regulatory and Payment Landscape Look Like?" By Ateev Mehrotra, Bill Wang, and Gregory Snyder, The Commonwealth Fund, August 5, 2020, https://www.commonwealthfund.org/publications/issue-briefs/2020/aug/telemedicine-post-pandemic-regulation (Accessed 11/2/20).
119 *Ibid.*
120 For more detail on the challenges of implementation of the *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*, please see the September 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Introduction" Vol. 13, Issue 9, https://www.healthcapital.com/hcc/newsletter/09_20/HTML/TELEMEDICINE/convert_introduction_to_telemedicine_9.22.20a.php (Accessed 10/12/20).
121 For the purposes of this series, the terms "telemedicine" and "telehealth" will be considered to be synonymous, with the former used exclusively for the sake of consistency.
122 See the September 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Introduction" Vol. 13, Issue 9 (September 2020), https://www.healthcapital.com/hcc/newsletter/09_20/HTML/TELEMEDICINE/convert_introduction_to_telemedicine_9.22.20a.php (Accessed 10/12/20).
123 See the October 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Reimbursement" Vol. 13, Issue 10 (October 2020), https://www.healthcapital.com/hcc/newsletter/10_20/HTML/TELE/convert_telemedicine_reimbursement_10.26.20.php (Accessed 11/2/20).
124 See the November 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Regulatory" Vol. 13, Issue 11 (November 2020), https://www.healthcapital.com/hcc/newsletter/11_20/HTML/TELE/convert_telemedicine_regulatory_11.21.20.php (Accessed 11/30/20).
125 "Family Physicians and Telehealth: Findings from a National Survey" By Kathleen Klink et al., Robert Graham Center, October 30, 2015, http://www.graham-center.org/content/dam/rgc/documents/publications-reports/reports/RGC%202015%20Telehealth%20Report.pdf (Accessed 9/11/20), p. 3-4.
126 "What Are the Advantages of Telehealth Nursing" AMD Global Telemedicine, October 1, 2019, http://www.amdtelemedicine.com/blog/article/telemedicine-skilled-nursing-facilities-benefits (Accessed 9/11/20).
127 "FH Healthcare Indicators and FH Medical Price Index 2019: An Annual View of Place of Service Trends and Medical Pricing" FAIR Health, April 2019, https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/FH%20Healthcare%20Indicators%20and%20FH%20Medical%20Price%20Index%202019%20-%20A%20FAIR%20Health%20White%20Paper.pdf, p. 25-26 (Accessed 9/15/20).
128 *Ibid.*
129 "Fact Sheet: Telehealth" American Hospital Association, February 2019, https://www.aha.org/system/files/2019-02/fact-sheet-telehealth-2-4-19.pdf (Accessed 11/30/20), p. 1.

130 "In a Competitive Market, Telehealth Can Be a Valuable Commodity" By Eric Wicklund, mHealth Intelligence, May 18, 2018, https://mhealthintelligence.com/news/in-a-competitive-market-telehealth-can-be-a-valuable-commodity (Accessed 12/2/20).
131 *Ibid.*
132 "Telehealth 2018: Vendor Assessment and Market Outlook" Chilmark Research, https://go.chilmarkresearch.com/hubfs/Telehealth%202018%20-%20Vendor%20Assessment%20and%20Market%20Outlook.pdf, p. 15-17 (Accessed: 9/11/20).
133 *Ibid.*
134 *Ibid.*
135 "Telemedicine and prostate cancer survivorship: a narrative review" By Nnenaya Q. Agochukwu, Ted A. Skolarus, and Daniela Wittmann, Mhealth, Vol. 4, No. 45 (October 2018), p. 1, 7-8.
136 "Crossing the Telemedicine Chasm: Have the U.S. Barriers to Widespread Adoption of Telemedicine Been Significantly Reduced?" By Cynthia LeRouge and Monice J. Garfield, International Journal of Environmental Research and Public Health, Vol. 10, No. 12, p. 6473, 6475-6476.
137 "Patient Characteristics Associated With Choosing a Telemedicine Visit vs Office Visit With the Same Primary Care Clinicians" By Mary Reed, Jie Huang, Ilana Graetz, Catherine Lee, Emilie Muelly, Chris Kennedy, and Eileen Kim, Journal of the American Medical Association, June 17, 2020, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2767244 (Accessed 9/11/20).
138 "On-demand synchronous audio video telemedicine visits are cost effective" By Garrison Nord, Kristin Rising, Roger Band, Brendan Carr, and Judd Hollander, The American Journal of Emergency Medicine, Vol. 37, No. 5 (August 2018), p. 890; "Telemedicine and prostate cancer survivorship: a narrative review" By Nnenaya Q. Agochukwu, Ted A. Skolarus, and Daniela Wittmann, Mhealth, Vol. 4, No. 45 (October 2018), p. 1, 7-8.
139 "Trump Administration Proposes to Expand Telehealth Benefits Permanently for Medicare Beneficiaries Beyond the COVID-19 Public Health Emergency and Advances Access to Care in Rural Areas" Centers for Medicare & Medicaid Services, August 3, 2020, https://www.cms.gov/newsroom/press-releases/trump-administration-proposes-expand-telehealth-benefits-permanently-medicare-beneficiaries-beyond (Accessed 9/11/20).
140 "HHS Issues New Report Highlighting Dramatic Trends in Medicare Beneficiary Telehealth Utilization amid COVID-19" Department of Health and Human Services, July 28, 2020, https://www.hhs.gov/about/news/2020/07/28/hhs-issues-new-report-highlighting-dramatic-trends-in-medicare-beneficiary-telehealth-utilization-amid-covid-19.html (Accessed 9/11/20).
141 *Ibid.*
142 *Ibid.*
143 For more detail on these policies, see the September 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Introduction" Vol. 13, Issue 9, https://www.healthcapital.com/hcc/newsletter/09_20/HTML/TELEMEDICINE/convert_introduction_to_telemedicine_9.22.20a.php (Accessed 10/12/20).
144 For more detail on reimbursement, see the October 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Reimbursement" Vol. 13, Issue 10, https://www.healthcapital.com/hcc/newsletter/10_20/HTML/TELE/convert_telemedicine_reimbursement_10.26.20.php (Accessed 11/2/20).
145 "Use and Content of Primary Care Office-Based vs Telemedicine Care Visits During the COVID-19 Pandemic in the US" By G. Caleb Alexander, Matthew Tajanlangit, James Heyward, Omar Mansour, Dima M. Qato, and Randall S. Stafford, JAMA Network Open, Vol. 3, No. 10 (October 2, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2771191 (Accessed 12/2/20).
146 *Ibid.*
147 "Telehealth grew wildly popular amid Covid-19. Now visits are plunging, forcing providers to recalibrate" By Casey Ross, STAT News, September 1, 2020,

https://www.statnews.com/2020/09/01/telehealth-visits-decline-covid19-hospitals/ (Accessed 11/30/20).

148 *Ibid.*

149 *Ibid.*

150 "Telemedicine Market: 2020 COVID-19 Impact Industry Analysis By Size Estimation, Growth Rate, Share, Trends, Merger, New Developments, Competitive Landscape, Regional Analysis With Global Forecast To 2026" MarketWatch, September 7, 2020, https://www.marketwatch.com/press-release/telemedicine-market-2020-covid-19-impact-industry-analysis-by-size-estimation-growth-rate-share-trends-merger-new-developments-competitive-landscape-regional-analysis-with-global-forecast-to-2026-2020-09-07 (Accessed 12/2/20).

151 *Ibid.*

152 "Will telemedicine create perfect competition?" By Adam E. Block and Michael S. Adelberg, Medical Economics, September 22, 2020, https://www.medicaleconomics.com/view/will-telemedicine-create-perfect-competition (Accessed 12/2/20).

153 *Ibid.*

154 *Ibid.*

155 "The Complexities of Physician Supply and Demand: Projections From 2018 to 2033" Association of American Medical Colleges, June 2020, p. vii

156 *Ibid.*

157 "Telehealth: Technology meets health care" Mayo Clinic, May 15, 2020, https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/telehealth/art-20044878 (Accessed 12/16/20); "Using Telehealth to Make Patient Rounding More Efficient and Effective" By Eric Wicklund, mHealth Intelligence, September 28, 2020, https://mhealthintelligence.com/news/using-telehealth-to-make-patient-rounding-more-efficient-and-effective (Accessed 12/16/20).

158 "Will There Be Competition for Doc Talent Because of Telehealth?" By John Lynn, Healthcare IT Today, August 14, 2020, https://www.healthcareittoday.com/2020/08/14/will-there-be-competition-for-doc-talent-because-of-telehealth/ (Accessed 12/16/20).

159 *Ibid.*

160 See the October 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Reimbursement" Vol. 13, Issue 10 (October 2020), https://www.healthcapital.com/hcc/newsletter/10_20/HTML/TELE/convert_telemedicine_reimbursement_10.26.20.php (Accessed 11/2/20).

161 *Ibid.*

162 *Ibid.*

163 For the purposes of this series, the terms "telemedicine" and "telehealth" will be considered to be synonymous, with the former used exclusively for the sake of consistency.

164 See the September 2020 *Health Capital Topics* article entitled, "Valuation of Telemedicine: Introduction" Vol. 13, Issue 9 (September 2020), https://www.healthcapital.com/hcc/newsletter/09_20/HTML/TELEMEDICINE/convert_introduction_to_telemedicine_9.22.20a.php (Accessed 10/12/20).

165 See the October 2020 *Health Capital Topics* article entitled, "Valuation of Telemedicine: Reimbursement" Vol. 13, Issue 10 (October 2020), https://www.healthcapital.com/hcc/newsletter/10_20/HTML/TELE/convert_telemedicine_reimbursement_10.26.20.php (Accessed 11/2/20).

166 See the November 2020 *Health Capital Topics* article entitled, "Valuation of Telemedicine: Regulatory" Vol. 13, Issue 11 (November 2020), https://www.healthcapital.com/hcc/newsletter/11_20/HTML/TELE/convert_telemedicine_regulatory_11.21.20.php (Accessed 11/30/20).

167 See the December 2020 *Health Capital Topics* article entitled, "Valuation of Telemedicine: Competition" Vol. 13, Issue 12 (December 2020), https://www.healthcapital.com/hcc/newsletter/12_20/HTML/TELE/convert_telemedicine_competition_12.17.20b.php (Accessed 12/28/20).

168 "Crossing the Telemedicine Chasm: Have the U.S. Barriers to Widespread Adoption of Telemedicine Been Significantly Reduced?" By Cynthia LeRouge and Monice J. Garfield,

International Journal of Environmental Research and Public Health, Vol. 10, No. 12, p. 6473.

169 *Ibid*, p. 6473-6474.

170 *Ibid*, p. 6473; see the September 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Introduction" Vol. 13, Issue 9; see the October 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Reimbursement" Vol. 13, Issue 10; see the November 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Regulatory" Vol. 13, Issue 11.

171 LeRouge and Garfield, p. 6473-6476.

172 *Ibid*, p. 6474.

173 See the September 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Introduction" Vol. 13, Issue 9.

174 "Connecting America: The National Broadband Plan" Federal Communications Commission, https://transition.fcc.gov/national-broadband-plan/national-broadband-plan.pdf (Accessed 12/16/20) p. xi.

175 *Ibid*, p. 201.

176 *Ibid*; "Hosted Vs. Cloud-based EMR Systems: What's the Difference?" PracticePerfect, March 15, 2019, https://practiceperfectemr.com/blog/hosted-vs-cloud-based-emr-systems-whats-the-difference/ (Accessed 12/28/20).

177 PracticePerfect, March 15, 2019.

178 Federal Communications Commission, p. 201.

179 *Ibid*.

180 "Innovation in telemedicine technology: An entrepreneur's perspective" By Yulun Wang, Healthcare IT News, May 6, 2013, https://www.healthcareitnews.com/news/innovation-telemedicine-technology-entrepreneurs-perspective (Accessed 12/16/20).

181 "FCC Authorizes Over $61.8 Million In Funding For Rural Broadband" Federal Communications Commission, October 10, 2019, https://docs.fcc.gov/public/attachments/DOC-360165A1.pdf (Accessed 12/28/20).

182 *Ibid.*

183 "Keeping Rural Communities Connected while Socially Distanced" American Farm Bureau Federation, August 10, 2020, https://www.fb.org/market-intel/keeping-rural-communities-connected-while-socially-distanced (Accessed 12/28/20).

184 Federal Communications Commission, p. 201-202; LeRouge and Garfield, Vol. 10, No. 12, p. 6476.

185 "Telemedicine, Telehealth, and Health Information Technology" The American Telemedicine Association, May 2006, https://www.who.int/goe/policies/countries/usa_support_tele.pdf?ua=1 (Accessed 12/16/20), p. 3.

186 "12 Technologies Used in Telehealth Programs" Becker's Health IT, August 15, 2013, https://www.beckershospitalreview.com/healthcare-information-technology/12-technologies-used-in-telehealth-programs.html (Accessed 12/16/20).

187 "How the virtual health landscape is shifting in a rapidly changing world" By Ken Abrams, Urvi Shah, Casey Korba, and Natasha Elsner, Deloitte Insights, July 9, 2020, https://www2.deloitte.com/us/en/insights/industry/health-care/physician-survey.html (Accessed: 12/28/20).

188 *Ibid*.

189 "Telehealth: Technology meets health care" Mayo Clinic, May 15, 2020, https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/telehealth/art-20044878 (Accessed 12/16/20).

190 "Telehealth Systems" By Oren Mechanic, Yudy Persaud, and Alexa Kimball, StatPearls, July 26, 2020, https://www.ncbi.nlm.nih.gov/books/NBK459384/ (Accessed 9/11/20); "Telemedicine and Telehealth" HealthIT.gov, September 24, 2020, https://www.healthit.gov/topic/health-it-health-care-settings/telemedicine-and-telehealth (Accessed 12/16/20).

191 "HHS Issues New Report Highlighting Dramatic Trends in Medicare Beneficiary Telehealth Utilization amid COVID-19" Department of Health and Human Services, July 28, 2020, https://www.hhs.gov/about/news/2020/07/28/hhs-issues-new-report-highlighting-dramatic-trends-in-medicare-beneficiary-telehealth-utilization-amid-covid-19.html

(Accessed 8/6/20); "Life in Rural America: Part II" National Public Radio, May 2019, https://media.npr.org/documents/2019/may/NPR-RWJF-HARVARD_Rural_Poll_Part_2.pdf (Accessed 9/15/20), p. 10.

192 Mayo Clinic, May 15, 2020.

193 "What are the basic technical requirements for telehealth?" By Teresa Iafolla, eVisit, May 12, 2016, https://blog.evisit.com/virtual-care-blog/what-are-the-basic-technical-requirements-for-telehealth (Accessed 12/28/20).

194 *Ibid*.

195 "Telemedicine Devices, Equipment, Technologies & Products" eVisit, https://evisit.com/resources/telemedicine-telehealth-equipment/ (Accessed: 12/28/20).

196 "Technology Requirements in Telemedicine" American Academy of Allergy, Asthma & Immunology, https://www.aaaai.org/practice-resources/running-your-practice/practice-management-resources/Telemedicine/technology (Accessed 12/16/20); Iafolla, May 12, 2016.

197 "Telemedicine Devices, Equipment, Technologies & Products" eVisit, (Accessed: 12/28/20).

198 "Trump Administration Proposes to Expand Telehealth Benefits Permanently for Medicare Beneficiaries Beyond the COVID-19 Public Health Emergency and Advances Access to Care in Rural Areas" Centers for Medicare & Medicaid Services, August 3, 2020, https://www.cms.gov/newsroom/press-releases/trump-administration-proposes-expand-telehealth-benefits-permanently-medicare-beneficiaries-beyond (Accessed 9/11/20); Department of Health and Human Services, July 28, 2020.

199 "Philips Wins FDA Clearance and Launches EMS Remote Monitoring and Defibrillation Solution in U.S." By Michael Batista, Medgadget, July 30, 2020, https://www.medgadget.com/2020/07/philips-wins-fda-clearance-and-launches-ems-remote-monitoring-and-defibrillator-solution-in-u-s.html (Accessed 12/16/20); "Drawing Biomedical Electronics Directly Onto Skin" Medgadget, July 30, 2020, https://www.medgadget.com/2020/07/drawing-biomedical-electronics-directly-onto-skin.html (Accessed 12/16/20); "PulseNmore At-Home Tele-Ultrasound for Pregnant Women" Medgadget, August 10, 2020, https://www.medgadget.com/2020/08/pulsenmore-at-home-tele-ultrasound-for-pregnant-women.html (Accessed 12/16/20); "Stryker Unveils Wireless Hospital Bed with Smart Monitoring Features" Medgadget, October 22, 2020, https://www.medgadget.com/2020/10/stryker-unveils-wireless-hospital-bed-with-smart-monitoring-features.html (Accessed 12/16/20).

200 American Academy of Allergy, Asthma & Immunology, (Accessed 12/16/20).

201 "Telemedicine during COVID-19: Benefits, limitations, burdens, adaptation" By Bill Siwicki, Healthcare IT News, March 19, 2020, https://www.healthcareitnews.com/news/telemedicine-during-covid-19-benefits-limitations-burdens-adaptation (Accessed 12/16/20); "What Are the Limits of Telehealth?" By Lisa Esposito, U.S. News, May 13, 2020, https://health.usnews.com/conditions/articles/what-are-the-limits-of-telehealth (Accessed 12/16/20); American Academy of Allergy, Asthma & Immunology, (Accessed 12/16/20).

202 Esposito, May 13, 2020.

Valuation of ASCs and OBLs: Distinctions

[This is the first article in a four-part series regarding Valuation of ASCs and OBLs. This installment was published in February 2021.]

Introduction

Until approximately 40 years ago, virtually all surgeries were performed in hospitals.[1] Since the 1970s, however, the outpatient services industry has grown at a steady pace, precipitated in part by the *American Medical Association's* (AMA's) 1971 adoption of a resolution endorsing the concept of outpatient surgery under general and local anesthesia for selected procedures and patients.[2]

This resulting shift to outpatient care has resulted in the advent of a growing number of diverse outpatient office-based facilities tailored to meet the accelerated growth in demand for healthcare services, leading to the establishment of, among other enterprises, ambulatory surgery centers (ASCs), and, more recently, office-based laboratories (OBLs). Currently, there are nearly 6,000 ASCs[3] and nearly 700 OBLs[4] in the U.S.

At the same time, this rapid increase has resulted in increased regulatory scrutiny of the formation, ownership, alignment, and transactions related to these outpatient entities. Consequently, it is important for those involved in any prospective transaction (or formation) to understand the differences between these two types of outpatient facilities, and the implications thereof.

This article is the first in a four-part series and will focus on the characteristics of and general trends related to ASCs and OBLs.

Defining ASCs

ASCs are distinct, Medicare-certified outpatient healthcare facilities that provide services to patients who do not require inpatient hospital admission and a stay lasting more than 24 hours.[5] ASCs may be classified as *single specialty* or *multi-specialty*, and may be owned by hospitals, physicians, or other healthcare enterprises. These enterprises are reimbursed by Medicare under their own separate prospective payment system.[6]

Since their inception more than four decades ago, ASCs have played an increasingly crucial role in the medical community.[7] Physicians are attracted to ASCs due to the ability to set and maintain their own schedule, customize their surgical environments, and use specialized staff, which minimizes turnaround time and maximizes the number of procedures that can be efficiently and conveniently performed.[8] In short, physicians typically find greater professional autonomy over their work environment and the quality of care provided in ASCs.[9]

As noted above, ASCs have increased in number over recent years, due in part to the potential for higher quality of care and greater efficiencies provided at these facilities, derived from technological and surgical procedure innovations.[10] In particular, improved anesthesia and utilization of safe,

minimally invasive techniques has driven this migration toward ASCs.[11] Patients report preference for ASCs due to their lower copays, convenient locations, short wait times, and ease of scheduling.[12] This growth, however, has slowed in recent years. From 2000 to 2006, the number of ASCs grew from about 3,000 to nearly 4,700, over a 50% increase.[13] By contrast, there was only about a 20% growth in the number of ASCs between 2006 and 2018.[14] The ASC industry was estimated to produce $29.5 billion in revenue in 2020, including $5.8 billion in profits.[15] In 2020, the global ASC market was valued at $84.4 billion, with nearly half of the ASC market share in North America.[16] From 2019 to 2029, this industry is expected to grow at a *compound annual growth rate* (CAGR) of approximately 6%.[17]

Concentration in the ASC industry is low, with the four largest ASCs expected to generate less than 15% of total revenue.[18] However, experts expect industry consolidation to increase over the next five years as the number of partnerships, including those with hospitals, and ASC acquisitions continue to rise.[19] Most hospitals, in fact, now provide outpatient services (96% as of 2019) and outpatient surgery (93% as of 2019).[20] The prevalence of these outpatient procedures provided by hospitals has increased over the past ten years, with outpatient surgery seeing especially high surges.[21]

Defining OBLs

OBLs, also known as office-based endovascular centers, access centers, or office interventional suites, are physician offices wherein a number of services are offered. Similar to ASCs, OBLs can be *single specialty* or *multi-specialty* and can have a number of ownership structures. However, unlike ASCs, OBL procedures (because they are located in a physician office) are reimbursed under the Medicare Physician Fee Schedule.[22]

OBLs are typically operated and utilized by vascular surgeons, interventional radiologists, cardiologists, or other specialists, and services provided include: cardiovascular, endovascular, venous, and non-vascular services; cardiac procedures, such as diagnostic coronary angiograms, coronary stenting, electrophysiology services; device implants, including pacemakers, defibrillators, loop recorders, and biventricular pacers; lower extremity endovascular revascularizations, such as chronic total occlusion and complex limb salvage procedures; renal and mesenteric revascularizations; and, subclavian stenting.[23] Of these procedures, peripheral vascular intervention, cardiac services, and interventional radiology made up the majority of the OBL market share in 2019.[24]

While slower to materialize than ASCs, OBLs have increased rapidly over the past few years, for reasons similar to ASCs, e.g., opportunities for physician ownership, the "*expedient patient experience*"[25] and "*favorable outpatient procedural reimbursement*."[26]

In 2020, the global OBL market was valued at $9 billion.[27] Similar to ASCs, an increasing focus on outpatient procedures (due to their cost-saving potential)

will also likely lead to an increase in OBLs. From 2020 to 2027, this industry is expected to grow by a CAGR of approximately 7%.[28]

Conclusion

The number of healthcare services provided at ASCs and OBLs continues to increase due in part to the rapidly evolving technological advances that allow many services and procedures to be performed in a safe, high quality, and, often, less costly environment than at many inpatient providers. The healthcare industry's increasing emphasis on value-based reimbursement (VBR) will likely only lead to greater investment and growth in these two industries in the future.

The next three parts of this series will focus on various issues related to the valuation of ASCs and OBLs. The second installment discuss the regulatory environment in which these enterprises operate, while the third and fourth installments will focus on the value drivers for ASCs and OBLs, respectively.

Valuation of ASCs and OBLs: Regulatory Environment

[This is the second article in a four-part series regarding Valuation of ASCs and OBLs. This installment was published in March 2021.]

Introduction

This article is the second installment in a four-part series on valuation considerations for *ambulatory surgery centers* (ASCs) and *office-based laboratories* (OBLs), and the differences between these outpatient facilities. The first article in this series introduced the ASC and OBL industry, including reimbursement distinctions and the reasons behind the rapid growth of both enterprises over the past few decades.

At the same time that ASCs and OBLs were growing in both supply and in demand, increased regulatory scrutiny of the formation, ownership, alignment, and transactions related to these outpatient entities also grew. Consequently, it is important for those involved in any prospective transaction (or formation) to understand the regulatory environments in which both of these types of facilities operate, including a specific focus on the provisions of the Stark Law and *Anti-Kickback Statue* (AKS).

It should be noted that, in some cases, outpatient facilities are operated as a hybrid, wherein the facility is utilized for ASC procedures on some days, and for OBL procedures on other days. In these situations, the (more stringent) regulations related to ASCs would apply.

Stark Law

The Stark Law governs those physicians (or their immediate family members) who have a financial relationship (i.e., an ownership/investment interest or a

compensation arrangement) with an entity, and prohibits those individuals from making Medicare referrals to those entities for the furnishing of *designated health services* (DHS).[29] DHS encompasses the following items and services:

(1) Clinical laboratory services;
(2) Physical therapy services;
(3) Occupational therapy services;
(4) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;
(5) Radiation therapy services and supplies;
(6) Durable medical equipment and supplies;
(7) Parenteral and enteral nutrients, equipment, and supplies;
(8) Prosthetics, orthotics, and prosthetic devices and supplies;
(9) Home health services;
(10) Outpatient prescription drugs;
(11) Inpatient and outpatient hospital services; and,
(12) Outpatient speech-language pathology services.[30]

OBLs and ASCs are generally not subject to Stark Law restrictions because they typically do not furnish DHS. However, in the event that the ASC/OBL is performing DHS (e.g., radiology services), *and* that DHS is not reimbursed by Medicare as part of a composite rate,[31] then any financial relationship between the physicians and the hospital, and their connection to the ASC/OBL, may be subject to Stark, the application of which regulations (and any appropriate exceptions) would be determined by the structure of the financial relationship between the parties (e.g., direct/indirect, compensation/ownership investment).

AKS

The AKS makes it a felony for any person to "*knowingly and willfully*" solicit or receive, or to offer or pay, any "*remuneration*," directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[32] Of note, interpretation and application of the AKS under case law has created precedent for a regulatory hurdle known as the *one purpose* test, under which test healthcare providers violate the AKS if even *one purpose* of the arrangement in question is to offer remuneration deemed illegal under the AKS.[33]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[34] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to the U.S. Department of Health & Human Services (HHS) to protect certain business arrangements by means of promulgating several *safe harbors*,[35] which set forth regulatory criteria that, if met, shield an arrangement from regulatory liability, and are meant to protect transactional arrangements unlikely to result in fraud or abuse.[36] Failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[37]

Under the AKS, ASCs and OBLs are treated differently. Specifically, ASCs must meet specific AKS *safe harbor* provisions, so that any

ownership/investment interest in an ASC is not considered remuneration. For example, the operating and recovery room space must be exclusively dedicated to the ASC, all patients referred to the entity by an investor must be fully informed of the investor's ownership interest, and all of the following applicable standards must be met within one of the categories set forth in the table below.

Additionally, the below safe harbors are only available to those ASCs that meet the following statutory definition:

"*any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with [the Centers for Medicare & Medicaid Services] CMS to participate in Medicare as an ASC…*"[38]

Because no federal licensing is required to operate an OBL,[39] they would not be considered an ASC under the AKS (as defined above). Consequently, the specific facts and circumstances related to a given transaction, such as the structure of the hospital-physician joint venture and the various financial relationships included (e.g., OBL space rental, information technology), will guide the applicability of AKS, and its associated safe harbors.

Conclusion

The continued increase in the number of healthcare services provided at ASCs and OBLs may be inhibited by the complex healthcare regulatory scheme that governs the formation, ownership, alignment, and transactions related to these outpatient entities. Consequently, these entities must take care not to enter into transactions and arrangements that may subsequently be found to be legally impermissible, so as not to become subject to substantial penalties. In fact, while the majority of hospital ASCs are operated as physician joint ventures, only about one-third in 2020 allowed their employed physicians to invest in those ASCs.[40] This portion was the lowest seen in several years and is likely related to hospitals' desire to avoid risk.[41]

This complex regulatory scheme presents an opportunity for valuation professionals to work with healthcare providers considering a potential transaction, as well as healthcare legal counsel, to ensure that prospective transactions and arrangements are in compliance with current laws, as well as satisfy applicable regulatory thresholds. Evidence shows that hospitals will continue to invest in ASCs,[42] and they and other providers may feel more comfortable with also obtaining a certified opinion prepared in compliance with professional standards by an independent credential valuation professional (under the advice of legal counsel) and supported by adequate documentation as to whether each of the proposed elements of the transaction are both at *Fair Market Value* and *commercially reasonable*, so as to establish a risk adverse, defensible position that the transactional arrangement can withstand regulatory scrutiny.

Table: ASC Exceptions to the AKS[43]

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

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

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

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

Valuation of ASCs and OBLs: ASC Value Drivers

[This is the third article in a four-part series regarding Valuation of ASCs and OBLs. This installment was published in April 2021.]

Introduction

As discussed in the first and second installments of this four-part series, the shift to outpatient care in the healthcare industry has resulted in the advent of a growing number of diverse outpatient office-based facilities tailored to meet the accelerated growth in demand for healthcare services, leading to the

establishment of, among other enterprises, *ambulatory surgery centers* (ASCs) and, more recently, *office-based laboratories* (OBLs).

Part 1 introduced and defined ASCs and OBLs, while Part 2 detailed the regulatory environment in which both of these outpatient facilities operate. This third installment will discuss valuation considerations (i.e., value drivers and investment risk factors) for ASCs, while the fourth installment will discuss the value considerations specific to OBLs. While the value drivers of ASCs are similar to those of other healthcare outpatient enterprises, there are several specific dynamics related to ASCs that should be taken into consideration during the appraisal process.

Scope of Services

The scope of services provided by a particular freestanding outpatient enterprise is a key element impacting the overall indication of value attributed to that enterprise. For example, multi-specialty ASCs allow for diversification of risks if one specialty receives a reduction in reimbursement.[44] Additionally, simply offering more than one specialty may create more volume and revenue for all of the providers involved.[45]

Advancements in technology and clinical practice have expanded the provision of surgical procedures in ambulatory settings.[46] The specialization of ASCs that billed Medicare in 2019 are shown below in Table 1.

Table 1: ASC Specializations, 2019[47]

	Type of ASC	Number of ASCs	Share of All ASCs
1	**Single Specialty**	3,356	65%
2	Gastroenterology	1,082	21%
3	Ophthalmology	1,057	21%
4	Pain management	619	12%
5	Dermatology	209	4%
6	Urology	134	3%
7	Cardiology	88	2%
8	Podiatry	83	2%
9	Orthopedics/Musculoskeletal	32	1%
10	Respiratory	26	1%
11	OB/GYN	13	<1%
12	Neurology	6	<1%
13	Other	7	<1%
14	**Multispecialty**	1,787	35%
15	**Total**	5,143	100%

Capacity

Capacity is another key element that impacts the value attributable to ASCs. One measure of capacity for ASCs is the amount of physical space utilized in the provision of services. For example, the number of operating rooms (ORs) available, as well as average turnover rate, can be used as measures of ASC capacity. These metrics can be compared to normative industry benchmark survey data related to comparable enterprises and ASCs.

Revenue Stream

ASCs have a low to moderate level of revenue volatility.[48] This is due in large part to the indispensable nature of medical procedures, wherein demand for surgeries is not subject to revenue fluctuation based on economic climate.[49] Moreover, as healthcare costs continue to rise, many insurers and patients will view ASCs as a cost-effective, yet high-quality, option.[50] As a result of these factors, it is reasonable to assume that the ASC industry will exhibit a slight uptick in revenue over the next five years, driven in large part by demand from the rapidly growing elderly population.[51] However, an increase in demand is likely to lead to increased revenue volatility.[52]

Since 2010, ASC growth has slowed, due in large part to revenue issues such as the proliferation of high-deductible health plans.[53] The cost-shifting mechanism has contributed to patients behaving far more cost-consciously with regards to their healthcare purchases. However, because patients are taking an increasingly active role in their healthcare, ASCs may benefit from offering a more economical (yet high-quality) option to patients, as ASCs have long led the way in cost-effective, quality care.

Additional considerations may include the implementation of a bundled payment system, which currently exists under the Ambulatory Surgical Center Fee Schedule (ASCFS), whereby the integral services and items utilized within the primary service being provided are reimbursed via a single payment. Bundled payments may be implemented through the various measures of productivity; for example, the Outpatient Prospective Payment System (OPPS) bundles items and services within a single Ambulatory Payment Classification (APC).[54] On the surface, bundled payments may seem to depress revenue for ASCs, but the payment model may actually benefit ASCs the most in the increasingly competitive value-based environment.[55] ASCs are well positioned to participate in bundled payment models because they provide similar procedures as hospitals at a lower cost, while also tracking expenses more easily than hospitals.[56] Further, bundled payments encourage patients to choose ASCs for surgeries and encourage payors to move patients to ASCs, thereby potentially increasing an ASC's volume.[57] Bundled payments can also ensure that ASCs are paid faster and can encourage even greater price transparency.[58]

Other considerations regarding reimbursement yield that are likely to impact the revenue streams of ASCs include:

(1) Quality reporting programs;
(2) Method and frequency of payment rate updates;

(3) Stability of payment rates – for example, reductions in reimbursement to curb utilization and spending are applied more often to certain billing codes;
(4) Referring physician utilization trends – such as increased scrutiny of physician referrals under fraud and abuse laws may impact patient volumes; and,
(5) Dependence on payor mix.

For ASCs, where reimbursement yield for certain services (e.g., surgical procedures) is subject to continuously changing payment rates, the projection of revenue streams by individual modality, instead of for the enterprise as a whole, may be more appropriate.

While payors have driven their beneficiaries to greater ASC utilization because of the potential cost savings,[59] a wide Medicare reimbursement gap still exists between ASCs and *hospital outpatient departments* (HOPDs), which gap ASCs have been fighting to reduce over the past years.[60] Although the *Centers for Medicare and Medicaid Services* (CMS) cut reimbursement rates for many physician specialties beginning in 2021,[61] ASCs were able to avoid some of the COVID-19 elective surgery restrictions that targeted only inpatient settings and, subsequently, some of the huge losses in revenue experienced by hospitals nationwide.[62]

Payor Mix

The typical payor mix for ASCs in 2019 (by percent of total revenue) is set forth in Table 2.

Table 2: Typical ASC Payor Mix[63]

	Payor	% of Total Revenue
1	Commercial	40.3%
2	Government (Medicare, Medicaid, Worker's Compensation, etc.)	33.4%
3	Other	17.5%
4	Out-of-Pocket Payments	8.8%

The reimbursement yield of a given ASC is significantly impacted by whether the particular facility bills on an in-network or out-of-network (OON) basis for a particular insurance plan. Under certain insurance coverage plans, patients are given financial incentives – e.g., lower deductibles and co-insurance payments – to see providers that are considered to be "in-network," referring to a contractual relationship entered into by the provider with the payor to offer services at a discounted rate.[64] In an effort to mitigate higher reimbursement rates for OON services, certain payors have instituted internal fee schedules that cap the allowable charge that these payors will reimburse providers for OON services.[65]

Further, many states (as well as the federal government) recently have passed, or have been attempting to pass, bills on the ability of providers to "balance bill" and have set forth caps on the pay for OON care at a regional insurer's typical negotiated rate.[66] At the end of 2020, Congress passed the *No Surprises Act*, which contains consumer protections against surprise billing, including: requiring that health plans cover surprise bills at in-network rates, prohibiting balance billing, banning OON providers from sending patients bills for excess charges, and giving states and the federal government more enforcement powers, among other provisions.[67] These attempts to cap OON charges may result in a decreased reimbursement yield for those ASCs that rely on an OON strategy.

Operating Expenses

ASCs generally have a much higher share of expenses for medical supplies and drugs than hospitals and physician practices.[68] Similar to other industries in the healthcare sector, wages represent one of the largest expenses,[69] although they comprise a much smaller share of expenses than an average hospital.[70] Rent and capital costs also comprise a smaller share of ASCs' expenses than those costs would be for a physician office.[71]

Additional considerations regarding the operating expenses incurred by an ASC include:

(1) The size of the facility; e.g., the number of operating rooms and the number of cases;
(2) The ability of the ASC to manage supply costs;
(3) Whether the management of an ASC is performed by a third party; and,
(4) Whether the ASC employs a medical director.

In addition to the types of operating expenses incurred by an ASC, the amount of *fixed* and *variable* expense should be considered when performing an appraisal, as each type of expense is projected differently.

Capital Structure

ASCs incur significant expenditures for depreciable assets, including highly advanced surgical tools and equipment.[72] Various regulations require ASCs to keep electronic records, have tools for disposal, and comply with costly building regulations.[73] As a result of these factors, access to capital is a significant concern for ASC operators. Due to anticipated rapid advancements in medical technology, ASC operators will likely need to continue to invest in advanced medical technology to keep long-term costs down and to compete with other ASCs and hospitals.[74] Overall, capital investments have cancelled out wage growth in the ASC industry.[75]

The implications of the capital structure decision for freestanding outpatient enterprises, including ASCs, are similar to those of physician professional practices:

(1) The mix of debt and equity financing affects the risk-adjusted required rate of return for investment in the subject enterprise.
(2) Debt financing is typically cheaper than equity financing.
(3) Financing costs reflect the risks associated with each type of capital provided. For example:
    (a) Debt financing typically considers the four C's of the obligor: **c**redit risk (default risk) of the borrower, **c**apacity of the borrower to make timely repayments of both principal and interest (short term liquidity and interest coverage), **c**ollateral to cover the lender in case of borrower default, and an analysis of the **c**ovenants included in the indenture agreement.[76]
    (b) Equity financing considers the risks associated with an investment in the residual ownership interest (subordinate to any debt holders) of the subject enterprise.

Note that the amount of debt utilized by a specific freestanding outpatient enterprise will likely be impacted by: (1) the age of equipment and other technology utilized by the enterprise; and, (2) the enterprise's dependence on technology; for example, an ASC will have higher capital needs related to obtaining and maintaining surgical equipment.

Data and information pertaining to the most probable capital structure of an ASC can be derived from normative industry benchmark survey data, as well as comparable publicly traded company data, for those ASCs that have comparable publicly-traded companies. Additionally, the capital structure can be determined through techniques such as the iterative method. For the purpose of establishing the fair market value of an ASC, it is important to utilize formulas based on market values of equity and debt, rather than book values.[77]

Overall, it appears that ASCs currently have adequate access to capital because the number of ASCs has continued to increase (change in the number of ASCs is the best available indicator of their ability to obtain capital[78]), and hospital systems and other providers have significantly incorporated ASCs into their business strategies.[79] Further, the industry's continued growth indicates that capital is not difficult to obtain for such ventures.[80]

The successful and profitable business model of ASCs has attracted significant capital investment from investors, including hospitals, other physicians, and non-healthcare industry parties, e.g., venture capital and private equity.[81] Interest from these parties stem largely from the ongoing shift of services from the inpatient to outpatient setting and the potential profitability of ASCs.[82] Capital investment in the industry is expected to remain stable in the future even as industry profit, measured as earnings before interest and taxes, is expected to decrease slightly in the future from its current place at 19.7% due to pressured reimbursement rates.[83]

Suppliers

Suppliers in healthcare can include pharmaceutical companies and medical instrument companies.[84] In general, enterprises such as ASCs achieve a significant amount of their bargaining power from their size, as larger enterprises, with greater patient populations, represent a larger portion of business for vendors, and therefore, have more negotiating power than smaller enterprises. In addition, those larger ASCs that are able to reap the benefits of this increased market leverage may be able to lower operating costs by negotiating lower supply prices, thereby improving profit margins, which may increase the indication of value of the enterprise.

Subject Entity Specific/Non-Systematic Risk

While investors in a particular ASC would have additional investment opportunities available to them—e.g., government bonds, equity indexes—the discount rate utilized to present-value all the expected future net economic benefits should consider these opportunity costs as well as any idiosyncratic risk associated with an investment in the specific subject enterprise. This subject-entity-specific/non-systematic (idiosyncratic) risk for freestanding outpatient enterprises such as ASCs would include the various risk factors that are inherent and specific to the enterprise being valued, as well as the enterprise's operational performance compared to the most probable performance of similar enterprises as reported in normative industry benchmark survey data. Subject-entity-specific/non-systematic risk factors for most ASCs include, but are not necessarily limited to, the following:

(1) The uncertainty related to the continuity of the projected revenue stream based on the probability of achieving the projected productivity volume and the efficacy of the projected reimbursement yield utilized in the analysis;
(2) The risk related to the probability of achieving industry-indicated operational and financial benchmarks utilized in the analysis;
(3) The competitive marketplace within which the ASC operates; and,
(4) The historical operations of the ASC in comparison to the industry benchmarks.

Examples of subject-entity-specific/non-systematic risk considerations related to the valuation of an ASC include, but are not necessarily limited to:

(1) The diversity of specialties and services offered at the enterprise being valued;
(2) The percentage of OON patient volumes;
(3) Capital needs related to the facility and equipment;
(4) Operating performance;
(5) The stability and relative size of current and future reimbursement revenues; and,
(6) Relationships with independent surgeons/referring physicians in the market service area of the subject enterprise.

Conclusion

ASCs are performing an increasingly wider array of complex procedures and ancillary services, which present important revenue opportunities for industry operators. Changes in federal requirements with respect to reimbursement and site(s) of service for specific offerings can prove detrimental to operators focused on these segments. Talent and specialized physicians are required and largely determine the amount of payor and consumer demand for the provision of these services in the outpatient setting.

Revenue for ASCs is likely to be driven by cost-conscious patients seeking to have procedures performed at a lower cost.[85] Health systems have continued to invest in ASCs because of these low costs, despite lower reimbursement rates, and the potential to free up inpatient capacity for other patients.[86] ASCs will likely continue to form joint ventures with hospitals and other healthcare systems to retain high-quality physicians and ensure the capacity required to meet high patient volumes.[87] ASCs have also received high scores in patient and physician satisfaction that will only add to their viability.[88] As more insurers prefer the use of outpatient settings for procedures, ASCs will likely see sustained growth and valuation prospects going forward, but profitability, by contrast, is expected to fall over the next several years.[89] Nevertheless, the portion of providers planning on increasing their investment in ASCs rose from 44% in 2019 to 67% in 2020, a clear sign of continued interest and commitment.[90]

Valuation of ASCs and OBLs: OBL Value Drivers

[This is the final article in a four-part series regarding Valuation of ASCs and OBLs. This installment was published in May 2021.]

Introduction

This article is the fourth and final installment of the four-part series discussion valuation considerations and distinctions between ambulatory surgery centers (ASCs) and office-based laboratories (OBLs). Part three of this series covered value driver considerations related to ASCs, and this article will cover those considerations for OBLs. While the value drivers identified for OBLs are similar to those of ASCs, there are specific dynamics related to OBLs that should be taken into consideration during the appraisal process.

Scope of Services and Capacity

Almost all outpatient endovascular cases may be performed in the office-based intervention lab setting. Services provided in OBLs include: cardiovascular, endovascular, venous, and non-vascular services; cardiac procedures, such as diagnostic coronary angiograms, coronary stenting, and electrophysiology services; device implants, including pacemakers, defibrillators, loop recorders,

and biventricular pacers; lower extremity endovascular revascularizations, such as chronic total occlusion and complex limb salvage procedures; renal and mesenteric revascularizations; and subclavian stenting.[91]

Conversion from the hospital and ASC setting to the office-based setting may require a transition period, from both a clinical and logistical capacity. Other considerations include payor requirements and contractual/legal requirements (such as licensing and accreditation requirements, as well as noncompete agreements). Determination of the service mix of procedures offered in each OBL requires consideration of the volume required to make the service offering safe and profitable.

Revenue Stream

The primary drivers of the movement of these performed services from a hospital setting to an outpatient office setting include more convenient locations, shorter appointment wait times, better outcomes for patients, greater control of technology and staffing, improved reimbursement for physician owners, and cost savings for payors (quite possibly in reverse order of influence). Historically, physicians performing these procedures in a hospital setting only received the professional component; i.e., the "facility" fee rate under the Medicare Physician Fee Schedule (MPFS).[92] Medicare and many private insurance payors reimburse for procedures performed in the OBL setting at the "non-facility" or "global" fee rate; consequently, the physician practice payment includes both professional and technical components.[93]

As noted above, the MPFS differentiates between two distinct revenue streams for medical services; i.e., a professional services component and an ancillary services and technical component (ASTC). Within the professional services component, procedures may have different rates depending on whether they were provided in a facility or non-facility setting, as determined by the place of service.[94] The "non-facility" fee is typically much higher than the facility fee, from two times the facility fee.[95] Since the physician practice incurs all the expenses from the procedures performed in the physician office, the higher fee is to reimburse the physicians for the technical component of the service provided by the physician office, such as supplies, staff costs, equipment, and other office overhead expenses.[96]

Payor Mix

As in most vascular practices, the patients of OBLs are mostly Medicare beneficiaries. This payor mix has the same impact on OBLs as it may have on ASCs. While many commercial insurance plans may reimburse OBLs at a higher non-facility rate, there are still some major commercial insurance payors as well as some health maintenance organizations (HMOs) and local independent practice associations that do not.

Operating Expenses

For OBLs, like ASCs, supplies—such as catheters, balloons, guidewires, stents, laser fibers, pharmaceuticals, and disposables—are a significant expense in performing procedures. The cost of supplies depends greatly on an OBL's case mix. It is very easy to tie up a substantial amount of capital resources in supply inventory for endovascular procedures because so many different devices are used. Therefore, an OBL's inventory management and pricing can have a significant impact on the bottom line.

Staff costs also comprise a significant portion of an OBL's operating cost. Staffing at an OBL typically includes registered nurses, scrub technicians, radiology technicians, medical assistants, and administrative/clerical personnel. The experience and training of the staff to the unique requirements of an OBL, as compared to a hospital setting, has a substantial impact on its operations. Compliance with governmental regulations and accrediting organizations, such as the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), and The Joint Commission, as well as proper billing and coding to ensure prompt payment, are also imperative to the success of an OBL.

Capital Structure

The startup of an OBL may require significant office build-out and equipment purchases. Capitalization, for the purposes of this discussion, is the acquisition of assets for the operation of the OBL. Capitalization needs for a start-up venture may include build-out, equipment, supplies, and working capital, and such requirements may exceed $1 million.[97] Additionally, considering the revenue and collection cycle of startup OBLs, the practice will require working capital to fund operations until the collection cycle catches up. Further, as described above, the cost to maintain supply inventory may be considerable.

Due to the substantial startup costs, many OBLs are owned by multiple parties (or through a joint venture). Funding may come in the form of cash, assets, or services. Examples of assets contributed include use of office space, equipment, and intangible assets, such as the use of a trade name or intellectual property. Examples of services contributed include the use of personnel staff and management services. If capital contributions are in a form other than cash, a determination of the fair market value of those contributions are required to comply with a number of applicable Anti-Kickback Statute (AKS) safe harbors, as discussed in Part Two of this series.[98]

Suppliers

Similar to all businesses, bargaining power with suppliers can have a direct impact on the profitability of the OBL. To date, group purchasing organizations (GPOs) have not provided much benefit to OBLs in terms of pricing for endovascular devices. However, another type of supplier, management companies that partner with the physicians and their practices for development, management, and operations, are prevalent in the OBL market. These companies, such as National Cardiovascular Partners (NCP), Envision

Healthcare, and Surgery Partners, assist with navigating regulations and supply purchasing and allow physicians to mitigate some of their financial risk.[99] Key manufacturers, such as Philips Healthcare and Siemens Healthineers, have also been entering into partnerships with physicians to set up OBLs, equipping laboratories with required instruments and providing complete solutions from start to end, which is expected to further propel the OBL market.[100]

Subject-Entity-Specific/Non-Systematic Risk

The subject-entity-specific/nonsystematic (idiosyncratic) risk factors for OBLs may be similar to those for ASCs (at different levels). Additional risk factors related to the value of OBLs for consideration include:

(1) Procedure mix may move to more complex procedures best suited for the ASC setting (e.g., hemodialysis thrombectomy, pacemakers) – is the build-out of the OBL up to ASC specifications in the event of conversion to an ASC or OBL/ASC hybrid?

(2) Payor acceptance of the higher non-facility fee rate reimbursed by Medicare and many commercial payors.

Conclusion

Like ASCs, OBLs are increasingly performing a wide array of complex procedures and ancillary services, which present important revenue opportunities. Available talent, changes in federal reimbursement requirements, admission rates, and consumer demand largely influence the provision of these services offered by OBLs in the outpatient setting. Growth in the number OBLs, like for ASCs, is driven by a desire to lower costs for patients and the healthcare system, and joint ventures formed with other healthcare entities are likely to increase in coming years.

While ASCs offer a broader scope of services, OBLs are traditionally easier and less expensive to open and operate. The combination of the two sites of service into one facility (i.e., an OBL/ASC hybrid facility) is gaining attractiveness to providers who seek to increase service offerings while also mitigating the risk that payors may decrease rates in one setting over another. All of these factors and more are important to take into account when conducting a valuation of an OBL.

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1 "History of ASCs" Ambulatory Surgery Center Association, https://www.ascassociation.org/advancingsurgicalcare/asc/historyofascs (Accessed 2/4/21).

2 *Ibid.*

3 "Number of ASCs Per State" Advancing Surgical Care, May 2020, https://www.ascassociation.org/advancingsurgicalcare/asc/numberofascsperstate (Accessed 2/4/21).

4 "Outpatient Endovascular and Interventional Society" https://oeisociety.com/ (Accessed 2/4/21).

5 "Ambulatory Surgical Center Payment System" Centers for Medicare & Medicaid Services, MLN Fact Sheet, March 2020, https://www.cms.gov/Outreach-and-Education/Medicare-

Learning-Network-MLN/MLNProducts/Downloads/AmbSurgCtrFeepymtfctsht508-09.pdf (Accessed 2/4/21), p. 2.

6 *Ibid*, p. 6.

7 "Ambulatory Surgery Centers: A Positive Trend in Health Care" Ambulatory Surgery Center Association, 2013, http://higherlogicdownload.s3.amazonaws.com/ASCACONNECT/142533d1-73af-4211-9238-7f136c02de93/UploadedImages/About%20Us/ASCs%20-%20A%20Positive%20Trend%20in%20Health%20Care.pdf (Accessed 2/4/21), p. 1.

8 *Ibid.*

9 *Ibid*; "Chapter 5 Ambulatory Surgical Center Services" In "Report to the Congress: Medicare Payment Policy" Medicare Payment Advisory Commission, March 2020, http://medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf (Accessed 2/4/21), p. 150.

10 Medicare Payment Advisory Commission, March 2020, p. 149.

11 Ambulatory Surgery Center Association, 2013, p. 5.

12 *Ibid*; Medicare Payment Advisory Commission, March 2020, p. 149-150.

13 Ambulatory Surgery Center Association, 2013, p. 5.

14 *Ibid*, p. 5; "Section 7: Ambulatory Care" In: "Health Care Spending and the Medicare Program" Medicare Payment Advisory Commission, July 2020, http://www.medpac.gov/docs/default-source/data-book/july2020_databook_sec7_sec.pdf?sfvrsn=0 (Accessed 2/4/21), p. 94.

15 "US Industry (Specialized) Report OD5971: Ambulatory Surgery Centers" By Dmitry Diment, IBISWorld, December 2020, p. 7.

16 "Ambulatory Surgery Center Market Size, Share & Trends Analysis Report By Application (Orthopedics, Plastic Surgery, Ophthalmology, Gastroenterology, Pain Management), By Region, And Segment Forecasts, 2019 - 2026" Grand View Research, May 2019, https://www.grandviewresearch.com/industry-analysis/ambulatory-surgery-center-asc-market (Accessed 2/19/21).

17 *Ibid.*

18 IBISWorld, December 2020, p. 27.

19 *Ibid.*

20 Medicare Payment Advisory Commission, July 2020, p. 90.

21 *Ibid.*

22 *See, e.g.*, "Future of vascular surgery is in the office" By Krishna M. Jain, MD, et al., Journal of Vascular Surgery, Vol. 51 (February 2010), p. 509-514.

23 "Office-Based Labs: An Evolving Healthcare Model" By Jeffrey G. Carr, Cath Lab Digest, Vol. 25, Issue 11 (November 2017), https://www.cathlabdigest.com/article/Office-Based-Labs-Evolving-Healthcare-Model (Accessed 2/4/21).

24 "U.S. Office-based Labs Market Size, Share & Trends Analysis Report By Modality (Single Specialty Labs, Hybrid Labs), By Service, By Specialist, And Segment Forecasts, 2020 – 2027" Grand View Research, December 2020, https://www.grandviewresearch.com/industry-analysis/office-based-labs-obl-market (Accessed 2/4/21).

25 "Treatment outcomes and lessons learned from 5134 cases of outpatient office-based endovascular procedures in a vascular surgical practice" By PH Lin, et al., Vascular, Vol. 25, No. 2 (April 2017), available at: https://www.ncbi.nlm.nih.gov/pubmed/27381926 (Accessed 2/4/21), p. 115-22.

26 "The Need for Accreditation of Office-Based Interventional Vascular Centers" By Peter H. Lin, et al., Annals of Vascular Surgery, Vol. 38 (January 2017), available at: https://www.sciencedirect.com/science/article/abs/pii/S0890509616306689 (Accessed 2/4/21), p. 332-338.

27 "Grand View Research, December 2020.

28 *Ibid.*

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

30 *Ibid*, § 1395nn(h)(6)(A).

31 The regulations specifically note that "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)." "Definitions" 42 C.F.R. § 411.351.

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

33 "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 2/4/21), p. 4-5; "U.S. v. Greber" 760 F.2d 68, 69 (3d Cir. 1985).

34 Demske, July 28, 2015, p. 5.

35 *Ibid.*

36 "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.

37 "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 2/4/21), p. 1.

38 "Definitions" 42 U.S.C. § 416.2.

39 *See* "Survey Eligibility Criteria for Office-Based Surgery" The Joint Commission, https://www.jointcommission.org/-/media/tjc/documents/accred-and-cert/ahc/obs-eligibility-flyer.pdf (Accessed 2/4/21).

40 "Hospitals see opportunity, risk in ambulatory surgery centers" By Alex Kacik, January 25, 2021, Modern Healthcare, https://www.modernhealthcare.com/providers/hospitals-see-opportunity-risk-ambulatory-surgery-centers (Accessed 2/19/21).

41 *Ibid.*

42 *Ibid.*

43 "Exceptions: Ambulatory Surgery Centers" 42 C.F.R. § 1001.952(r) (2020).

44 "ASC single specialty vs. multispecialty—Which is best?" By Megan Wood, Becker's ASC Review, September 2, 2015, https://www.beckersasc.com/news-analysis/asc-single-specialty-vs-multispecialty-which-is-best.html (Accessed 2/4/21).

45 *Ibid.*

46 "Chapter 5 Ambulatory Surgical Center Services" In "Report to the Congress: Medicare Payment Policy" Medicare Payment Advisory Commission, March 2021, http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf (Accessed 4/1/21), p. 144.

47 *Ibid*, p. 145.

48 "US Industry (Specialized) Report OD5971: Ambulatory Surgery Centers" By Dmitry Diment, IBISWorld, December 2020, p. 7.

49 *Ibid.*

50 *Ibid.*

51 *Ibid.*

52 *Ibid.*

53 "Ambulatory Surgery Centers: A Positive Trend in Health Care" Ambulatory Surgery Center Association, 2013, http://higherlogicdownload.s3.amazonaws.com/ASCACONNECT/142533d1-73af-4211-9238-7f136c02de93/UploadedImages/About%20Us/ASCs%20-%20A%20Positive%20Trend%20in%20Health%20Care.pdf (Accessed 2/4/21), p. 5

54 Centers for Medicare and Medicaid Services, "Fact Sheets: Final 2009 Policy, Payment Changes for Hospital Outpatient Departments and Ambulatory Surgery Centers" (October 30, 2008), https://www.cms.gov/newsroom/fact-sheets/final-2009-policy-payment-changes-hospital-outpatient-departments-and-ambulatory-surgical-centers (accessed 2/4/21).

55 "Here's what ASCs need to know about bundled payments—6 takeaways" By Angie Stewart, Becker's Healthcare, September 4, 2018, https://www.beckersasc.com/asc-coding-billing-and-collections/here-s-what-ascs-need-to-know-about-bundled-payments-6-takeaways.html (Accessed 2/4/21).

56 *Ibid.*
57 *Ibid.*
58 "Surgery Centers Dive Into Bundled Payment Models" Relias Media, September 1, 2019, https://www.reliasmedia.com/articles/144870-surgery-centers-dive-into-bundled-payment-models (Accessed 2/4/21).
59 "4 big trends for ASCs in 2021" By Angie Stewart, Becker's Healthcare, December 10, 2020, https://www.beckersasc.com/asc-news/4-big-trends-for-ascs-in-2021.html (Accessed 2/4/21).
60 *Ibid.*
61 *Ibid.*
62 *Ibid.*
63 Diment, December 2020, p. 23-24.
64 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, 3rd ed., Chicago, IL: Health Administration Press, 2005, p. 38; "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, eds., 7th ed., Clifton Park, NY: Thomson Delmar Learning, 2008, p. 124.
65 "ASC and Payor Negotiations" By Gary Scott Davis, Kriste Goad, and Naya Kehayes, McDermott Will & Emery, 2012, https://docplayer.net/22112323-Asc-and-payor-negotiations.html (Accessed 2/4/21).
66 "Senate health bill includes pay cap for surprise bill disputes" By Susannah Luthi, Modern Healthcare (June 19, 2019), https://www.modernhealthcare.com/politics-policy/senate-health-bill-includes-pay-cap-surprise-bill-disputes (Accessed 2/4/21).
67 "Surprise Medical Bills: New Protections for Consumers Take Effect in 2022" Kaiser Family Foundation, February 4, 2021, https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/ (Accessed 4/1/21).
68 Medicare Payment Advisory Commission, March 2021, p. 155.
69 Diment, December 2020, p. 28.
70 Medicare Payment Advisory Commission, March 2021, p. 155.
71 *Ibid.*
72 Diment, December 2020, p. 38.
73 *Ibid*, p. 38-39.
74 *Ibid*, p. 38.
75 *Ibid*.
76 "Fixed Income Analysis for the Chartered Financial Analyst Program" By Frank Fabozzi, 2nd ed., New Hope, PA: Frank J. Fabozzi Associates, 2005, p. 572.
77 "Cost of Capital: Applications and Examples" By Shannon P. Pratt and Roger J. Grabowski, 3rd ed., Hoboken, NJ: John Wiley & Sons, Inc., 2008, p. 276-277.
78 Medicare Payment Advisory Commission, March 2021, p. 152.
79 *Ibid.*
80 *Ibid.*
81 Diment, December 2020, p. 16-17, 27.
82 See, e.g., "Financial Analysis 2018: Ambulatory Surgery Centers, Volume Two" Pennsylvania Health Care Cost Containment Council, October 2019, http://www.phc4.org/reports/fin/18/docs/fin2018report_volumetwo.pdf (Accessed 2/5/21).
83 Diment, December 2020, p. 13.
84 *Ibid*, p. 6.
85 *Ibid*, p. 10.
86 "Hospitals see opportunity, risk in ambulatory surgery centers" By Alex Kacik, January 25, 2021, Modern Healthcare, https://www.modernhealthcare.com/providers/hospitals-see-opportunity-risk-ambulatory-surgery-centers (Accessed 2/19/21).
87 Diment, December 2020, p. 10.
88 Kacik, January 25, 2021.
89 Diment, December 2020, p. 10.
90 Kacik, January 25, 2021.
91 "Office-Based Labs: An Evolving Healthcare Model" By Jeffrey G. Carr, Cath Lab Digest, Vol. 25, No. 11 (November 2017), https://www.cathlabdigest.com/article/Office-Based-Labs-Evolving-Healthcare-Model (Accessed 2/5/21).

92 "Financial Considerations for Office-Based Intervention Labs" By Hwa Kho and Sam Ahn, Endovascular Today, https://evtoday.com/pdfs/et0114_F4_Ahn.pdf (Accessed 2/5/21), p. 55.
93 *Ibid*.
94 "Details for title: 0108 - Facility vs. Non-Facility Reimbursement" Centers for Medicare & Medicaid Services, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Approved-RAC-Topics-Items/0108-Facility-vs-Non-Facility-Reimbursement.html (Accessed 2/5/21).
95 "Revised and Clarified Place of Service (POS) Coding Instructions" MLN Matters No. 7631, Centers for Medicare & Medicaid Services (April 1, 2013), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7631.pdf (Accessed 2/5/21).
96 "Facility versus Non-Facility in the Physician Fee Schedule" By Betsy Nicoletti, CodingIntel, January 29, 2018, https://www.codingintel.com/facility-non-facility-physician-fee-schedule/ (Accessed 2/5/21).
97 "Financial Considerations for Office-Based Intervention Labs" By Hwa Kho and Sam Ahn, Endovascular Today, https://evtoday.com/pdfs/et0114_F4_Ahn.pdf (Accessed 2/5/21), p. 57.
98 "Valuation of ASCs and OBLs Part II: Regulatory Environment" Health Capital Topics, Vol. 14, Issue 3 (March 2021), https://www.healthcapital.com/hcc/newsletter/03_21/HTML/ASC/convert_considerations-of-ascs-obls_part_two_3.25.21.php (Accessed 5/19/21).
99 "U.S. Office-based Labs Market Size, Share & Trends Analysis Report By Modality (Single Specialty Labs, Hybrid Labs), By Service, By Specialist, And Segment Forecasts, 2020 – 2027" Grand View Research, December 2020, https://www.grandviewresearch.com/industry-analysis/office-based-labs-obl-market (Accessed 2/4/21).
100 *Ibid.*

The Future of Healthcare in 2040: A Reflection Post-COVID-19

[Excerpted from the article published in February 2021.]

Introduction

On February 9, 2021, Deloitte Insights released a new report on future healthcare spending trends, which also included updates to its 2019 report on overall industry trends. The COVID-19 *public health emergency* (PHE) has accelerated many of the predictions and shifts discussed in the 2019 report, but delayed others. Trends in spending are important to consider in light of reimbursement, regulation, and broader healthcare trends. According to a 2019 report, the main points of change for the healthcare industry over the next 20 years will revolve around consumers; interoperability: a holistic, prevention-based focus on health and well-being; and the equipping of healthcare providers with the technology and knowledge to collect and utilize on-demand patient data.[1] This article will explore how the healthcare delivery environment may change over the next 20 years.

Overall Cost Trends

For nearly every year over the past six decades, U.S. healthcare spending as a percentage of *gross domestic product* (GDP) has increased.[2] In 1960, this share was only 5%, while by 2019, it had increased to 18%.[3] Healthcare spending is projected to reach $8.3 trillion, or approximately 18.4% of GDP, in 2040, more than double projected spending in 2020, according to the 2021 Deloitte report.[4] The report predicts that three realities will materialize by 2040:

(1) Savings from system investment into individuals' well-being[5] will be realized. The Deloitte expenditure estimate for 2040 was $3.5 trillion lower than projections from the *Centers for Medicare & Medicaid Services* (CMS), extrapolated to 2040.[6] Called a "*well-being dividend*," these savings are comprised of a return on investment for tools, systems, and procedures that allow consumers to take an active role in their health.

(2) Spending will shift from a majority care and treatment model to one allocated toward health and well-being. Prevention and early detection will be made easier by a wider availability of health monitoring technologies.

(3) Shifts in healthcare financing, a slowdown of mass-produced biopharmaceutical products, and the end of general hospital systems as they currently exist will bring significant changes to the healthcare economy.[7]

These three key trends, as well as general healthcare trends and changes in light of COVID-19, are discussed in further detail below. The remainder of the article will be devoted to a discussion of the interconnected changes between financial and general predictions.

Consumer-Led Care

In 2040, consumers will likely experience a radically different healthcare environment. Technology will allow patients to access their data and clinical services more easily, no matter their location.[8] Wearable devices have the potential to make this data available on-demand to consumers.[9] Treatment, such as at-home diagnostic testing and symptom management, will also be more readily available in multiple settings (including the patient's home), thanks to new technological developments.[10] Over the past decade, more surgeries and procedures have transitioned to more cost-effective and convenient outpatient settings.[11] In fact, outpatient care grew from less than one-third to nearly half of hospital revenue from 1994 to 2018.[12] Demand for inpatient services is likely to continue dropping, leading to increased *merger and acquisition* (M&A) activity[13] in the sector and, potentially, the end of the traditional, general hospital.[14] Care is likely to transition to more individualized, personalized care as a greater number of healthcare providers are able to collect and effectively utilize this patient data.[15] Personalized health information can allow consumers to be more active in their own health and well-being.[16] This trend has already taken off in the past decade: in 2020, a Deloitte survey of more than 1,500 consumers indicated that 42% of those surveyed used devices or technology to measure their fitness and health improvement goals – a significant increase from just 17% in 2013.[17] Further, randomized trials have shown improvement in physical activity through the use of wearable activity trackers, as measured by time engaged in moderate intensity physical activity or daily step counts.[18]

How organizations evolve their business models to meet the needs of these empowered consumers in the future may strongly influence the organization's viability.[19] These changes may be accelerated by increasing interoperability and creating interconnected health communities, which can shift the responsibility of well-being to the consumers.[20] Returns on investments included in this area, as well as in the related areas of interoperability and technology, principally constitute Deloitte's "*well-being dividend*."

Working Together: Interoperability between Providers and Systems

On March 9, 2020, the *U.S. Department of Health and Human Services* (HHS) finalized new interoperability rules that prevent information blocking practices, encourage more easily shareable *electronic health records* (EHRs), establish requirements for software that will allow patients to better access their own health data, and mandate that claims data through federal healthcare plans be shared with patients.[21] According to HHS, these rules, which took effect on January 1, 2021, represent "*the start of a new chapter in how patients experience American health care*."[22] Eventually, interoperability could lead to a more connected healthcare system, where data is securely shared among stakeholders (e.g., patients, hospitals, independent physician practices, pharmacies).[23] Each consumer would have a personalized image of their own well-being that was easily shared among providers (even those of different health systems) and would replace the disjointed and disconnected healthcare system that exists today.[24] The government, as the primary payor of healthcare

services in the U.S., has great influence and power in making this vision a reality. Policies that support interoperability and data collection and sharing would help drive these developments, while new regulations would empower consumers and ensure that their privacy and security are protected.[25]

New entrants to, and non-traditional players in, the healthcare market can seize opportunities by delivering healthcare that empowers consumers with convenience, affordability, and a better experience of care.[26] Promoting data sharing, transparency, and interoperability will be vital steps to lowering the barriers to entry for these new players.[27] Striking a balance between innovation and safety may create a more sustainable healthcare business model that would endure well past 2040.[28]

Prevention, Early Detection, and Well-Being

Chronic disease is the leading cause of death and disability in the U.S., as well as a main driver in rising annual healthcare costs.[29] In fact, 60% of adults have a chronic disease, and 40% have two or more chronic diseases.[30] Heart disease, cancer, lung disease, kidney disease, diabetes, Alzheimer's disease, and stroke are all highly prevalent chronic diseases.[31] Treatments for these conditions are constantly evolving, especially for cancer and diabetes, thanks to technological innovations. Promising advances in immunotherapy, therapeutic viruses, vaccines, epigenetics, starvation methods, and nanoparticles have not yet led to a "*cure*" for cancer, but are making progress toward improving patients' odds against the disease and keeping ahead of growing tumors.[32]

Because healthcare is traditionally focused on disease treatment instead of prevention, with about 80% of healthcare spending used to diagnose patients and treat them after they become sick, it is no wonder that the rise in complex, chronic conditions has led to increases in costs for the healthcare system.[33] Future investments in consumer-centric technologies (such as those discussed above) may help lead to a shift to well-being care wherein most funds are spent on prevention, early detection, and encouraging mental, physical, spiritual, and other forms of well-being and health.[34]

These advances may also lead to further widespread changes in the insurance systems and business models that dominate the healthcare system. Health insurance today is financed primarily by premium payments made to private insurance companies, which distribute their risk across many individuals.[35] However, with technological advancements and a greater focus on prevention enhancing providers' abilities to detect and prevent diseases, consumers may begin to demand a shift to a system more closely tailored to their lifestyle and behaviors, rather than to risks in the greater population.[36] This transformation has already begun: business models are beginning to shift to rewarding behaviors that promote well-being.[37] These models can provide more effective care through an emphasis on well-being and efficient data utilization.[38] In future projections, models such as these will become increasingly prevalent.[39]

Technological Advancements

Innovations in healthcare technology, including those that enhance the collection, analysis, and distribution of data, are growing exponentially. These new technologies are a major focus for future healthcare predictions. As mentioned above, the use of wearable trackers and monitors by patients hold great potential for the healthcare industry.[40] Telemedicine has also proven to be a useful tool, especially in eliminating geography as a barrier to access and reaching patients who are unable to leave their homes.[41]

Streamlined regulatory processes and collaboration, as seen with the COVID-19 vaccine, may also work to bring diagnostic tests and therapies to the market more quickly. The Deloitte report further expects the number of new preventative and curative advances available to consumers to grow exponentially between now and 2040.[42] Cell and gene therapies, as well as new vaccines, will likely be used to prevent, treat, and cure a wide range of diseases.[43] Interoperable data and *artificial intelligence* (AI) also hold great potential to allow for early illness identification.[44] Moving forward, governmental reimbursement and regulations will be vital to encouraging the development and utilization of these technological advances.

Conclusion

Healthcare is likely to move to a more patient- and prevention-centered system in the near future. Technology and data interoperability, as well as reimbursement and regulation, will drive this systematic change. Allowing consumers to access more personalized data related to their health will ideally increase the responsibility they feel and encourage healthier habits and a greater focus on a multi-faceted view of well-being. This implementation will challenge providers and raise costs, as healthcare expenditures are predicted to rise dramatically in the next 20 years, both in real dollars and as a share of GDP. However, investment in these technologies and improvements could also translate to real improvements in the rates of chronic diseases among the U.S. population and could create a tangible, trillion dollar return on investment on the well-being of Americans.

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1 "Forces of change: The future of health" Deloitte Insights, 2019, https://www2.deloitte.com/content/dam/insights/us/articles/5169_forces-of-change-future-of-health/DI_Forces-of-change_Future-of-health.pdf (Accessed 2/18/21), p. 2.

2 "Breaking the cost curve" By Kulleni Gebreyes, Andy Davis, Steve Davis, and Maulesh Shukla, Deloitte Insights, February 9, 2021, https://www2.deloitte.com/us/en/insights/industry/health-care/future-health-care-spending.html (Accessed 2/18/21).

3 *Ibid.*

4 *Ibid.*

5 Deloitte defines well-being as "*wholistic… where the health of the whole individual is considered.*" They include physical, mental, spiritual, social, emotional, equitable, and even financial health in their definition. Further, "*[a]chieving and maintaining a state of well-being might encompass everything from a healthy diet and exercise, to addressing drivers of health and inequity, to using cell and gene therapy, and other advanced therapies, to*

prevent, treat, or cure today's illnesses." Gebreyes, Davis, Davis, and Shukla, February 9, 2021.

6 For more information on the newest CMS projections, see "National Health Expenditure Projections, 2019–28: Expected Rebound In Prices Drives Rising Spending Growth" By Sean P. Keehan, Gigi A. Cuckler, John A. Poisal, Andrea M. Sisko, Sheila D. Smith, Andrew J. Madison, Kathryn E. Rennie, Jacqueline A. Fiore, and James C. Hardesty, Health Affairs, Vol. 39, No. 4 (April 2020), p. 705.

7 Gebreyes, Davis, Davis, and Shukla, February 9, 2021.

8 *Ibid.*

9 *Ibid.*

10 Deloitte Insights, 2019, p. 5.

11 *Ibid.*

12 "The potential for rapid consolidation of health systems" By Traci Prevost, Ion Skillrud, Wendy Gerhardt, and Debanshu Mukherjee, Deloitte Insights, December 10, 2020, https://www2.deloitte.com/us/en/insights/industry/health-care/hospital-mergers-acquisition-trends.html (Accessed 2/19/21).

13 For more information about 2020 M&A activity and future trends, see the February topics article "Merger & Acquisition Activity Slowed in 2020 But Poised to Accelerate in 2021".

14 "Prevost, Skillrud, Gerhardt, and Mukherjee, December 10, 2020; "Gebreyes, Davis, Davis, and Shukla, February 9, 2021.

15 Gebreyes, Davis, Davis, and Shukla, February 9, 2021.

16 *Ibid.*

17 "Are consumers already living the future of health?" By David Betts, Leslie Korenda, and Shane Giuliani, Deloitte Insights, August 13, 2020, https://www2.deloitte.com/us/en/insights/industry/health-care/consumer-health-trends.html (Accessed 2/18/21).

18 "Wearable Technology To Reduce Sedentary Behavior And CVD Risk In Older Adults: A Pilot Randomized Clinical Trial" By Lisa Roberts, Byron Jaeger, Liliana Baptista, Sara Harper, Anna Gardner, Elizabeth Jackson, Dorothy Pekmezi, Bhanuprasad Sandesara, Todd M Manini, Stephen Anton, and Thomas Buford, Clinical Interventions in Aging, Vol. 14 (2019), p. 1817; Gebreyes, Davis, Davis, and Shukla, February 9, 2021; "Consumer-Based Wearable Activity Trackers Increase Physical Activity Participation: Systematic Review and Meta-Analysis" By Katie-Jane Brickwood, Greig Watson, Jane O'Brien, and Andrew Williams, JMIR mHealth and uHealth, Vol. 7, No. 4 (2019), p. 1.

19 Gebreyes, Davis, Davis, and Shukla, February 9, 2021.

20 *Ibid.*

21 "HHS Finalizes Historic Rules to Provide Patients More Control of Their Health Data" U.S. Department of Health & Human Services, https://www.hhs.gov/about/news/2020/03/09/hhs-finalizes-historic-rules-to-provide-patients-more-control-of-their-health-data.html (Accessed 2/18/21).

22 *Ibid.*

23 Gebreyes, Davis, Davis, and Shukla, February 9, 2021; "Interoperability in Healthcare" Healthcare Information and Management Systems Society, https://www.himss.org/resources/interoperability-healthcare (Accessed 2/19/21).

24 Gebreyes, Davis, Davis, and Shukla, February 9, 2021.

25 *Ibid.*

26 *Ibid.*

27 *Ibid.*

28 *Ibid.*

29 "Chronic Diseases in America" Centers for Disease Control and Prevention, January 12, 2021, https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm (Accessed 2/18/21).

30 *Ibid.*

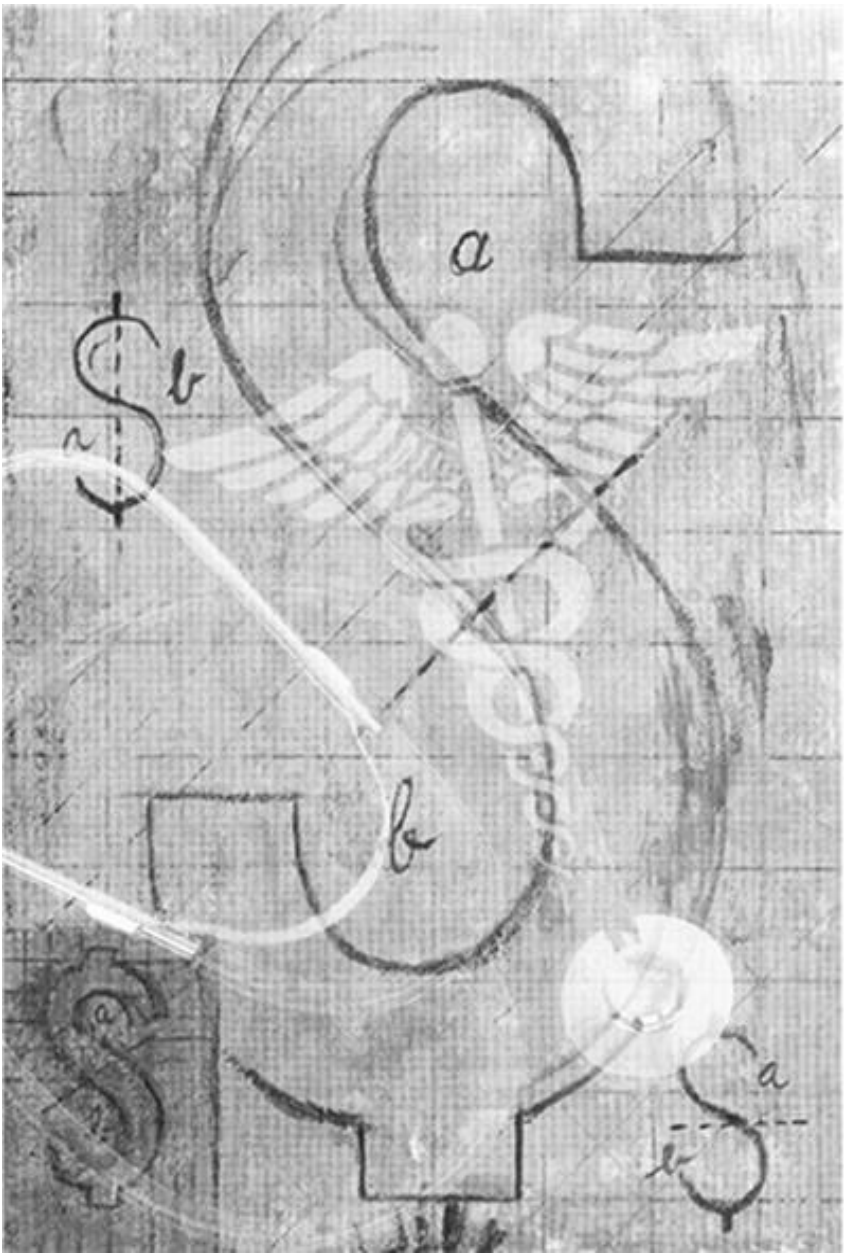
31 *Ibid.*

32 "The state of cancer: Are we close to a cure?" By Maria Cohut, MedicalNewsToday, March 2, 2018, https://www.medicalnewstoday.com/articles/321106 (Accessed 2/18/21).

33 Gebreyes, Davis, Davis, and Shukla, February 9, 2021.

34 *Ibid.*

35 *Ibid.*
36 *Ibid.*
37 *Ibid.*
38 *Ibid.*
39 *Ibid.*
40 *Ibid.*
41 *Ibid*; "HHS Issues New Report Highlighting Dramatic Trends in Medicare Beneficiary Telehealth Utilization amid COVID-19" Department of Health and Human Services, July 28, 2020, https://www.hhs.gov/about/news/2020/07/28/hhs-issues-new-report-highlighting-dramatic-trends-in-medicare-beneficiary-telehealth-utilization-amid-covid-19.html (Accessed 2/18/21).
42 Gebreyes, Davis, Davis, and Shukla, February 9, 2021.
43 *Ibid.*
44 *Ibid.*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II. REIMBURSEMENT TOPICS

Gap Between Private Insurance and Medicare Hospital Payments Increased in 2018

[Excerpted from the article published in September 2020.]

On September 18, 2020, the nonprofit *Research and Development* (RAND) Corporation published a research report, which found that private insurance companies pay prices that are on average 240% higher than what Medicare pays for the same hospital services.[1]

The report analyzed data from 2016 through 2018 across 49 states and Washington D.C.[2] The only excluded state was Maryland, for which data was collected but not included in the study because of the state's all-payor rate setting program, where hospitals by default charge prices equal to private payors and Medicare.[3] RAND data included only community hospitals such as *inpatient prospective payment system* (IPPS) hospitals and *critical access hospitals* (CAHs).[4] Other facilities such as specialty hospitals, *skilled nursing facilities* (SNFs), inpatient rehabilitation facilities, and *Veterans Administration* (VA) facilities were excluded from the data.[5] This study was conducted based on a convenience sample[6] of 120 self-insured employers of various sizes and from various industries.[7] Data also came from *all-payor claims databases* (APCDs), but only in six states.[8] APCDs are state databases of claims data and provider files reported by insurers, which are usually required by state mandates.[9] In total, the sample included data from over 3,000 hospitals, almost 48 million claims, and $33.8 billion in spending by private payors.[10] In order to make hospital comparisons, RAND created a pricing algorithm based on Medicare's fee schedules and compared these payments to two different ways of calculating private payments: (1) *standardized prices*,[11] where standardized units are created based on average intensity of services, and (2) *relative prices*,[12] where Medicare reimbursement is used a benchmark from which ratios are calculated.[13]

To ensure more reliable and applicable pricing information, the RAND study has been expanding their report each year, increasing from one state in the first edition in 2017 to all but one in this third edition.[14] This edition also included professional fees, or the amounts charged by physicians, which is less commonly found in research on private and public payor payments to hospitals, as many choose to only focus on hospital facility fees.[15]

Specifically, the report found that RAND-calculated relative prices for private payors were 231% and 267% more expensive than Medicare for inpatient and outpatient services, respectively, with an average discrepancy of 247%.[16] The variation between states was significant: states such as Alaska, Florida, Tennessee, South Carolina, and West Virginia had relative prices upwards of 325% of Medicare, while others such as Arkansas, Michigan, and Rhode Island, had prices less than 200% of Medicare.[17] For this data, the variations in payments between the $33.8 billion in private spending and the $14.1 billion in simulated Medicare payments made for a difference of $19.7 billion, or a

potential savings of 58% over private insurance costs.[18] In fact, the current study shows a compounded rate of increase of 5.1% per year, much higher than 1.6% that was estimated in the 2019 edition of this report.[19] The inclusion of more employers as well as professional fees, however, may be contributing factors to this large difference between studies.[20]

The RAND report also included data as to how quality and safety ratings were related to prices above Medicare. To do this, hospitals were split into three groups: low prices (less than or equal to 1.5 times Medicare rates), medium prices (between 1.5 and 2.5 times Medicare rates), and high prices (greater than or equal to 2.5 times Medicare rates).[21] Hospice Compare data, including star quality ratings, were pulled from the *Centers for Medicare and Medicaid Services* (CMS), and safety data was obtained from the Leapfrog Group. The data showed high-quality, low-cost options for employers: while high-cost hospitals show higher proportions of five-star ratings than low-cost hospitals, 91% of low-cost hospitals received three or more stars, and 17% of high-cost hospitals received two stars or under.[22] For safety ratings, letter grades across hospital costs were similar, with 51% of those in the low-cost category and 60% in the high-cost category earning a grade of A or B.[23] On the other end of the grading spectrum, 14% of low-cost hospitals and 6% of high-cost hospitals scored a grade of D or F.[24]

With this report, RAND aims to combat the "*high and rising health care costs*" that employers face.[25] Employers, as discussed in the report, may often rely on insurers or others to negotiate fair contracts with providers.[26] However, a lack of price transparency from hospitals makes it difficult to compare hospital prices and value.[27] Further, if employers have their prices negotiated for them, they often have no way to evaluate the value of these contracts.[28] The data also indicate no correlation between the prices a hospital charged to commercial payors and the amount of patients with public insurance, contrary to the so-called *cost-shifting* idea that many propose as a primary reason for this widening gap between private and public costs.[29] The study's lead author attributed this gap to other factors such as reputation, quality, or market dominance outside of patient care factors[30] and hopes that reports and data such as this will help give employers a better position for negotiating, similar to that gained by insurers and hospitals through consolidation, and will further equip employers with the knowledge that low-cost hospitals in many areas can also have similar safety and quality ratings as high-cost hospitals.[31] Publishing this data may allow employers to demand better value for their costs of care, which have been a cause of concern among employers as their healthcare costs increase at a much faster rate than government payor spending.[32] RAND also hopes that the data will benefit the 153 million Americans, or 57% of the nonelderly population, who have health insurance through employers.[33] While many providers and insurers are enacting "*gag clauses*" to prohibit greater price transparency to employers or patients, the RAND study seeks to shine a light on payment gaps and the costs of healthcare.[34]

1 "Nationwide Evaluation of Health Care Prices Paid by Private Health Plans: Findings from Round 3 of an Employer-Led Transparency Initiative" By Christopher M. Whaley, et al., RAND Corporation, 2020, https://employerptp.org/wp-content/uploads/2020/09/RAND-3.0-Report-9-18-20.pdf (Accessed 9/18/20), p. 13.
2 *Ibid*.
3 *Ibid*, p. 3.
4 *Ibid*.
5 *Ibid*.
6 In this context, a *convenience sample* means that only employers who chose to participate were included in the data. This was not a random sample of all employers.
7 Whaley, et al., RAND Corporation, 2020, p. 6.
8 The six states were Connecticut, Colorado, Delaware, Maine, New Hampshire, and Rhode Island. *Ibid*, p. 6.
9 "All-Payer Claims Databases" Agency for Healthcare Research and Quality, February 2018, https://www.ahrq.gov/data/apcd/index.html (Accessed 9/21/20).
10 Whaley, et al., RAND Corporation, 2020, p. 13.
11 In this report, standard prices are defined as the "*average allowed amount per standardized unit of service, where services are standardized using Medicare's relative weights*." *Ibid*, p. vii.
12 In this report, relative prices are defined as the "*ratio of the actual private allowed amount dived by the Medicare allowed amount for the same services provided by the hospital*." *Ibid*, p. vii.
13 *Ibid*, p. 8-10.
14 *Ibid*, p. 2; "RAND 1.0" Employers' Forum of Indiana, https://employerptp.org/rand-1/ (Accessed 9/21/20).
15 "Nationwide Evaluation of Health Care Prices Paid by Private Health Plans: Findings from Round 3 of an Employer-Led Transparency Initiative" By Christopher M. Whaley, et al., RAND Corporation, 2020, https://employerptp.org/wp-content/uploads/2020/09/RAND-3.0-Report-9-18-20.pdf (Accessed 9/18/20), p. 2-3.
16 Whaley, et al., RAND Corporation, 2020, p. viii.
17 *Ibid.*
18 *Ibid*, p. 13.
19 *Ibid.*
20 *Ibid.*
21 *Ibid*, p. 18.
22 *Ibid*, p. 19.
23 *Ibid*, p. 19-20.
24 *Ibid*, p. 20.
25 *Ibid*, p. 1.
26 *Ibid*.
27 *Ibid*.
28 *Ibid*, p. 2.
29 "Gap between what private insurers and Medicare pay hospitals is growing" By Tara Bannow, Modern Healthcare, September 18, 2020, https://www.modernhealthcare.com/payment/gap-between-what-private-insurers-and-medicare-pay-hospitals-growing (Accessed 9/18/20).
30 *Ibid*.
31 Whaley, et al., RAND Corporation, 2020, p. 1-4.
32 *Ibid*, p. 2.
33 *Ibid*, p. 1.
34 *Ibid*.

Personal and National Healthcare Expenditures Grow in 2019

[Excerpted from the article published in January 2021.]

On December 16, 2020, the *Centers for Medicare & Medicaid Services* (CMS) released their *National Healthcare Expenditures* (NHE) report. The recent analysis conducted by the Office of the Actuary at CMS found that NHE grew 4.6% between 2018 and 2019.[1] This rate is essentially the same as in 2018 and is consistent with the growth reported since 2016.[2] In 2019, NHE was $11,582 per person, an increase from 2018 of over $400 per person.[3] Further, NHE comprised 17.7% of the U.S. *gross domestic product* (GDP), which is also similar to the proportion of 17.6% reported in 2018, and confirms that healthcare spending is increasing at a faster rate than the nation's GDP is growing.[4]

As was the case between 2017 and 2018, personal healthcare spending grew quickly between 2018 and 2019. As in 2018, this spending category accounted for 84% of total spending, but increased 5.2% in 2019, compared to only 4.1% in 2018.[5] The main factors for this increase were the growth in spending for:

(1) Hospital care (6.2% in 2019, 2% higher than 2018);
(2) Prescription drugs (5.7% in 2019, nearly 2% higher than 2018); and,
(3) Physician and clinical services (4.6% in 2019, 0.6% higher than 2018).[6]

This growth in spending was offset by declining net costs for health insurance,[7] due to the 2019 repeal of the *Health Insurance Tax* (HIT).[8] HIT was only in place between 2014 and 2016, and again in 2018 (with Congress suspending the HIT in 2017 and again in 2019), and was intended to be one way of paying for the coverage expansions included in the *Patient Protection and Affordable Care Act* (ACA).[9] The 2019 data are in contrast to 2018, when the net cost of health insurance[10] grew 13.2% from the reinstatement of HIT that year.[11] HIT was reinstated for the year 2020 but was permanently repealed as of late 2019 for all calendar years (CYs) after 2020.[12]

The 2019 suspension of HIT appeared to also have implications on the breakdown of spending by payor and on medical prices. Medicare spending increased more in 2019 than in 2018 (6.7% growth compared to 6.3%), while the growth in private insurance spending slowed (3.7% in 2019 versus 5.6% in 2018), and Medicaid spending decreased slightly (growth of 2.9% and 3.1% in 2019 and 2018, respectively).[13] Consistent with the increases in personal healthcare spending described above, personal spending for all three payors increased by 1% between 2018 and 2019, even though overall expenditure growth slowed for some.[14] As expected, medical prices grew at a slower rate (1.1%) than in 2018 (2.3%) from the suspension of HIT.[15] In this situation, however, unlike for payors, growth in personal healthcare prices was comparable between 2018 and 2019, while overall prices experienced lower increases.[16]

The report attributed several other factors to the growth in NHE. Interestingly, residual use and intensity[17] almost doubled its proportion of per capita growth in 2019 compared to 2018 (61% of the share compared to 34%, respectively), for a growth rate of 2.5% in 2019.[18] An aging population and other demographic factors accounted for 12% of per capita expenditures in 2019.[19] Faster growth in spending by the federal government and other private entities were offset by slowed increases in spending by private businesses, state and other local governments, and households.[20]

Growing healthcare costs have been recognized as a critical, but difficult, issue to tackle. Recent policy decisions by the Trump Administration have attempted to decelerate these rising costs. For example, in October 2020, CMS published the healthcare transparency final rule,[21] as a follow up to President Trump's June 2019 executive order on "*Improving Price and Quality Transparency*."[22] The healthcare transparency rule aims to lower costs by forcing hospitals to provide more transparent pricing information to consumers in order to allow patients to make more informed decisions regarding their care.[23]

The recent NHE report highlights the difficulty in changing the trajectory of these rising costs, however. It has long been known that an aging population could significantly accelerate healthcare costs.[24] This, together with the growing chronic disease burden in the U.S., has created other potential problems, including a shortage of physicians (especially in primary care and certain surgical specialties) and increased hospital and emergency department (ED) use.[25] Having multiple chronic conditions has been found to increase hospital use, a further contributor to rising costs that was highlighted in the NHE report.[26] In order to combat these issues, legislation and reimbursement structure changes (such as the shift to telemedicine) have focused on decreasing hospital readmissions and ED visits, in order to increase the quality of care given to patients while decreasing the costs of that care.[27]

Importantly, the 2019 NHE report does not take into account changes in NHE as a result of the COVID-19 pandemic. At the beginning of the declared *public health emergency* (PHE) in the U.S., hospital admissions fell dramatically.[28] For several months, hospitals did not perform many of their typical elective procedures and remained at low capacity.[29] By mid to late summer, however, admissions had rebounded to within 16% of pre-PHE numbers.[30] At the end of 2020, hospitalizations related to COVID-19 hit record highs, putting substantial stress on hospital capacity.[31] From the start of the PHE, healthcare systems, providers, and other care centers have been burdened with testing and treating COVID-19 patients, attempting to source scarce personal protective equipment (PPE) for their workers, and training staff to convert in-person services to telemedicine. Individuals with pre-existing conditions, who may be more likely to utilize hospital resources, were instead encouraged to remain in their homes whenever possible due to their increased risk of detrimental effects from COVID-19 infection.[32] How this PHE, as well as other legislative changes (such as HIT) put into place, will affect the 2020 NHE remains to be seen.

1 "National Health Care Spending In 2019: Steady Growth For The Fourth Consecutive Year" By Anne B. Martin, et al., Health Affairs, Vol. 40, No. 1 (January 2021), p. 1.
2 *Ibid*; "National Health Care Spending In 2018: Growth Driven By Accelerations In Medicare And Private Insurance Spending" By Micah Hartman, Anne B. Martin, Joseph Benson, Aaron Catlin, and The National Health Expenditure Accounts Team, Health Affairs, Vol. 39, No. 1 (January 2020), p. 8.
3 Martin, et al., Vol. 40, No. 1, p. 1; Hartman, Martin, Benson, Catlin, and The National Health Expenditure Accounts Team, Vol. 39, No. 1, p. 8.
4 Martin, et al., Vol. 40, No. 1, p. 1, 9.
5 *Ibid*, p. 1; Hartman, Martin, Benson, Catlin, and The National Health Expenditure Accounts Team, Vol. 39, No. 1, p. 8.
6 Martin, et al., Vol. 40, No. 1, p. 1.
7 The net cost of health insurance is defined as the amount of insurance spending attributed to nonmedical expenses, including administration, taxes, and underwriting gains or losses. Martin, et al., Vol. 40, No. 1, p. 1.
8 Section 9010 of the Patient Protection and Affordable Care Act (ACA) imposes a fee on each covered entity engaged in the business of providing health insurance for United States health risks. "Affordable Care Act Provision 9010 - Health Insurance Providers Fee" Internal Revenue Service, December 6, 2019, https://www.irs.gov/businesses/corporations/affordable-care-act-provision-9010 (Accessed 12/17/20); Martin, et al., Vol. 40, No. 1, p. 1.
9 "ACA Provisions In New Budget Bill" By Katie Keith, Health Affairs, December 20, 2019, https://www.healthaffairs.org/do/10.1377/hblog20191220.115975/full/ (Accessed 12/17/20).
10 Health insurance costs are calculated for private health insurance including fully insured group or commercial insurance, direct-purchase or non-group insurance, and self-insured insurance and other insurance programs such as are Medicare Advantage and stand-alone Medicare Part D plans, Medicaid managed care plans, Children's Health Insurance Program managed care plans, the majority of workers' compensation insurance plans, and the health portion of property and casualty insurance. Martin, et al., Vol. 40, No. 1, p. 10.
11 Hartman, Martin, Benson, Catlin, and The National Health Expenditure Accounts Team, Vol. 39, No. 1, p. 8.
12 "Affordable Care Act Provision 9010 - Health Insurance Providers Fee" Internal Revenue Service, December 6, 2019, https://www.irs.gov/businesses/corporations/affordable-care-act-provision-9010 (Accessed 12/17/20); "Further Consolidated Appropriations Act, 2020" Pub. L. No. 116-94, § 502, 133 Stat. 2534, 3119 (December 20, 2019).
13 Martin, et al., Vol. 40, No. 1, p. 1.
14 Personal health care spending by payor does not include government administration and net costs of health insurance, which are both included in calculating total expenditures. Martin, et al., Vol. 40, No. 1, p. 1, 3-4.
15 *Ibid*, p. 4.
16 *Ibid*.
17 Residual use and intensity reflects growth in nominal healthcare spending while excluding any growth in the population, changes in the demographic mix of the population, and medical price growth; it is calculated by removing the effects of population, demographic factors (age and time to death), and price growth from the nominal expenditure level.
18 Martin, et al., Vol. 40, No. 1, p. 4-5, 10.
19 *Ibid*, p. 4.
20 *Ibid*, p. 5-6.
21 "Transparency in Coverage Final Rule Fact Sheet (CMS-9915-F)" Centers for Medicare and Medicaid Services, October 29, 2020, https://www.cms.gov/newsroom/fact-sheets/transparency-coverage-final-rule-fact-sheet-cms-9915-f (Accessed 12/17/20).
22 "Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First" The White House, June 24, 2019,

https://www.whitehouse.gov/presidential-actions/executive-order-improving-price-quality-transparency-american-healthcare-put-patients-first/ (Accessed 12/17/20).

23 For more details on this final rule and its provisions, see the November 2020 Health Capital Topics article entitled, "CMS Final Rule Brings Transparency to Healthcare Industry" Vol. 13, Issue 11 (November 2020), https://www.healthcapital.com/hcc/newsletter/11_20/HTML/PRICE/convert_price_transparency_final_rule_11.24.20.php (Accessed 12/17/20).

24 "The Effects Of Aging And Population Growth On Health Care Costs" By Daniel N. Mendelson and William B. Schwartz, Health Affairs, Vol. 12, No. 1 (Spring 2013), p. 119.

25 "An Aging Population And Growing Disease Burden Will Require A Large And Specialized Health Care Workforce By 2025" By Timothy M. Dall, et al., Health Affairs, Vol. 32, No. 11 (November 2013), p. 2013; "The Complexities of Physician Supply and Demand: Projections From 2018 to 2033" Association of American Medical Colleges, June 2020, p. vii.

26 "Health Care Utilization and Costs of Elderly Persons With Multiple Chronic Conditions" By Thomas Lehnert, et al., Medical Care Research and Review, Vol. 68, No. 4 (January 2011), p. 403-404.

27 See the October 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Reimbursement" Vol. 13, Issue 10 (October 2020).

28 "The Impact Of The COVID-19 Pandemic On Hospital Admissions In The United States" By John D. Birkmeyer, et al., Health Affairs, Vol. 39, No. 11 (November 2020), p. 2010.

29 *Ibid*.

30 *Ibid*

31 "New data, dashboard provide information on Covid-19 hospital capacity" By Pinar Karaca-Mandic, STAT News, December 10, 2020, https://www.statnews.com/2020/12/10/new-data-dashboard-provide-information-on-covid-19-hospital-capacity/ (Accessed 12/17/20); "COVID-19 Hospitalizations Hit Record Highs. Where Are Hospitals Reaching Capacity?" By Will Stone, NPR, November 10, 2020, https://www.npr.org/sections/health-shots/2020/11/10/933253317/covid-19-hospitalizations-are-surging-where-are-hospitals-reaching-capacity (Accessed 12/17/20).

32 Birkmeyer, et al., Vol. 39, No. 11, p. 2015; Lehnert, et al., Vol. 68, No. 4, p. 403-404.

Final MCIT Rule Authorizes New Medicare Coverage Pathway

[Excerpted from the article published in February 2021.]

On January 14, 2021, the *Centers for Medicare & Medicaid Services* (CMS) published a final rule entitled, "*Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary*" to expedite Medicare coverage for *"new and innovative technologies*."[1] This final rule is in response to the October 3, 2019 Executive Order entitled, "*Executive Order on Protecting and improving Medicare for Our Nation's Seniors*,"[2] which directed the Secretary of the *Department of Health & Human Services* (HHS) to propose regulation that will encourage innovation and streamline the approval, coverage, and coding process for items and services eligible for Medicare coverage.[3]

In an effort to meet these directives, this final rule: (1) introduces the Medicare Coverage of Innovative Technology (MCIT) Pathway, a pathway that will provide *Food and Drug Administration* (FDA)-designated breakthrough medical devices four-year, nationwide Medicare coverage on the same day as FDA market authorization; and, (2) codifies the term "*reasonable and necessary*," a criterion used to determine whether a device is eligible for Medicare coverage.[4]

Current Pathways to Medicare Coverage

Current rules specify that Medicare coverage for a medical device can be awarded through one of several pathways described below:[5]

(1) National Coverage Determinations (NCDs) – A nationwide determination as to whether or not an item or service will be covered by Medicare. NCDs typically take 9-12 months to complete;[6]
(2) Local Coverage Determinations (LCDs) – Coverage that is awarded for a specific geographic region by a Medicare Administrative Contractor (MAC). This process can take upwards of 9 to 12 months to complete;[7]
(3) Claim-by-Claim Adjudication – Coverage that is awarded by a MAC on a claim-by-claim basis. This coverage pathway accounts for the majority of claims;[8] and,
(4) Parallel Review – A process that allows the FDA and CMS to simultaneously review submitted clinical data in an effort to reduce the time between FDA approval and a CMS NCD. This process generally requires that devices have a significant amount of clinical evidence.[9]

These pathways often result in an expensive and lengthy process for innovators.[10] Because of the administrative burden these pathways place on innovators and device manufacturers, Medicare beneficiaries' access to breakthrough medical devices is delayed.[11] Moreover, the LCD and Claim-by-Claim Adjudication pathways create discontinuity in Medicare coverage across geographic areas and among Medicare beneficiaries.[12]

The MCIT Pathway will provide four-year, nationwide coverage for eligible devices as early as the same day as FDA market authorization.[13] Not only will this eliminate the lag between FDA market authorization and Medicare coverage (and reimbursement), but it will also remove the administrative burden of securing an LCD for each geographic area.[14]

MCIT Pathway Eligibility

It is important to note that not all devices will be eligible for the MCIT Pathway. For a device to be eligible for coverage under the pathway, the device must: (1) have a Medicare benefit category; and, (2) be an FDA-designated breakthrough medical device.[15]

Only devices that are covered by Medicare benefits will be eligible for the MCIT Pathway.[16] For example, statutory definitions of Medicare benefits specify that home medical equipment must be durable in order to be covered under Medicare.[17] As a result, single-use home medical equipment does not fall within a Medicare benefit category, thus making it ineligible for the MCIT Pathway.[18]

The *Breakthrough Device Program* is a voluntary FDA program that provides an expedited FDA review and authorization process for designated medical devices and device-led combination products (including some diagnostic tests).[19] To be eligible for the breakthrough device designation, the device:

(1) Must provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating conditions; and,
(2) Must:
    (a) Represent breakthrough technology;
    (b) Have no approved or cleared alternative;
    (c) Offer significant advantages over existing alternatives; or,
    (d) Show that availability is in the best interest of patients.[20]

The unique attributes required by the FDA Breakthrough Devices Program will exclude the majority of medical devices from being eligible for the MCIT Pathway.[21] However, as participation in the Breakthrough Devices Program continues to grow, the number of devices eligible for the MCIT Pathway will as well.[22] As of May 2020, 298 devices had been awarded breakthrough device distinction, including 136 devices in 2019 and 50 devices in the first five months of 2020.[23] With breakthrough device distinction being a prerequisite for the attractive MCIT Pathway, it is likely that participation in the Breakthrough Devices Program will continue to grow.

In addition to the breakthrough devices that received FDA market authorization on or after the MCIT final rule's effective date – March 15, 2021 – breakthrough devices that were approved in the two years prior to the final MCIT rule's effective date will also be eligible for the MCIT Pathway.[24]

Although some commenters expressed a desire for the MCIT Pathway to be available to non-breakthrough medical devices, CMS held the eligibility requirements for the MCIT firm between the proposed and final rule, citing the

immediate need for more rapid approval of breakthrough medical devices while acknowledging the needs to promote innovation of all Medicare eligible items and services.[25]

Coverage under the MCIT Pathway and Beyond

As previously stated, under the MCIT Pathway, device manufacturers will be eligible for nationwide Medicare coverage as early as the same day of FDA market authorization.[26] However, device manufacturers can select the date on which they would like Medicare coverage to begin within two years of FDA market authorization.[27] This will allow manufacturers to align their manufacturing and distribution cycles with the start of their Medicare coverage period.[28]

Medicare coverage under the MCIT Pathway will last for four years.[29] At the end of those four years, innovators can continue Medicare coverage through an NCD, LCDs, or Claim-by-Claim Adjudication.[30]

The MCIT Pathway allows innovators to collect any necessary clinical data to support their application for Medicare coverage post-MCIT, during the four years of pathway participation (while receiving Medicare reimbursement for those devices).[31] Additionally, innovators will be able to begin pursuing an NCD or LCDs during their four years of coverage under the MCIT Pathway, removing the burden of no Medicare coverage (and no reimbursement) from breakthrough-device innovators.[32]

Codifying the Definition of "Reasonable and Necessary"

In addition to establishing the MCIT Pathway, the MCIT final rule codified the definition of "*reasonable and necessary*."[33] In order for an item or service to be covered by Medicare, the item or service in question must be *"reasonable and necessary for the diagnosis or treatment of illness or injury*."[34]

Under the current definition of "*reasonable and necessary*," as defined in the Program Integrity Manual, a service or item is considered "*reasonable and necessary*" if it is: (1) safe and effective; (2) not experimental or investigational; and, (3) appropriate for Medicare beneficiaries.[35]

An item or service is considered appropriate for Medicare beneficiaries if it:

(1) Is provided in compliance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition;
(2) Is provided in a setting appropriate for the patient's medical needs and conditions;
(3) Is ordered and administered by qualified personnel;
(4) Meets but does not exceed the patient's medical need; and,
(5) Provides a similar or greater level of benefit as an existing and available alternative.[36]

The MCIT final rule will not only codify this existing, long standing definition, but will also expand the criteria for "appropriate" items and services.[37] An item or service that does not satisfy the previously-listed criteria will be considered "appropriate" if it is covered under a commercial insurance plan's coverage policy.[38]

The expansion of criterion 3 (an item or service must be appropriate for Medicare beneficiaries) of the "*reasonable and necessary*" definition will expand Medicare beneficiaries' access to medically beneficial items and services by allowing items and services that would not otherwise be eligible for Medicare coverage, to be covered, without compromising the safety of beneficiaries.[39]

Impact of MCIT Final Rule

Medical technology industry stakeholders have voiced support for the new MCIT Pathway since it was first proposed in August 2020.[40] Interest groups, including the Advanced Medical Technology Association (AdvaMed), Medical Device Manufacturers Association (MDMA), and the National Venture Capital Association (NVCA), submitted comments during the comment period, expressing enthusiasm for the new pathway as well as some reservations over the restrictions of coverage under the MCIT Pathway.[41]

Overall, the new MCIT Pathway will allow Medicare beneficiaries to have access to breakthrough medical technology much earlier than they would under the currently available pathways.[42] Additionally, this new pathway will provide much needed predictability to innovators and device manufacturers, and possibly encourage further investment in medical device startups.[43]

The MCIT Final Rule becomes effective on March 15, 2021.[44]

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1 "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary": Final Rule" Federal Register, Vol. 86, No. 9 (January 14, 2021), p. 2987; "CMS unleashes innovation to ensure our nation's seniors have access to the latest advancements" Centers for Medicare & Medicaid Services, January 12, 2021, https://www.cms.gov/newsroom/press-releases/cms-unleashes-innovation-ensure-our-nations-seniors-have-access-latest-advancements (Accessed 1/22/21).
2 "Executive Order 13890 of October 3, 2019: Protecting and Improving Medicare for Our Nation's Seniors" Federal Register, Vol. 84, No. 195 (October 8, 2019), p. 53573.
3 Federal Register, Vol. 86, No. 9 (January 14, 2021), p. 2988.
4 *Ibid*, p. 2987- 2988.
5 This list describes the pathways that are most often available to medical devices, but is not comprehensive of all available Medicare Coverage Pathways.
6 Federal Register, Vol. 86, No. 9 (January 14, 2021), p. 2989.
7 *Ibid*.
8 *Ibid*.
9 *Ibid*.
10 Centers for Medicare & Medicaid Services (CMS), January 12, 2021.
11 *Ibid*.
12 *Ibid*.
13 *Ibid*.
14 *Ibid*.

15 Federal Register, Vol. 86, No. 9 (January 14, 2021), p. 2988.
16 *Ibid*.
17 *Ibid*.
18 *Ibid*.
19 "Breakthrough Devices Program: Guidance for Industry and Food and Drug Administration Staff" U.S. Food & Drug Administration (FDA), December 18, 2018, https://www.fda.gov/media/108135/download (Accessed 1/22/21).
20 *Ibid*.
21 *See* "FDA Breakthrough Devices Program nears 300 designations" By Susan Kelly, MedTechDive, May 27, 2020, https://www.medtechdive.com/news/fda-breakthrough-devices-orteq-archerdx-terumo-thermedical-helius-photopharmics/578562/ (Accessed 1/25/21).
22 Federal Register, Vol. 86, No. 9 (January 14, 2021), p. 2988.
23 Kelly, May 27, 2020.
24 Federal Register, Vol. 86, No. 9 (January 14, 2021), p. 3009.
25 *Ibid*, p. 2991.
26 Centers for Medicare & Medicaid Services (CMS), January 12, 2021.
27 *Ibid*.
28 *Ibid*.
29 Federal Register, Vol. 86, No. 9 (January 14, 2021), p. 2993.
30 *Ibid*.
31 "Proposed Medicare Coverage of Innovative Technology (CMS-3372-P)" Centers for Medicare & Medicaid Services (CMS), August 31, 2020 https://www.cms.gov/newsroom/fact-sheets/proposed-medicare-coverage-innovative-technology-cms-3372-p (Accessed 1/22/21).
32 *Ibid*.
33 Federal Register, Vol. 86, No. 9 (January 14, 2021), p. 2993.
34 Social Security Act (SSA) § 1862(a)(1)(A).
35 Federal Register, Vol. 86, No. 9 (January 14, 2021), p. 2993.
36 *Ibid*.
37 *Ibid*.
38 *Ibid*.
39 *Ibid*.
40 "Re: CMS-3372-P: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" National Venture Capital Association (NVCA), November 2, 2020, available at: https://nvca.org/wp-content/uploads/2020/11/NVCA-CMS-Comments-re-MCIT-Pathway-11022020.pdf (Accessed 1/25/21); "Advanced Medical Technology Association Issues Public Comment on Centers for Medicare & Medicaid Services Proposed Rule" InsuranceNewsNet, November 23, 2020, https://insurancenewsnet.com/oarticle/advanced-medical-technology-association-issues-public-comment-on-centers-for-medicare-medicaid-services-proposed-rule (Accessed 1/25/21); "Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary'' [CMS–3372–P]" Medical Device Manufacturers Association (MDMA), November 2, 2020, available at: https://cdn.ymaws.com/www.medicaldevices.org/resource/resmgr/reimbursement_wg_docs/2020-11-2--_MDMA_to_CMS_Re-_.pdf (Accessed 1/25/21).
41 *Ibid*.
42 Federal Register, Vol. 86, No. 9 (January 14, 2021), p. 2989.
43 National Venture Capital Association (NVCA), November 2, 2020.
44 Federal Register, Vol. 86, No. 9 (January 14, 2021), p. 2987.

New Evidence for Private Payor Savings Through Bundled Payments

[Excerpted from the article published in March 2021.]

A new RAND Corporation study on bundled payments in the private sector was published in the March 2021 issue of Health Affairs.[1] The study analyzed data from over 2,000 procedures performed as part of a direct payment program by Carrum Health between 2016 and 2020,[2] and found significant savings from this bundled payment program, without any significant changes in quality.[3] This study adds important evidence to the argument in favor of bundled payments and is especially important because it examines the under-studied area of bundled payment models from commercial payment systems.

While fee-for-service payments[4] still dominate U.S. healthcare reimbursement models, bundled payments, also known as *episode-based payments*, offer an alternative payment structure that has received increasing attention in recent years, especially from the *Centers for Medicare & Medicaid Services* (CMS).[5] Bundled payments are single payments for all healthcare services corresponding to a specific treatment or condition.[6] Healthcare providers who accept bundled payments from a payor assume the financial risk for all costs of medical services that exceed the bundled payment amount for the particular treatment or condition.[7] Bundled payments operate under the assumption that the model will incentivize providers to lower costs and reduce unnecessary services.[8]

The first modern iteration of bundled payments from CMS was the *Medicare Participating Heart Bypass Center Demonstration*, which took place from 1991 through 1996.[9] The short-lived test, which involved only four hospitals, showed promising results.[10] The hospitals in the program were able to significantly lower costs related to bypass surgery while simultaneously maintaining quality.[11] However, later research into the demonstration project found that cost reductions actually came from nursing management and pharmacy changes.[12] In 2006, bundled payments gained significant attention when Geisinger Health System implemented its "*ProvenCare*" model, which packaged coronary heart bypass surgery into one bundled price.[13] The model proved much more successful than originally anticipated, and with extraordinary quality results, including a significantly shorter length of stay for patients in the model.[14]

The results of the *ProvenCare* program helped spur considerable support for more widespread use of bundling. Over the next ten years, beginning with the 2010 *Patient Protection and Affordable Care Act* (ACA), CMS made significant moves toward bundled payment models.[15] First, CMS created the *Bundled Payments for Care Improvement* (BPCI) Initiative, which created four broad models of care wherein payments are bundled for a particular type of care.[16] Subsequently, CMS implemented a payment system for joint replacement surgery, called the *Comprehensive Care for Joint Replacement*

(CJR) model, in 2016.[17] Joint replacements are the most common surgery among Medicare beneficiaries,[18] and the cost and quality can vary significantly.[19] This model has been relatively less successful, with recent evidence indicating that the only type of CJR model clinical episode that results in cost savings is lower extremity joint replacement.[20] While these savings: were lower than predicted; may be partially explained by participant demographics; and, may hold less benefit for newer program participants, positive early results from bundled payment programs, including overall cost savings to participating hospitals,[21] encouraged CMS to pursue bundled payment models further and create a new BPCI Advanced Model in 2018.[22]

The new RAND study on private bundled payments showed significant cost savings. The mean prices for spinal fusion, joint replacement, and bariatric surgery – the three most common procedures – decreased by 29.1% (from $98,944 to $69,780), 18.4% (from $38,498 to $31,355), and 6% (from $29,225 to $27,625), respectively.[23] Price variation also decreased significantly for all three procedures.[24] A reduction in episode prices of $4,229 was observed for all three procedures, with 85% of these savings going to the self-insured employers. However, both employer and patient spending decreased, with patients seeing the greatest reductions in terms of relative costs.[25] Further, savings grew over time: prices decreased by $4,402 in the first year of implementing the bundled model and by $6,225 in the second year and thereafter.[26] Employers and patients saw a similar rate of decrease over time in their costs, from $3,712 in year one to $5,963 after and from $499 in year one to $550 after, respectively.[27] Researchers tested their hypothesis both with and without accounting for patient-level covariates in their model and observed similar results, suggesting that any patient characteristics that were not accounted for and model choice likely did not confound study results.[28]

Despite the potential cost savings, published research has focused primarily on CMS and public payor programs, leaving private payor bundled payments severely under-studied.[29] This subject has been difficult to research mainly due to a lack of coordinated incentives for providers, payors, and patients which has led to numerous implementation issues.[30] Payment systems have largely been unable to identify providers willing to participate in a bundled payment system, connect willing providers with payors capable of processing these payments, and encourage patients to utilize these bundled arrangements when receiving care.[31] While the potential savings would benefit employers, payors, and patients, the issue of building a solid evidence base becomes a double-edged sword because, according to the RAND study's lead author, "*employers don't want to be the first ones to adopt something this new…[but] if employers aren't clamoring for these types of models and want to pass rising healthcare costs down to employees, there's not a large incentive for private payers to invest in these plans*."[32] Future savings, however, seem to be not just probable, but within reach, for private payors – savings which also will be passed down to employers and patients. As the public market continues to explore new bundled payment models, studies such as RAND's will be integral in encouraging private payors, employers, and patients to follow.

1 "An Employer-Provider Direct Payment Program Is Associated With Lower Episode Costs" By Christopher M. Whaley, et al., Health Affairs, Vol. 40, No. 3 (March 2021), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.01488 (Accessed 3/24/21).
2 *Ibid.*
3 *Ibid.*
4 Fee-for-service payments are those where providers and healthcare systems receive payments for each service performed. *Ibid.*
5 *Ibid*, p. 445.
6 "Analysis of Bundled Payment" RAND Corporation, 2020, https://www.rand.org/pubs/technical_reports/TR562z20/analysis-of-bundled-payment.html (Accessed 3/5/21).
7 *Ibid.*
8 *Ibid.*
9 "Medicare Participating Heart Bypass Center Demonstration" Centers for Medicare and Medicaid Services, 2020, https://innovation.cms.gov/medicare-demonstrations/medicare-participating-heart-bypass-center-demonstration (Accessed 3/5/21).
10 "Medicare Participating Heart Bypass Center Demonstration: Executive Summary Final Report" By Jerry Cromwell, et al., Health Economics Research Inc., July 1998, https://innovation.cms.gov/Files/Migrated-Medicare-Demonstration-x/Medicare_Heart_Bypass_Executive_Summary.pdf (Accessed 3/5/21), p. ES-9 – ES-12.
11 *Ibid*, p. ES-9 – ES-12.
12 RAND Corporation, 2020.
13 "'ProvenCare': a provider-driven pay-for-performance program for acute episodic cardiac surgical care" By AS Casale, et al., Annals of Surgery, Vol. 246, No. 4 (October 2007), p. 613-614.
14 *Ibid*, p. 621-630.
15 "Side-by-side comparison of major health care reform proposals" Henry J. Kaiser Family Foundation, 2010, p. 28.
16 "Bundled Payments for Care Improvement (BPCI) Initiative: General Information" Centers for Medicare and Medicaid Services, 2020, https://innovation.cms.gov/initiatives/bundled-payments/ (Accessed 3/5/21).
17 "Comprehensive Care for Joint Replacement Model" Centers for Medicare and Medicaid Services, January 6, 2020, https://innovation.cms.gov/initiatives/cjr (Accessed 3/5/21).
18 *Ibid.*
19 "A Collaborative Of Leading Health Systems Finds Wide Variations In Total Knee Replacement Delivery And Takes Steps To Improve Value" By Ivan M. Tomek, et al., Health Affairs, June 2012, Vol. 31, No. 6, p. 1329.
20 "The Impact Of Bundled Payment On Health Care Spending, Utilization, And Quality: A Systematic Review" By Rajender Agarwal, et al., Health Affairs, Vol. 39, No. 1 (January 2020), p. 50.
21 "Spending and quality after three years of Medicare's bundled payments for medical conditions: quasi-experimental difference-in-differences study" By Joshua A. Rolnick, et al., British Medical Journal, June 17, 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7298619/ (Accessed 3/5/21).
22 "Spending And Quality After Three Years Of Medicare's Voluntary Bundled Payment For Joint Replacement Surgery" By Amol S. Navathe, et al., Health Affairs, Vol. 39, Issue 1 (January 2020), p. 64; Agarwal, et al., (January 2020), p. 55-56; "BPCI Advanced" Centers for Medicare and Medicaid Services, 2020, https://innovation.cms.gov/initiatives/bpci-advanced (Accessed 3/5/21).
23 Whaley, et al., (2021), p. 448.
24 *Ibid*, p. 448-449.
25 *Ibid*, p. 449
26 *Ibid*, p. 449-450.
27 *Ibid*, p. 450.
28 *Ibid.*
29 *Ibid*, p. 445.
30 *Ibid*.
31 *Ibid*, p. 445-446.
32 "Bundled payments reduce surgery costs by 10.7%" By Alex Kacik, Modern Healthcare, March 1, 2021, https://www.modernhealthcare.com/payment/bundled-payments-reduce-surgery-costs-107 (Accessed 3/5/21).

IPPS and LTCH PPS Proposed for 2022

[Excerpted from the article published in May 2021.]

On April 27, 2021, the *Centers for Medicare & Medicaid Services* (CMS) released its proposed rules for payment and policy updates for the Medicare *Inpatient Prospective Payment System* (IPPS) and the *Long-Term Care Hospital* (LTCH) *Prospective Payment System* (PPS) for fiscal year (FY) 2022.[1] Other than the changes in IPPS and LTCH payment rates, the most notable portion of the proposed rule is the health equity incentives proposed by CMS.[2] Additionally, CMS has proposed to use data from FY 2019 in the 2022 proposed rule because utilization and spending data from FY 2020 may be skewed due to the COVID-19 public health emergency (PHE).[3] This *Health Capital Topics* article discusses the various provisions outlined in CMS's proposed rule.

IPPS Payment Rate Updates

The proposed rule includes an estimated 2.8% total increase in operating payments for general acute care hospitals paid under IPPS if the hospital participates in the *Hospital Inpatient Quality Reporting* (IQR) Program and is a meaningful *electronic health record* (EHR) user.[4] The payment increase is lower than the FY 2021 increase of 3.1%.[5] This percentage increase translates to a growth in Medicare spending on inpatient hospital services of approximately $3.4 billion in 2022, before adjusting for Medicare disproportionate share hospital (DSH) payments and uncompensated Medicare payments.[6] CMS predicts that Medicare DSH and uncompensated care payments by approximately $0.9 billion, resulting in an overall hospital payment increase of $2.5 billion.[7] Other payment adjustments hospitals may be subject to under the proposed IPPS rule include:

(1) "*Payment reductions for excess readmissions under the Hospital Readmissions Reduction Program*;"
(2) "*Payment reduction (1 percent) for the worst performing quartile under the Hospital Acquired Condition Reduction Program*;" and,
(3) "*Upward and downward adjustments under the Hospital Value-Based Purchasing Program*."[8]

LTCH PPS Payment Rate Updates

For 2022, LTCH PPS payments will increase overall by 1.4%, or $52 million, a reversal of last year's decrease of 0.9%.[9] Further, for FY 2022, LTCH discharges paid the standard payment rate are expected to increase by 1.2%, while LTCH discharges paid the site neutral payment are expected to increase by 3%, for FY 2022.[10] LTCH discharges can be paid in one of two ways:

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

ventilator for at least 96 hours, and must have not been assigned to psychiatric or rehabilitation services upon discharge; or,

(2) A site neutral rate – For all other discharges that do not meet the above criteria.[11]

For 2022, discharges paid the site neutral payment will comprise 25% of all LTCH cases and 10% of all LTCH PPS payments, the same composition as in 2021.[12]

New Technology Add-On Payments

In the FY 2021 IPPS Proposed Rule, CMS considered 24 applications for the new technology add-on payments (NTAP) program and approved 13 technologies in the final rule.[13] For FY 2022, CMS proposed to extend NTAP for 14 technologies that would otherwise be discontinued.[14] NTAP is additional reimbursement that provides "add-on" payments (up to 65%) to hospitals for the use of technology that may not be included in the diagnosis-related group bundled payment due to the novelty of that technology.[15] CMS's proposal to extend NTAP for those 14 technologies emanates from concerns related to COVID-19, similar to IPPS data (discussed above).[16] Further, CMS proposed establishing the New COVID-19 Treatments Add-On Payment (NCTAP) to incentivize hospitals to provide new COVID-19 treatments and minimize any payment disruption for inpatient discharges through the end of the COVID-19 PHE.[17]

Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program is a quality reporting program that may reduce payments to hospitals that fail to meet quality reporting requirements.[18] CMS is looking to adopt five new measures, remove five measures, make changes to EHR certification requirements, and adopt outcome measures for COVID-19 mortality and elective total hip and/or knee arthroplasty.[19] The proposed measures to adopt include: Maternal Morbidity Structural measure; a COVID-19 Vaccination Coverage Among Health Care Personnel measure; a Hybrid Hospital-Wide All-Cause Risk Standardized Mortality measure; and two medication-related adverse event electronic clinical quality measures (eCQMs).[20] Additionally, CMS is looking to remove the following five measures: the Death Among Surgical Inpatients with Serious Treatable Conditions measure; the Exclusive Breast Milk Feeding measure; the Admit Decision Time to Emergency Department Departure Time for Admitted Patients measure; and two stroke-related eCQMs.[21]

Additional Proposals – Health Equity

CMS also made a notable proposal seeking stakeholder feedback to closing gaps in health equity related to graduate medical education (GME) and quality programs. First, CMS is looking to distribute 1,000 new Medicare-funded medical residency positions to train physicians under the 2021 *Consolidated Appropriations Act*, a trillion dollar spending bill that seeks to provide economic relief from the COVID-19 PHE.[22] Beginning in FY 2023, 200 residency slots per year will be added, prioritizing those hospitals that serve

populations and demographics with the greatest need.[23] CMS's additional funding for new residency positions added between FY 2023 and FY 2031 is estimated to total $1.8 billion.[24] Second, CMS is seeking to close the health equity gap in quality programs in parallel with President Joe Biden's Executive Order (EO) on Advancing Racial Equity and Support for Underserved Communities.[25] President Biden's EO revoked two of the Trump Administration's EOs that banned diversity and inclusion training for federal employees, and pledged that equal opportunity and diversity would be a primary focus in his next four years.[26] CMS issued a request for information within the proposed rule to stakeholders on ideas to address inequities in health outcomes throughout the U.S. CMS is also exploring collecting a minimum set of demographic data elements from hospitals at the time of patient admission and using electronic data nationwide to move toward developing quality measures.[27]

Conclusion

The American Hospital Association (AHA) quickly expressed their enthusiasm for the health equity programs proposed by CMS, as well as the proposed adjustments to help hospitals financially through the end of the COVID-19 PHE.[28] AHA's Executive Vice President stated that many are applauding the CMS for helping hospitals and health systems after these facilities rose to the challenge of treating COVID-19 patients and saving lives.[29] The Association of American Medical Colleges (AAMC) also expressed support for the GME health equity program, but recommended that no hospital should receive more than one full-time equivalent resident per year.[30] Comments from industry stakeholders on the IPPS and LTCH PPS Proposed Rule are due to CMS by June 28, 2021.[31]

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1 "Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Rates Proposed Rule (CMS-1752-P)" Centers for Medicare & Medicaid Services, April 27, 2021, https://www.cms.gov/newsroom/fact-shescal-year-fy-2022-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care (Accessed 5/6/21).

2 *Ibid.*

3 *Ibid.*

4 *Ibid.*

5 "Fiscal Year (FY) 2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Proposed Rule (CMS-1735-P)" Centers for Medicare & Medicaid Services, May 11, 2020 https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute (Accessed 5/7/21).

6 Centers for Medicare & Medicaid Services, April 27, 2021.

7 *Ibid.*

8 "Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program" May 10, 2021, Federal Register Vol. 86, No. 88,

https://www.govinfo.gov/content/pkg/FR-2021-05-10/pdf/2021-08888.pdf (Accessed 5/13/21), p. 25075-25076

9 Centers for Medicare & Medicaid Services, May 11, 2020.

10 Centers for Medicare & Medicaid Services, April 27, 2021.

11 "Long Term Care Hospitals Payment Systems" Medicare Payment Advisory Commission, October 2018, http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_18_ltch_final_v2_sec.pdf?sfvrsn=0 (Accessed 5/14/21).

12 Centers for Medicare & Medicaid Services, April 27, 2021.

13 Federal Register Vol. 86, No. 88, p. 25074.

14 Centers for Medicare & Medicaid Services, April 27, 2021.

15 Federal Register Vol. 86, No. 88, p. 25074.

16 *Ibid*.

17 *Ibid*.

18 Centers for Medicare & Medicaid Services, April 27, 2021.

19 *Ibid.*

20 Federal Register Vol. 86, No. 88, p. 25562.

21 *Ibid*.

22 *Ibid*, p. 25077, 25083.

23 *Ibid*, p. 25083.

24 Centers for Medicare & Medicaid Services, April 27, 2021.

25 Federal Register Vol. 86, No. 88, p. 25557.

26 "Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" Presidential Actions, January 20, 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/ (Accessed 5/13/21).

27 Centers for Medicare & Medicaid Services, April 27, 2021.

28 "CMS issues hospital IPPS proposed rule for FY 2022" American Hospital Association, April 27, 2021, https://www.aha.org/news/news/2021-04-27-cms-issues-hospital-ipps-proposed-rule-fy-2022#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid,and%20submit%20quality%20measure%20data, (Accessed 5/14/21).

29 *Ibid.*

30 "AAMC Proposes Graduate Medical Education Changes in FY 2022 IPPS Proposed Rule" Association of American Medical Colleges, April 30, 2021, https://www.aamc.org/advocacy-policy/washington-highlights/cms-proposes-graduate-medical-education-changes-fy-2022-ipps-proposed-rule (Accessed 5/14/21).

31 "FY 2022 IPPS Proposed Rule Homepage" CMS, April 27th, 2021, https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-proposed-rule-home-page (Accessed 5/7/21).

Effect of Negative Credit Shocks on Hospital Quality

[Excerpted from the article published in May 2021.]

A recent study from the National Bureau of Economic Research (NBER) indicates that quality and patient outcomes suffer in hospitals that cannot maintain their relationships with banks and their lines of credit.[1] The NBER study measured quality and cost data in Medicare-certified hospitals from 2010 to 2016, during which banks were undergoing annual stress tests.[2] Regulatory "stress tests" are annual assessments from the Federal Reserve, put in place after the Great Recession in 2008, to examine a bank's ability to survive an impending economic crisis.[3] These stress tests caused banks to loan less frequently to risky borrowers, such as hospitals, and when hospitals are extended less credit they must transfer their focus elsewhere to increase profitability.[4] To quickly make up for the credit loss, hospitals look to increase patient volume, which leads to the delivery of less effective care. Other outlets that hospitals consider to stay afloat that may have an effect on quality include seeking investors from private equity firms or merging with large health systems.

Every hospital needs capital to cover their everyday operating costs, to keep up with medical and technological innovations, and to grow their organization.[5] Before starting any new project or program, like any business activity, hospitals must raise the appropriate funding through borrowing or investment. Investor-owned hospitals depend on debt and equity investments, while tax-exempt hospitals rely on partnership and long-term debt in the form of bonds. Banks become less generous to lend money to hospitals when trying to decrease their risk or increase their capital due to hospitals having greater-than-normal yields on municipal bonds.[6] Healthcare municipal bonds, the main source of funding for 70% of hospitals, are the common measure used to study the credit risk of hospitals and help forecast long-term risks.[7]

As noted above, the Federal Reserve completes an annual stress test/assessment of the largest banks to ensure they have a healthy amount of operating capital. Prior to 2008, capital adequacy requirements were fairly lenient – banks only had to hold a minimum level of capital, which was often dependent on the bank's headquarters location. Under the Dodd-Frank Act stress tests (DFAST), large bank holding companies with assets larger than $10 billion undergo assessments that monitor the risk taking and capital adequacy following economic downturns.[8] These regulations were created to assess and disclose to the public a financial institution's ability to survive during credit shocks while absorbing major losses.[9] Institutions that do not pass certain regulations may be penalized by the Federal Reserve due to bankruptcy risks and inability to meet their debt obligations in adverse economic situations. The penalties may be in the form of fines, restrictions from paying dividends, or a moratorium in mergers and acquisitions until they are able to raise their capital requirements.[10] Consequently, the impacts of this "what-if" risk analysis caused banks to reduce

credit to some hospital borrowers (who are considered a riskier lending proposition) or increase interest rates.[11]

When the NBER study initially examined hospitals affected by banks undergoing stress tests from the Federal Reserve, large banks held a majority of the market share for hospital lending.[12] In fact, 26 banks were the lenders to over 500 hospitals at the time of the first DFAST in 2012.[13] Due to the banks restricting risky funding after the Great Recession, hospitals had to switch lenders, spread their debt across multiple sources, and/or increase patient revenues.[14] Consequently, these "credit crunched" hospitals that seek to become more profitable through changes in operations tend to see a decrease in quality or performance outcomes.[15] When hospitals are unable to get outside financing, they seek to grow utilization and increase the amount of revenue generated per patient. However, the NBER study did not find changes in hospital staffing or charge ratios, but rather an increase in bed utilization and increases in the number of services and procedures provided to a patient.[16] More specifically, the NBER study looked at occupancy and discharge rates of inpatient beds, medical staff compensation, and intensive care unit (ICU) bed utilization. In times of a credit shock, it was found that among inpatient services, admissions and length of stay increased; for outpatient services, the number of tests and procedures also increased.[17] Lastly, hospitals reduced less lucrative services such as high utilization of ICU beds, and saw an increase in physicians providing more expensive services or billing services at higher amounts.[18] While these shifts in operations may lead to a decrease in quality outcomes, they can also lead hospitals to overall revenue increases following a negative credit shock.[19]

Lower quality care during a credit shock happens over a broad spectrum of measures, including higher wait times, less effective care, lower patient satisfaction scores, and higher rates of readmission.[20] The NBER study found that hospitals' failure to provide timely interventions increased up to 20%, and almost 1,700 readmissions occurred as a consequence of negative credit shocks.[21] This practice of hospitals increasing their revenues with higher patient admissions and procedure utilization is the antithesis of the movement toward value-based reimbursement models. Further, hospitals have met opposition in trying to cut costs due to the Centers for Medicare & Medicaid Services (CMS) incentivizing quality measures and value based payments under the Patient Protection and Affordable Care Act (ACA).[22] Now, many hospitals have been put in a bind due to Medicare and Medicaid reimbursement becoming more closely tied to quality measures. Hospitals that make up for lost financing from lenders through sacrificing quality will be exposed to Medicare payment reductions and again send them looking for new sources of revenue.[23]

The struggle between hospital financing and quality could ultimately lead hospitals to seek funding from private investors or to merge with other health systems, either of which may also negatively impact quality. Over the past decade, private equity firms have acquired hospitals at an increasing rate, and have strong incentive to improve the efficiency and quality of care, reduce

readmissions, and increase patient satisfaction scores.[24] However, studies have found that while private equity-acquired hospitals may experience an increase in net income and charges per inpatient day post-acquisition, only a subset of quality measures improved.[25] Similarly, a study of hospital mergers found that hospital quality post-transaction stayed relatively similar, but "patient experience" satisfaction scores declined.[26] Other researchers have similarly suggested that while consolidation transactions had no effect on quality, prices increased post-transaction, negatively impacting patient satisfaction and access to care.[27]

Ultimately the NBER study concluded that hospitals, like any other business, must manage a multitude of risks including their clinical outcomes, competitive marketplace, regulatory requirements, reimbursement cuts, and financial risks that follow credit trends.[28] Thus, following a credit shock, banks must narrow their loan portfolio and tag higher interest rates to riskier loans.[29] This places hospitals in the middle of a vicious circle: Their mission and purpose are tied to caring for the community and improving quality for their patients, but an increase in financial pressure may cause them to sacrifice quality for the sustainability of their business.

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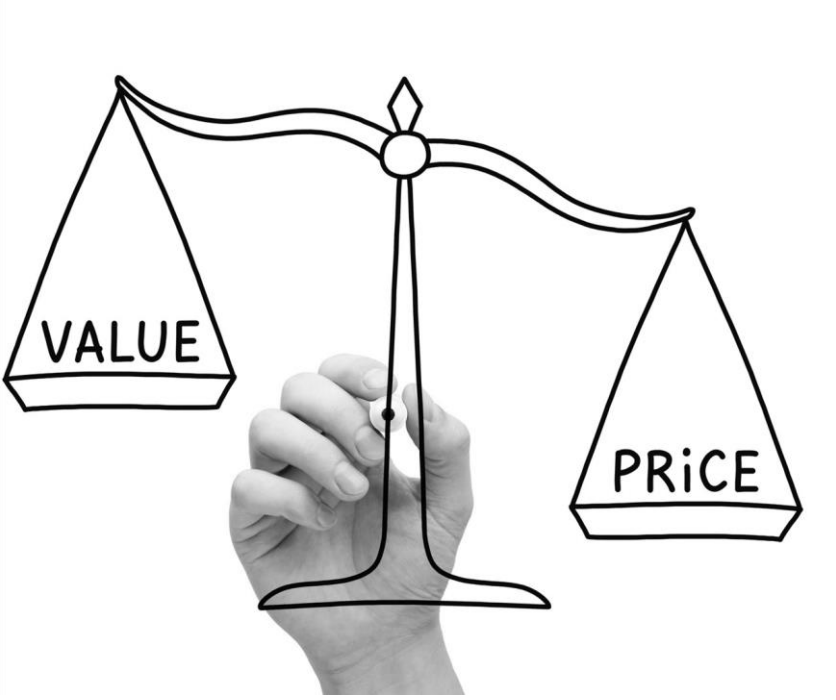
1 "Merchants of Death: The Effect of Credit Supply Shocks on Hospital Outcomes" By Cyrus Aghamolla, et al., NBER Working Paper No. 28709, April 2021, https://www.nber.org/papers/w28709 (Accessed 4/27/21).
2 *Ibid.*
3 "Quality declines when hospitals have trouble borrowing, study finds" By Michael Brady, Modern Healthcare, April 26, 2021, https://www.modernhealthcare.com/finance/quality-declines-when-hospitals-have-trouble-borrowing-study-finds (Accessed 4/27/21).
4 *Ibid.*
5 "Access to capital for hospitals: the realities, the consequences" The Keckley Report, July 23, 2018, https://www.paulkeckley.com/the-keckley-report/2018/7/23/access-to-capital-for-hospitals-the-realities-the-consequences (Accessed 4/27/21).
6 Brady, April 26, 2021.
7 "Good for your Fiscal Health? The Effect of the Affordable Care Act on Healthcare Borrowing Costs" By Pengjie Gao, et al., Comparative Political Economy: Fiscal Policy eJournal (September 30, 2019), available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3458657 (Accessed 4/27/21).
8 Aghamolla, et al., April 2021.
9 "Bank Stress Tests" By Justin Pritchard, The Balance, February 14, 2021, https://www.thebalance.com/what-is-a-bank-stress-test-4165161 (Accessed 4/27/21); "Stress Tests and Capital Planning" Board of Governors of the Federal Reserve System, August 10, 2020, https://www.federalreserve.gov/supervisionreg/stress-tests-capital-planning.htm#:~:text=Dodd%2DFrank%20Act%20stress%20testing,support%20operations%20during%20adverse%20economic (Accessed 4/27/21).
10 Pritchard, February 14, 2021.
11 Aghamolla, et al., April 2021.
12 *Ibid.*
13 *Ibid.*
14 Brady, April 26, 2021.
15 Aghamolla, et al., April 2021.
16 Brady, April 26, 2021.
17 Aghamolla, et al., April 2021.
18 *Ibid.*

19 Brady, April 26, 2021.
20 Aghamolla, et al., April 2021.
21 *Ibid.*
22 "Correlation between hospital finances and quality and safety of patient care" By Dean D. Akinleye, et al., PLOS One, August 16, 2019, https://doi.org/10.1371/journal.pone.0219124 (Accessed 4/27/21).
23 Brady, April 26, 2021.
24 "Private Equity and Hospitals" By Janet Colwell, ACP Hospitalist, December 2020, https://acphospitalist.org/archives/2020/12/private-equity-and-hospitals.htm (Accessed 4/27/21).
25 "Changes in Hospital Income, Use, and Quality Associated With Private Equity Acquisition" By Joseph D. Bruch, et al., JAMA Network, August 24, 2020, https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2769549 (Accessed 5/19/21).
26 "Hospitals Merged. Quality Didn't Improve." By Melanie Evans, Modern Healthcare, January 1, 2020, https://www.wsj.com/articles/hospitals-merged-quality-didnt-improve-11577916000 (Accessed 4/27/21).
27 "Patient satisfaction may decline after hospital acquisition" By Gene Emery, Reuters, January 1, 2020. https://www.reuters.com/article/us-health-hospitals-acquisition/patient-satisfaction-may-decline-after-hospital-acquisition-idUSKBN1Z023K?feedType=RSS&feedName=healthNews (Accessed 4/27/21).
28 "Smart Moves: How Hospitals Manage Risk When Borrowing" By Nick Gesue, Kass Matt, and Lancaster Pollard, Becker's Hospital CFO Report, reprinted from The Capital Issue, July 12, 2013, https://www.beckershospitalreview.com/finance/smart-moves-how-hospitals-manage-risk-when-borrowing.html (Accessed 4/27/21).
29 Aghamolla, et al., April 2021.



Healthcare Costs Projected to Grow in 2022

[Excerpted from the article published in June 2021.]

A June 2021 PricewaterhouseCoopers (PwC) report found that healthcare costs have been on a steady decline for the past decade, but trailing effects from the COVID-19 pandemic could cause increases above anticipated rates over the next several years. In 2007, the annual cost growth for healthcare spending was 11.9% and declined steadily until 2017, where it floated between 5.5% and 6.0% until 2020.[1] However, projected healthcare cost growth for 2022 is expected to reach 6.5% due to factors such as deferred or forgone care, increased mental health issues, preparation for future pandemics, and investment in digital tools.[2] While still lower than the projected 7.0% growth for 2021, 2022's projected cost growth still raises concerns as healthcare expenditures near 20% of the gross domestic product (GDP).[3] This *Health Capital Topics* article will examine the expected inflators and deflators of the cost growth projected for 2022, as well as pertinent medical cost trends.

Higher Utilization Due to Deferred Care

Deferred or forgone care in 2020 during the COVID-19 pandemic caused health spending to be lower than expected. However, with some of that care expected to be returning into 2022, healthcare spending will likely increase. According to a June 2021 PwC Health Research Institute (HRI) study, 15% of Americans deferred some type of care between March and September 2020, along with over half of commercially-insured patients in the U.S. skipping an annual preventative exam.[4] After the economic recession that started in February 2020, the rebound in healthcare spending and utilization could be seen as the healthcare industry regained momentum. However, patients, providers, and payors may experience different spending implications based on the type of care forgone or deferred. First, services that were forgone by patients included: the aforementioned annual preventative care; diagnostic imaging and laboratory testing that may no longer be needed; and, surgery that was replaced with less invasive interventions.[5] These services had decreased utilization and spending in 2020 and thus far 2021, but there will likely be no significant impact in 2022.[6] Second, the HRI report includes necessary, non-urgent procedures that patients deferred and plan to reschedule at a later date. Without this access to care in 2020, spending and utilization were expected to increase in 2021 and again in 2022.[7] Third, higher cost activity will result from deferred care, which will lead to worsening conditions and subsequently require more specialized interventions. Deferred care such as preventative screenings and untreated diabetes will likely increase healthcare utilization and spending due to the deterioration of the patient's condition.[8]

Worsening Population and Mental Health

In addition to deteriorating health conditions that patients may experience due to forgone or deferred care, mental health and the overall health of the population have been negatively affected by the COVID-19 pandemic and are

expected to impact healthcare costs in 2022.[9] A concerning trend looming from COVID-19 is the gaps exposed in the U.S. mental health system. Not only did a majority of Americans report depression or anxiety due to the pandemic, but mental health claims showed a noticeable increase in the past 12 months.[10] Notably, this trend was more pronounced in the teenage and young adult populations.[11] With annual mental health spending already more than $200 billion, worsening mental health among the U.S. population could lead to other health problems and complications, resulting in higher utilization and spending in other lines of care.[12]

The HRI study also found that individuals developed poor health behaviors during the COVID-19 pandemic as a result of stay-at-home orders, quarantines, and isolation.[13] Poor health behaviors can cause direct and indirect costs that can quickly accumulate.[14] Lack of exercise, poor nutrition, cigarette smoking, and abuse of alcohol, opioids, and other substances were behaviors that all increased during the pandemic.[15] When these behaviors become prolonged habits, they can lead to additional health burdens, chronic conditions, and increased healthcare spending for the U.S. as a whole.[16]

Preparations for the Future of COVID-19 and Next Pandemic

Another way cost and utilization are expected to be impacted in 2022 is through the testing, treatment, and vaccination of COVID-19 patients. Health systems are being told to prepare for the possibility of COVID-19 becoming a persistent, seasonal disease.[17] Costs for testing and treating COVID-19 patients are expected to shrink, but it is unclear how long the U.S. government will continue to pay for vaccines, and further, how much manufacturers will charge for them.[18] Even with 52% of Americans fully vaccinated as of June 3, 2021, many will still need seasonal vaccinations or booster shots to ensure herd immunity.[19] These steps still may not prevent winter surges or new variants that continue to appear. Hospitals and health systems may need to plan and budget for seasonal COVID-19 utilization and over-burdened intensive care units in the winter months, along with hospitalizations from other seasonal viruses such as the flu.[20]

Health systems are not only calling for preparation related to seasonal spikes in COVID-19 infections, but also for emergency preparedness related to any future pandemics, after the many burdens experienced by unprepared facilities during the early months of 2020.[21] The HRI study predicts that payors and employers are bracing for increased spending as pandemic readiness is expected to inflate medical cost trends in 2022.[22] After most hospitals, health systems, and other providers experienced a supply chain shortage or disruption during the first wave of COVID-19, many healthcare executives are looking to invest in some type of forecasting.[23] At least 80% of provider executives plan on investing in predictive modeling, with smaller percentages of 31% and 23% planning to invest in scenario planning and simulations, respectively.[24]

In addition to forecasting supply chain disruptions, increased spending typically is required to sustain public health preparedness capabilities.[25] A report from McKinsey & Company estimates the economic disruption from

COVID-19 to amount to over $16 trillion lost in global GDP.[26] Despite those costs, prevention of future pandemics could cost between $85 billion and $130 billion initially, and up to $50 billion per year to sustain these efforts.[27]

Digital Investments

Aside from preparations for seasonal spikes in COVID-19 infections, as well as for future pandemics, providers are using telemedicine investment to diversify sources of revenue and keep relationships with patients. Telemedicine was able to ameliorate some access and cost issues during the pandemic, and providers want to continue to invest in these digital services.[28] While telemedicine utilization is down from its April 2020 levels, it is still significantly higher compared to pre-pandemic levels.[29] Before the onset of COVID-19, telemedicine only accounted for 1% of all physician visits, but has sustained a level of approximately 20% of all physician visits through the end of 2020.[30] With the Centers for Medicare & Medicaid Services (CMS) increasing the number of covered telemedicine services, those utilization rates may be here to stay. While telemedicine has the potential to improve access to healthcare, many patients and physicians have their doubts about diagnoses from telemedicine visits. On one hand, telemedicine's ability to increase access brings more patients into the healthcare system that may not have a pressing need to seek care and creates higher downstream utilization.[31] On the other hand, it may catch patients in earlier stages of chronic conditions, who might have gone to the more expensive emergency department (ED) for treatment when their condition worsened.[32]

Deflators

While there are multiple inflators expected to increase healthcare costs in 2022, value-based care is expected to deflate costs.[33] First, patients are looking to access lower-cost sites of care instead of the hospital, ED, or traditional physician office. Patients are also starting to shop around for care, instead of seeking the nearest, most immediate care. Most notably is the reduction in ED utilization. At the beginning of 2021, ED patient volume was still down a quarter from pre-pandemic levels.[34] Keeping the utilization of this expensive setting down could result in significant cost savings; the HRI study found that a drop of 10% in non-emergency ED visits could save almost $1 billion annually.[35]

Will Anticipated Trends be Inflators or Deflators?

The HRI study's researchers will be keeping an eye on specific trends in 2022 – drug spending, cybersecurity, and surprise billing regulations – to determine whether they are inflators or deflators of healthcare costs.[36] In past years, specialty drug spending was a consistent driver of medical cost trends. More recently, the Food and Drug Administration has approved costly cell and gene therapies, with many more anticipated approvals in the next five years.[37] Cell and gene therapies have major cost implications due to their high price tags, but the ability to treat rare, or previously untreatable, diseases such as Alzheimer's. To put the cost of cell and gene therapy in perspective, nearly two million

people who have been diagnosed with Alzheimer's are covered under Medicare, and one year of the new Alzheimer's drug (Adulhelm) costs $56,000.[38] To cover just a quarter of patients for this treatment would cost Medicare an additional $29 billion annually.[39] The FDA has raised concerns with its hasty approval of Adulhelm, which is expected to increase all prescription drug spending by 8% and non- retail drug spend by 25%.[40] Further, the U.S. expects a boom of biosimilars, prescription drugs that are "copies" of biologic drugs which are made up of living proteins but with slight variations from batch to batch.[41] Biosimilars can be used to treat diseases like arthritis, Crohn's disease, or psoriasis, and are expected to be a relatively cost-effective treatment option, saving upward of $100 billion over the next three years.[42] Another notable trend is the expected rise in cybersecurity costs, as cyberattacks, ransomware attacks, and data breaches on healthcare systems have increased in recent years, and can compromise a health system's ability to effectively operate.[43] Health systems have attempted to stay one step ahead of hackers by employing automated and artificially intelligent systems.[44] Such technology requires a large upfront investment, but many health systems would rather invest in cybersecurity upfront than retrospectively spend (more) money as the result of a breach or attack.[45] Lastly, medical cost trends may be affected by the No Surprises Act, which limits the amount providers may charge patients for "surprise out-of-network" bills.[46] The law, which will take effect at the beginning of 2022, aims to lower premiums and help consumers better anticipate their medical bills.[47] However, because providers will consequently receive smaller, in-network reimbursements, this could lead to increases in arbitrary costs that the patient does not see, such as administrative costs, which would still drive healthcare costs as spending shifts from the patient to the payor.[48]

Conclusion

As the latter half of 2021 approaches, the true medical cost inflators and deflators will become more clear. Experts are predicting that deferred care (which is anticipated to return post-pandemic) will be the main inflator, with poor health outcomes, digital investments, telemedicine utilization, and pandemic preparation not far behind.[49] With health expenditures approaching 20% of the GDP, every healthcare provider will be looking for ways to reduce costs. A notable deflator for 2022 will be the result of patients starting to shop around for care, embracing value-based care, and utilizing the ED less. Trends that could be either inflators or deflators of medical cost trends include cybersecurity, new legislation, and drug spending. While Americans return to some sense of normalcy, COVID-19 is expected to affect the U.S. healthcare industry for years to come.

1 "Medical cost trend: Behind the numbers 2022" PWC Health Research Institute, June 4, 2021, https://www.pwc.com/us/en/industries/health-industries/library/assets/pwc-hri-behind-the-numbers-2022.pdf (Accessed 6/10/21).
2 *Ibid.*
3 Current health expenditures are 17.7% of GDP. "Medical cost trend: Behind the numbers 2022" PWC Health Research Institute, June 4, 2021, https://www.pwc.com/us/en/industries/health-industries/library/assets/pwc-hri-behind-the-numbers-2022.pdf, (Accessed 6/10/21); "NHE Fact Sheet" Centers for Medicare & Medicaid Services, December 16, 2020, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet (Accessed 6/10/21).
4 PWC Health Research Institute, June 4, 2021.
5 *Ibid.*
6 *Ibid.*
7 *Ibid.*
8 *Ibid.*
9 *Ibid*.
10 "The Impact of COVID-19 on Pediatric Mental Health" A FAIR Health White Paper, March 2, 2021, https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/The%20Impact%20of%20COVID-19%20on%20Pediatric%20Mental%20Health%20-%20A%20Study%20of%20Private%20Healthcare%20Claims%20-%20A%20FAIR%20Health%20White%20Paper.pdf (Accessed 6/10/21).
11 PWC Health Research Institute, June 4, 2021.
12 "The ACA at 10: How has it impacted Mental Health Care?" By Jesse Baumgartner et al., the Commonwealth Fund, April 3, 2020, https://www.commonwealthfund.org/blog/2020/aca-10-how-has-it-impacted-mental-health-care (Accessed 6/10/21).
13 PWC Health Research Institute, June 4, 2021.
14 "The Lifetime Costs of Bad Health" By Mariacristina De Nardi, et al., National Bureau of Economic Research, October 2018, https://www.nber.org/system/files/working_papers/w23963/w23963.pdf (Accessed 6/18/21).
15 PWC Health Research Institute, June 4, 2021.
16 *Ibid.*
17 "The Potential Future of the COVID-19 Pandemic: Will SARS-CoV-2 Become a Recurrent Seasonal Infection?" By Christopher J.L. Murray, MD & Peter Piot, MD, JAMA Network, March 3, 2021, https://jamanetwork.com/journals/jama/fullarticle/2777343 (Accessed 6/10/21).
18 PWC Health Research Institute, June 4, 2021.
19 Additionally, 63% of Americans have received at least one shot as of June 3, 2021. "Press Briefing by White House COVID-19 Response Team and Public Health Officials" The White House, June 3, 2021, https://www.whitehouse.gov/briefing-room/press-briefings/2021/06/03/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-40/ (Accessed 6/10/21).
20 "The Potential Future of the COVID-19 Pandemic: Will SARS-CoV-2 Become a Recurrent Seasonal Infection?" By Christopher J.L. Murray, MD & Peter Piot, MD, JAMA Network, March 3, 2021, https://jamanetwork.com/journals/jama/fullarticle/2777343 (Accessed 6/10/21).
21 PWC Health Research Institute, June 4, 2021.
22 *Ibid*.
23 *Ibid*.
24 *Ibid*.
25 "Value-Based Models for Sustaining Emergency Preparedness Capacity and Capability in the United States" By Jesse Pines et al., National Academies of Sciences, Engineering, and Medicine, January 7, 2014, https://www.nap.edu/resource/21809/v2Final-white-paper-Preparedness-FinancingJan14.pdf (Accessed 6/10/21).

26 "Not the last pandemic: Investing now to reimagine public-health systems" By Matt Craven, et al., McKinsey & Company, May 21, 2021, https://www.mckinsey.com/industries/public-and-social-sector/our-insights/not-the-last-pandemic-investing-now-to-reimagine-public-health-systems# (Accessed 6/10/21).
27 *Ibid*.
28 PWC Health Research Institute, June 4, 2021.
29 "How Hospitals are building on COVID-19 telehealth momentum" By Jessica Kim Cohen, Modern Healthcare, December 30, 2020, https://www.modernhealthcare.com/care-delivery/how-hospitals-are-building-covid-19-telehealth-momentum (Accessed 6/10/21).
30 *Ibid.*
31 "Telehealth increases downstream care, study finds" By Alex Kacik, Modern Healthcare, April 20, 2021, https://www.modernhealthcare.com/operations/telehealth-increases-downstream-care-study-finds (Accessed 6/10/21).
32 *Ibid*.
33 PWC Health Research Institute, June 4, 2021.
34 *Ibid*.
35 *Ibid*.
36 *Ibid*.
37 "Medical cost trend: Behind the numbers 2022" PWC Health Research Institute, June 4, 2021, https://www.pwc.com/us/en/industries/health-industries/library/assets/pwc-hri-behind-the-numbers-2022.pdf (Accessed 6/10/21).
38 "FDA's Approval of Biogen's New Alzheimer's Drug Has Huge Cost Implications for Medicare and Beneficiaries" By Juliette Cubanski and Tricia Neuman, Kaiser Family Foundation, June 10, 2021, https://www.kff.org/medicare/issue-brief/fdas-approval-of-biogens-new-alzheimers-drug-has-huge-cost-implications-for-medicare-and-beneficiaries/ (Accessed 6/17/21).
39 *Ibid*.
40 Non-retail drug spending includes any drugs administers by hospitals or doctors. "Perspective: New Alzheimer's Drug is Projected to Increase National Health Expenditures by More Than One Percent" By George Miller, Ani Turner, and Corwin Rhyan, Altarum, June 16, 2021, https://altarum.org/news/new-alzheimer-s-drug-projected-increase-national-health-expenditures-more-one-percent (Accessed 6/17/21).
41 "Biosimilars Explained: Answers to Questions You've Been Asking" GHLF Creaky Joints, December 12, 2021, https://creakyjoints.org/treatment/what-are-biosimilars/ (Accessed 6/10/21).
42 *Ibid*; PWC Health Research Institute, June 4, 2021.
43 PWC Health Research Institute, June 4, 2021.
44 *Ibid*.
45 *Ibid*.
46 "Understanding the No Surprises Act" By Loren Alder et al., Brookings Institution, February 4, 2021, https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/02/04/understanding-the-no-surprises-act/ (Accessed 6/1021).
47 *Ibid*.
48 PWC Health Research Institute, June 4, 2021.
49 *Ibid*.

Next Generation ACO Model to End in 2021

[Excerpted from the article published in June 2021.]

Many accountable care organizations (ACOs) received disappointing news on May 21, 2021, when the Centers for Medicare & Medicare Services (CMS) announced that it would not be extending the Next Generation ACO (NGACO) model for 2022.[1] After five years and a dwindling number of participating ACOs, experts were split on whether or not CMS should keep the model in place for another year.[2] On one hand, stakeholders have argued for the NGACO model's extension until it can be replaced with or integrated into another program; however, others asserted that resources could not be properly invested with only one more year left in the program.[3] This *Health Capital Topics* article will review the background of the NGACO model, its effect on value-based care, thoughts from stakeholders, and plans among these stakeholders moving forward.

Background

The NGACO model was established under the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA), and launched by CMS in January 2016.[4] With 18 initial participating ACOs, the NGACO model built on past ACO experience from the Pioneer Model and Medicare Shared Savings Program (MSSP) and sought to set predictable financial targets, give providers more opportunities to coordinate care to beneficiaries, and ensure high quality care.[5] The number of participating NGACOs increased from its inception until its peak in 2018, with 51 participating ACOs, and has slowly declined over the past few years, to 35 participating ACOs in 2021.[6] In prior years, health systems reported pulling out of the NGACO model due to unachievable savings metrics, such that health systems were unable to earn shared savings payments.[7]

CMS's Center for Medicare & Medicaid Innovation Center (CMMI) created the NGACO model to test if financial incentives and an innovative payment system would provide sustainable utilization of resources, while enhancing quality and coordination of care.[8] The NGACO model is an Advanced Alternative Payment Model (APM) that sought to incentivize eligible physicians to participate in a high risk/high reward system.[9] While it is generally similar to the MSSP, some of the significant differences in the NGACO model include, first, the required risk-sharing arrangements. Under the NGACO model, the shared savings and losses are greater than the MSSP. Second, NGACOs must have at least 10,000 beneficiaries, in contrast to the MSSP's minimum of 5,000 beneficiaries.[10] Third, NGACOs are responsible for the first dollar above or below the discounted benchmark, while the MSSP has a minimum savings rate (MSR) and minimum loss rate (MLR), which provides a buffer for participants, i.e., they are not responsible for the first dollar of savings or losses.[11]

The goal of this approach to pay providers based on quality, rather than quantity, of care attempted to improve health outcomes and lower healthcare expenditures from the original fee-for-service (FFS) Medicare reimbursement model with the following core principles in mind:

(1) "*Protect Medicare fee-for-service beneficiaries' freedom to seek covered items and services from the Medicare-enrolled providers and suppliers of their choice;*
(2) Engaged beneficiaries in their care through benefit enhancements designed to improve the patient experience and reward seeking appropriate care from providers and suppliers participating in ACOs;
(3) Create a financial model with long-term sustainability;
(4) Utilize a prospectively-set benchmark that: (1) rewards quality; (2) rewards both improvement in and attainment of efficiency; and (3) ultimately transitions away from using an ACO's recent expenditures for purposes of setting and updating the benchmark;
(5) Mitigate fluctuations in aligned beneficiary populations and respect beneficiary preferences by supplementing a prospective claims-based alignment process with a voluntary alignment process; and
(6) Smooth ACO cash flow and support investment in care improvement capabilities through alternative payment mechanisms."[12]

Despite these high standards, NGACOs did not deliver as expected. The first three cohorts of ACOs contributed greatly to spending reduction, but after 2017, the model saw no appreciable declines in spending.[13] Meanwhile, in the past five years, quality remained constant with no significant improvements or declines.[14]

Effects on Value-Based Care

While some industry stakeholders are critical of the NGACO model, participating providers have generally been successful operating under the model. First, the NGACO model achieved approximately five times higher savings per beneficiary than MSSP ACOs.[15] Second, the NGACO model has reduced inpatient admissions, reduced total medical expenditures with care management programs, and increased beneficiaries' likelihood to participate in annual wellness visits.[16] Ultimately, NGACOs are fond of the model's high-risk/high-rewards reimbursement structure, in which they can reduce gross beneficiary spending, maintain quality of care, and implement benefit enhancement tools.[17] Specifically, ACOs are attracted to the opportunity to assume 80% to 100% risk of the difference from the calculated benchmark, with caps spanning from 5% to 15% for losses and savings.[18]

Conversely, a report from the National Opinion Research Center (NORC) at the University of Chicago found that the NGACO model's $348.6 million in spending reductions in its first three years was overstated.[19] The NORC report concluded that while the model did have Medicare spending reductions of 0.9%, it actually increased net spending by 0.3% after accounting for shared savings payments.[20] The NORC report also found that the NGACO model had minimal impact in reducing acute care hospital spending and stays, which

account for the largest part of Medicare Part A and B spending.[21] Additionally, many of the NGACO model participants were originally participants in the Pioneer Model or MSSP (i.e., had prior ACO experience).[22] NORC asserts that these reported spending improvements are modest in consideration of the amount of time these providers have participated in ACO models; in other words, these more mature ACOs should be able to generate more savings and achieve higher quality metrics than they actually did in the NGACO model.[23]

Thoughts from Stakeholders

Many organizations were extremely upset about the decision to end the program a year early. However, this news should not have come as a surprise. NGACOs were reportedly told in early 2020 that the model would be discontinued at the end of that year.[24] Not long after, the COVID-19 pandemic struck and in June 2020, CMS decided to extend the program for an additional year to reduce the burden on healthcare providers, who were responding to the public health crisis.[25] In April 2021, 14 industry stakeholders wrote to the Secretary of the U.S. Department of Health & Human Services (HHS) urging HHS to extend and reevaluate the NGACO model.[26] Notable healthcare provider associations, such as the Association of American Medical Colleges, American Hospital Association, and American Medical Group Association, as well as other industry players, claimed that the NGACO model had been successful in lowering Medicare spending and improving quality for beneficiaries over the past several years.[27] Further, these organizations asserted that it would be unfair to end the program suddenly, as many organizations have invested greatly in the program over the past five years, and because ACOs needed to apply to other ACO payment models a year ago to be eligible for the 2022 performance year.[28] Organizations have subsequently had to scramble to demonstrate that they meet qualifications for CMS's other risk-based models, such as the Global and Professional Direct Contracting (GPDC) Model, by June 14, 2021, or be moved into the MSSP, both of which models provide less flexibility than the NGACO model to adjust downstream payments.[29]

ACOs Moving Forward

In ending the NGACO model, CMS wants these ACOs to leverage their experience and operational capabilities in the GPDC model, which began in 2020 with an "implementation period" (where participants could begin aligning beneficiaries prior to the start of the first performance year) and commenced its first participation year on April 1, 2021.[30] GPDC is a risk-sharing model that focuses less on quality measures and more on outcomes and beneficiary experience.[31] Additionally, direct contracting entities (DCEs)[32] will focus their value-based plans on beneficiaries with complex chronic conditions.[33] DCEs have two voluntary risk-sharing options under the GPDC Model:

(1) Professional, which offers a low risk-sharing arrangement (50% savings/losses) and provides payment through a capitated, risk-adjusted, monthly plan for primary care services provided by the DCE called Primary Care Capitation (PCC).[34]

(2) Global, which offers the high risk-sharing option (100% savings/losses) and has two payment options available: PCC, as described above, and Total Care Capitation, where payment is provided through a capitated, risk-adjusted, monthly plan for all services provided by the DCE.[35]

The NGACO model was a program built on the lessons learned from previous attempts by CMS to transition healthcare payments away from volume-based, FFS reimbursement to payments based on high-quality, cost-effective care. While the NGACO model has had notable improvements over previous ACO model iterations, the program has its own shortcomings. CMS's decision to end the NGACO model is simply the next step in CMS's journey from *volume*-based to *value*-based reimbursement, wherein the agency continues to test and tweak various payment models to find a sufficient balance between high-quality and low-cost care while giving providers a sufficient number of value-based payment model choices in which to participate.

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1 "Next Generation ACO Model" Centers for Medicare & Medicaid Services, May 28, 2021, https://innovation.cms.gov/innovation-models/next-generation-aco-model (Accessed 6/1/21).

2 *Ibid.*

3 "CMS won't extend the Next Generation ACO Model through 2022" By Michael Brady, Modern Healthcare, May 21, 2021, https://www.modernhealthcare.com/payment/cms-wont-extend-next-generation-aco-model-through-2022?utm_source=modern-healthcare-daily-finance-friday&utm_medium=email&utm_campaign=20210521&utm_content=article3-headline (Accessed 6/1/21).

4 "Next Generation Accountable Care Organization (ACO) Model Fact Sheet" Center for Medicare & Medicaid Innovation, May 28, 2021, https://innovation.cms.gov/files/fact-sheet/nextgenaco-fs.pdf (Accessed 6/1/21).

5 *Ibid.*

6 *Ibid.*

7 "Seven ACOs drop out of NGACO, but don't say why" By Susan Morse, Healthcare Finance News, March 26, 2018, https://www.healthcarefinancenews.com/news/seven-acos-drop-out-next-generation-program-dont-say-why (Accessed 6/2/21).

8 "Next Generation ACO Model" Centers for Medicare & Medicaid Services, May 28, 2021.

9 Under the APM, physicians may become Qualified APM Participants (QPs) by meeting specific criteria such as using certified electronic health record technology, and providing payment for covered professional services. When QPs achieve the specific criteria, they receive benefits such as exclusion from the Merit-Based Incentive Payment System (MIPS) reporting requirements, a 5% APM incentive payment adjustment, and other APM-specific awards. "Next Generation Accountable Care Organization (ACO) Model Fact Sheet"; "Advanced Alternative Payment Models (APMs)" Quality Payment Program, Centers for Medicare & Medicaid Services, 2021, https://qpp.cms.gov/apms/advanced-apms (Accessed 6/2/21).

10 "Next Generation Accountable Care Organization (ACO) Model Fact Sheet" Center for Medicare & Medicaid Innovation, May 28, 2021.

11 "This NAACOS ACO comparison chart details the main elements of the three tracks in the Medicare Shared Savings Program and the Next Generation ACO model." National Association of ACOs, https://www.naacos.com/assets/docs/news/revisedsummaryaco-comparisonchart.pdf (Accessed 6/9/21); "ACO minimum savings/(loss) rates: Less is more?" By Charlie Mils and Chris Smith, Milliman, February 2020, https://us.milliman.com/-/media/milliman/pdfs/articles/aco_minimum_savings_loss_rates-less_is_more.ashx (Accessed 6/17/21).

12 for Medicare & Medicaid Innovation, May 28, 2021.

13 "Next Generation Accountable Care Organization (NGACO) Model; Findings at a Glance" Center for Medicare & Medicaid Services, August 31, 2020, https://innovation.cms.gov/data-and-reports/2020/nextgenaco-thirdevalrpt-ataglance (Accessed 6/1/21).
14 "Third Evaluation Report: Next Generation Accountable Care Organization Model Evaluation" National Opinion Research Center at the University of Chicago, September 2020, https://innovation.cms.gov/data-and-reports/2020/nextgenaco-thirdevalrpt-fullreport (Accessed 6/1/21).
15 "Impact of the Next Generation ACO Model" The Health Care Transformation Task Force, January 22, 2021, https://hcttf.org/wp-content/uploads/2021/01/HCTTF-Assessment_Impact-of-the-Next-Generation-ACO.pdf (Accessed 6/1/21).
16 *Ibid.*
17 "No Extension for Next Generation ACO Model After This Year" By Jacqueline LaPointe, RevCycle Intelligence, May 24, 2021, https://revcycleintelligence.com/news/no-extension-for-next-generation-aco-model-after-this-year (Accessed 6/1/21).
18 National Opinion Research Center at the University of Chicago, September 2020.
19 *Ibid.*
20 "CMS' Next Generation ACO Model to end this year" By Anuja Vaidya, Med City News, May 24, 2021, https://medcitynews.com/2021/05/cms-next-generation-aco-model-to-end-this-year/?rf=1 (Accessed 6/1/21).
21 National Opinion Research Center at the University of Chicago, September 2020.
22 *Ibid.*
23 *Ibid.*
24 "ACOs warn future of Next Gen program appears bleak" By Robert King, Fierce Healthcare, February 4, 2020, https://www.fiercehealthcare.com/payer/future-next-gen-acos-appears-bleak-critical-report-emergence-direct-contracting (Accessed 6/2/21).
25 "CMS Extends Next Gen ACO Model for 2021" NextGen ACO Coalition, June 3, 2020, https://nextgencoalition.org/news/cms-extends-next-gen-aco-model-for-2021/ (Accessed 6/17/21).
26 "Re: Extending the Next Generation Accountable Care Organization Model" Association of American Medical Colleges et al., April 12, 2021, https://www.aha.org/system/files/media/file/2021/04/aha-others-urge-hhs-to-extend-next-generation-aco-model-letter-4-12-2021.pdf (Accessed 6/1/21).
27 *Ibid.*
28 *Ibid.*
29 Brady, May 21, 2021.
30 "Global and professional Direct Contracting (GPDC)" Centers for Medicare & Medicaid Services, April 8, 2021, https://innovation.cms.gov/innovation-models/gpdc-model (Accessed 6/2/21).
31 *Ibid.*
32 Under the GPDC model, a DCE is "an ACO-like organization, comprised of health care providers and suppliers, operating under a common legal structure, which enters into an arrangement with CMS and accepts financial accountability for the overall quality and cost of medical care furnished to Medicare FFS beneficiaries aligned to the entity." "Direct Contracting Model: Professional and Global Options Model Overview Webinar" Centers for Medicare & Medicaid Services and Center for Medicare and Medicaid Innovation, December 11, 2019, https://innovation.cms.gov/files/slides/dc-model-options-overviewalignment-slides.pdf (Accessed 6/17/21), p. 12.
33 Centers for Medicare & Medicaid Services, April 8, 2021.
34 *Ibid.*
35 *Ibid.*

CMS Releases CY 2022 Physician Fee Schedule Proposed Rule

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On July 13, 2021, the Centers for Medicare & Medicaid Services (CMS) released its proposed Medicare Physician Fee Schedule (MPFS) for calendar year (CY) 2022. In addition to numerous payment updates in the MPFS, such as significant updates to the Merit-based Incentive Payment System (MIPS), new policies may preserve expanded telemedicine services through 2023 and clinicians may incur more difficulty earning bonuses under the Quality Payment Program (QPP) eligibility threshold. CMS also includes in the proposed rule a request for information (RFI) to address COVID-19 vaccine reimbursement proposals.

Payment Rate Updates for MPFS

In the 2021 MPFS final rule, CMS decreased the conversion factor to $34.89 (a nearly 7% reduction) compared to the 2020 conversion factor.[1] For 2022, CMS proposes to decrease the conversion factor by $1.31, to $33.58 (a 3.89% reduction).[2] Conversion factors are applied to relative value units (RVUs), i.e., the resources required to furnish a service, to become payment rates. Payment rate decreases for CY 2022 emanate from the one-time policy changes implemented last year.[3] For 2021, CMS *decreased* the conversion factor by over 10%, but it was offset by the Consolidated Appropriations Act of 2021 (CAA), which *increased* the conversion factor by 3.75% for 2021 only.[4]

The proposed conversion factor decrease for 2022 may have a less severe effect on specialties than the 2021 conversion factor decrease, with most payment changes increasing or decreasing no more than 2%.[5] Even though payment changes were modest for the majority of specialties, certain specialties could experience large payment reductions in 2022.[6] These reductions reflect budget-neutrality adjustment requirements[7] and increases in clinical labor pricing, which lower payments to specialties that utilize expensive equipment, such as interventional radiology. Conversely, primary care had historic boosts in the CY 2021 MPFS, which persist in the CY 2022 proposed fee schedule with 1-2% payment increases.[8] The table below summarizes the most significant proposed payment increases and decreases:

Proposed MPFS Payment Rate Changes for CY 2022[9]

Physician Specialty	Percent Change from CY 2021
Interventional Radiology	-5%
Oral Surgery	-4%
Portable X-Ray Supplier	+10%
Radiation Oncology	-5%
Vascular Surgery	-4%

Telemedicine Changes

CMS also proposes to allow certain telemedicine services to be covered under Medicare until December 31, 2023, as opposed to the calendar year in which COVID-19 ends.[10] While some patients, providers, and lawmakers seek to make these added services permanent, CMS claims it does not have sufficient information regarding the effects of expanding telemedicine services on Medicare and its beneficiaries.[11] CMS's goal in extending coverage for these services through 2023 is to alleviate the concerns of patients and providers that services would be ended abruptly, by creating a "glide path" while CMS gathers information and decides whether to add certain telemedicine services permanently.[12]

Additionally, CMS is proposing updates to several regulatory restrictions and requirements for telemedicine services. While CMS has sought to permanently expand some telemedicine services, expansion on a large scale would require action from Congress.[13] CMS proposes to permanently allow rural and underserved Medicare beneficiaries to access telemedicine services from their homes, which could prevent geographical access barriers, and is proposing to allow audio-only communication technology when used for the diagnosis, evaluation, or treatment of mental health disorders.[14] Previously, Medicare was unwilling to cover audio-only telemedicine services due to overutilization concerns. With the widespread use during the COVID-19 pandemic, clinicians realized that the visualization aspect of mental healthcare visits may not be critical.[15] Audio-only flexibility for mental health services may help to alleviate the shortage of mental health professionals and remove access barriers, such as those with poor bandwidth infrastructure and Medicare individuals who are not capable of (or do not consent to) audio-visual interaction with their clinician.[16]

Proposed Updates to QPP

Clinicians must participate in one of two quality incentivized programs under the QPP: default MIPS or voluntary Advanced Alternative Payment Models (APMs).[17] MIPS-eligible clinicians are subject to a payment adjustment based on their performance across four weighted categories: Cost, Quality, Improvement Activities, and Promoting Interoperability.[18] For CY 2022, CMS proposes to update the weights of the performance categories as follows: 30% for the Cost performance category (previously 20%); 30% for the Quality performance category (previously 40%); 15% for the Improvement Activities performance category (same as prior year); and 25% for the Promoting Interoperability performance category (same as prior year).[19] The total MIPS score (i.e., the performance threshold) is determined from these weighted categories, and any score above or below the threshold results in positive or negative adjustments, respectively. The threshold is determined from the mean MIPS performance score two years prior to the payment adjustment year.[20] For CY 2022 performance and CY 2024 payment, CMS proposes to increase the threshold from 60 to 75 points, meaning that it will be more difficult for clinicians to receive a positive payment adjustment.[21]

In the CY 2021 final rule, CMS introduced a replacement to the current MIPS framework, intending to move away from siloed reporting measures and focus on activities that are meaningful to a clinician's practice through the new MIPS Value Pathways (MVPs).[22] In the CY 2022 proposed rule, CMS introduces seven MVPs that would be available beginning with the 2023 performance year, which include: rheumatology; stroke care and prevention; heart disease; chronic disease management; emergency medicine; lower extremity joint repair; and, anesthesia.[23] CMS aims to sunset the current MIPS approach by the 2027 performance year, and is seeking stakeholder feedback on whether to similarly mandate participation in MVP.[24]

Besides the default MIPS track, eligible clinicians can choose to participate in Advanced APMs and avoid the MIPS reporting requirements and payment adjustments.[25] Participating clinicians that achieve qualifying APM status, also known as qualifying participants (QPs), can receive a 5% payment bonus during the corresponding payment year through CY 2024.[26] Clinicians that meet a slightly lower threshold qualify for Partial QP status, in which clinicians are exempt from reporting requirements, but do not qualify for payment incentives.[27] CMS proposes changes to increase physician participation and continue developing opportunities in Advanced APMs.[28] Specifically, CMS proposes changes to the conditions of a financial relationship and the formula for calculating the amount of compensation per unit for value-based arrangements.[29] CMS is motivated to make these changes to increase participation in value-based arrangements after finalized changes to the Stark Law[30] waived certain value-based arrangements between physicians and providers (e.g. Advanced APMs).[31]

Other Changes

First, CMS is proposing changes to non-physician practitioner (NPP) billing regulations, allowing providers such as physician assistants to bill Medicare directly for their services and reassign their rights to payment and benefits to any employer, facility, hospital, or physician group beginning January 1, 2022.[32] Further, CMS proposes that in evaluation and management settings, the provider who performs the majority of the work during split visits (e.g., a patient visit wherein both a physician and an NPP performs portions of the visit) will bill Medicare, which gives NPPs more autonomy for billing purposes.[33] Currently, both the physician and the NPP must bill Medicare if the NPP performs a majority of the visit, and the physician will bill Medicare if they perform a substantive portion of the visit or service.[34]

Second, CMS is proposing updates to the Medicare Shared Savings Program (MSSP) to give accountable care organizations (ACOs) more time to transition to electronic reporting. Initially set to begin in 2022, CMS proposes to allow ACOs to continue using the web interface reporting option until 2023 and phase in the new electronic clinical quality measure reporting requirement over the following three years.[35]

Third, CMS plans to grow the Medicare Diabetes Prevention Program (MDPP) expanded model, which aims to help people with prediabetes avoid developing

Type 2 Diabetes.[36] During COVID-19, CMS waived enrollment application fees and saw an increase in supplier enrollment.[37] For CY 2022, CMS plans to waive the enrollment application fee for all organizations that enroll in Medicare as an MDPP supplier on or after January 1, 2022.[38] CMS also proposes to improve patient access and program sustainability by replacing the current maintenance sessions phase with a one-year prevention program service period.[39]

COVID-19 Vaccine Request for Information

Before COVID-19, Medicare payment rates for physicians and mass immunizers administering preventative vaccines for illnesses such as the flu, pneumonia, and hepatitis B, had decreased by approximately 30%.[40] With growing stakeholder interest in public health due to the COVID-19 pandemic, CMS is seeking information on costs to determine payment rates for these services. Specifically, they are seeking information on:

(1) "The different types of health care providers who furnish vaccines and how have those providers changed since the start of the pandemic.

(2) How the costs of furnishing flu, pneumococcal, and hepatitis B vaccines compare to the costs of furnishing COVID-19 vaccines, and how costs may vary for different types of health care providers.

(3) How the COVID-19 [public health emergency] may have impacted costs, and whether health care providers envision these costs to continue."[41]

Comments from Stakeholders

Many stakeholders were quick to criticize and call on congressional intervention to prevent the nearly 4% reduction in the proposed conversion factor. The American College of Surgeons (ACS) claims that these reductions threaten patients' health equity and access, and they propose to stop annual reductions that restrict patient care altogether.[42] ACS expressed that the proposed conversion factor does not keep up with inflation and could negatively impact certain specialties, especially surgical procedures. Additionally, organizations such as the American Medical Association (AMA) and American College of Emergency Physicians opposed the payment cuts, urging Congress to extend the 3.75% increase under the CAA into 2022.[43]

The American Hospital Association (AHA) and AMA support CMS's expansion of telemedicine services beyond the end of the public health emergency. AMA further demonstrated their support by sharing findings from a COVID-19 Healthcare Coalition Telehealth Impact Study, which found that telemedicine has not increased patient visits and has served as a substitute for costly, in-person visits where patients would have visited urgent care clinics or emergency departments.[44] However, the Medicare Payment Advisory Commission (MedPAC)[45] urged Congress to be cautious of expanding telemedicine services permanently, expressing concern that CMS does not have enough information about how those expanded telemedicine services affect Medicare and its beneficiaries, healthcare access, and quality of care.[46]

Conclusion

While proposed payment changes in the CY 2022 MPFS were not well-accepted by stakeholders, many applauded CMS for extending telemedicine services and considering permanent retention of some of these changes as a way to improve health equity and patient access.[47] Changes made to the MPFS during COVID-19 helped to accelerate telemedicine utilization far beyond pre-pandemic levels. Now, Congress is seeking to further expand telemedicine and solidify its future in the healthcare industry. Currently, over 30 telemedicine bills have been introduced in the House and the Senate. CMS is open to comments and information on requested topics until September 13, 2021.[48]

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1 "Calendar Year (CY) 2022 Medicare Physician Fee Schedule Proposed Rule" Centers for Medicare & Medicaid Services, July 13, 2021, https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2022-medicare-physician-fee-schedule-proposed-rule (Accessed 7/14/21).

2 "CMS Releases CY 2022 Proposed Rule for Physician Fee Schedule Payments" American Hospital Association, July 14, 2021, https://www.aha.org/system/files/media/file/2021/07/cms-releases-cy-2022-proposed-rule-for-physician-fee-schedule-payments-bulletin-7-14-21.pdf (Accessed 7/15/21), p. 2.

3 *Ibid.*

4 Centers for Medicare & Medicaid Services, July 13, 2021.

5 "Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc." Federal Register, Vol. 86, No. 139, July 23, 2021, https://www.govinfo.gov/content/pkg/FR-2021-07-23/pdf/2021-14973.pdf (Accessed 7/26/21), p. 39122-39123.

6 *Ibid*.

7 Adjustments must remain budget neutral, which means that if some procedure codes are increased in value so that RVU expenditures differ by more than $20 million annually, other codes must consequently be reduced. "CMS Proposes Cut to 'Conversion Factor' in Medicare Physician Fee Schedule" By Joyce Frieden, Med Page Today, July 14, 2021, https://www.medpagetoday.com/practicemanagement/reimbursement/93577 (Accessed 7/19/21).

8 Federal Register, Vol. 86, No. 139, July 23, 2021, p. 39122-39123.

9 *Ibid*.

10 Centers for Medicare & Medicaid Services, July 13, 2021.

11 "MedPAC cautious on permanent telehealth expansion" By Michael Brady, Modern Healthcare, March 15, 2021, https://www.modernhealthcare.com/payment/medpac-cautious-permanent-telehealth-expansion (Accessed 7/14/21).

12 "CMS Proposes Physician Payment Rule to Improve Health Equity, Patient Access" Centers for Medicare & Medicaid Services, July 13, 2021, https://www.cms.gov/newsroom/press-releases/cms-proposes-physician-payment-rule-improve-health-equity-patient-access (Accessed 7/14/21).

13 "Medicare telehealth access preserved in physician pay rule—for now" By Michael Brady, Modern Healthcare, July 13, 2021, https://www.modernhealthcare.com/payment/medicare-telehealth-access-preserved-physician-pay-rule-now (Accessed 7/14/21).

14 Federal Register, Vol. 86, No. 139, July 23, 2021, p. 39224.

15 "CMS to Permanently Cover Audio-Only Telemedicine" By Kara Schoonover and Nathaniel Lacktman, Foley & Lardner, July 21, 2021, https://www.foley.com/en/insights/publications/2021/07/cms-cover-audio-only-telemedicine-mental-health (Accessed 7/22/21).

16 Centers for Medicare & Medicaid Services, July 13, 2021, https://www.cms.gov/newsroom/press-releases/cms-proposes-physician-payment-rule-improve-health-equity-patient-access (Accessed 7/14/21).
17 "Quality Payment Program Overview" Centers for Medicare & Medicaid Services, January 1, 2017, https://qpp.cms.gov/about/qpp-overview (Accessed 7/22/21).
18 Federal Register, Vol. 86, No. 139 (July 23, 2021), p. 39349.
19 "Traditional MIPS Overview" Centers for Medicare & Medicaid Services, updated July 13, 2021, https://qpp.cms.gov/mips/traditional-mips (Accessed 7/14/21); Federal Register, Vol. 86, No. 139 (July 23, 2021), p. 39349.
20 For instance, performance year 2019 would be paid in 2021 due to the lag between QPP's performance period and the payment year. Federal Register, Vol. 86, No. 139, July 23, 2021, p. 39349.
21 *Ibid*.
22 *Ibid*.
23 American Hospital Association, July 14, 2021, p. 6.
24 *Ibid.*
25 Federal Register, Vol. 86, No. 139 (July 23, 2021), p. 39337.
26 *Ibid*.
27 "Partial Qualified Participants (QP) Status," American Hospital Association, January 8, 2018, https://www.aha.org/other-resources/2018-01-08-partial-qualified-participants-qp-status (Accessed 7/14/21).
28 Federal Register, Vol. 86, No. 139 (July 23, 2021), p. 39323.
29 *Ibid*, p. 39323-39324.
30 The Stark Law prohibits physicians from self-referring Medicare beneficiaries to entities with which they have a financial relationship. The majority of the revised Stark Law went into effect on January 19, 2021 and included additional exceptions to encourage physicians to create and enter into arrangements that promote coordinated care without fear of violating the physician self-referral law. "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 85, No. 232, December 2, 2020, p. 77492-77493.
31 Federal Register, Vol. 86, No. 139 (July 23, 2021), p. 39323-39324.
32 *Ibid*, p. 39204-39205.
33 Centers for Medicare & Medicaid Services, July 13, 2021, https://www.cms.gov/newsroom/press-releases/cms-proposes-physician-payment-rule-improve-health-equity-patient-access (Accessed 7/19/21).
34 Federal Register, Vol. 86, No. 139 (July 23, 2021), p. 39204-39205.
35 *Ibid*, p. 39552.
36 *Ibid*, p. 39303-39304.
37 Centers for Medicare & Medicaid Services, July 13, 2021, https://www.cms.gov/newsroom/press-releases/cms-proposes-physician-payment-rule-improve-health-equity-patient-access (Accessed 7/14/21).
38 Federal Register, Vol. 86, No. 139 (July 23, 2021), p. 39304.
39 *Ibid*, p. 39304.
40 Centers for Medicare & Medicaid Services, July 13, 2021.
41 *Ibid.*
42 "American College of Surgeons wants Congress to intervene in Medicare payments" By Nathan Eddy, Healthcare Finance, July 16, 2021, https://www.healthcarefinancenews.com/news/american-college-surgeons-wants-congress-intervene-medicare-payment-freeze (Accessed 7/16/21).
43 "July 16, 2021: National Advocacy Update" American Medical Association, July 16, 2021, https://www.ama-assn.org/health-care-advocacy/advocacy-update/july-16-2021-national-advocacy-update (Accessed 7/16/21); "Another Major Regulation Released: CMS Issues the 2022 Physician Fee Schedule Proposed Reg" By Jeffery Davis, American College of Emergency Physicians, July 15, 2021**,** https://www.acep.org/federal-advocacy/federal-advocacy-overview/regs--eggs/regs--eggs-articles/regs--eggs---july-15-2021/ (Accessed 7/16/21).
44 American Medical Association, July 16, 2021.

45 MedPAC is an agency established by the Balanced Budget Act of 1997 and funded by U.S. taxpayers to advise Congress and CMS on issues affecting the Medicare program. "About MedPAC" Medicare Payment Advisory Commission, http://www.medpac.gov/-about-medpac- (Accessed 7/26/21).
46 Brady, July 13, 2021.
47 "The Good and Bad of the Medicare Physician Fee Schedule" By Jacqueline LaPointe, Revcycle Intelligence, July 14, 2021, https://revcycleintelligence.com/news/the-good-and-bad-of-the-medicare-physician-fee-schedule-proposal (Accessed 7/14/21).
48 Brady, July 13, 2021.

CMS Includes Several Changes in CY 2022 OPPS Proposed Rule

[Excerpted from the article published in July 2021.]

On July 19, 2021, the Centers for Medicare & Medicaid Services (CMS) released the proposed rule for the Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Centers (ASCs) for calendar year (CY) 2022. The proposed rule builds on President Joe Biden's July 9, 2021 executive order on "Promoting Competition in the American Economy," as it relates to increasing access and price transparency in the healthcare industry.[1] In a press release regarding the proposed rule, CMS stated their commitment to addressing the persistent health inequities in the U.S. and finding opportunities to improve data collection that will lead to policy changes to help meet the health needs of patients.[2] This year, the rule specifically proposes to increase outpatient payments, increase price transparency, reverse the elimination of the inpatient-only (IPO) list, and update the ASC-covered procedure list.

Payment Rate Updates

For CY 2022, CMS proposes to increase OPPS payment rates to hospital outpatient departments (HOPD) that meet specific quality reporting criteria by 2.3% – calculated from the proposed hospital inpatient market basket percentage increase of 2.5% *minus* the proposed productivity adjustment of 0.2%.[3] However, CMS proposes to continue the 2% statutory reduction for hospitals that fail to meet certain quality reporting requirements by applying a 0.9805 factor (also called "reporting factor") to all payments and copayments.[4] CMS estimates that it will provide approximately $82.7 billion in total payments to OPPS providers in 2022, a $10.8 billion increase from 2021.[5]

ASCs that meet the required quality criteria will also receive proposed payment rate increases of 2.3%, by way of the same calculation described above for OPPS payment rates.[6] CMS estimates that it will provide approximately $5.16 billion in total payments to ASCs in 2022, a $20 million decrease from 2021 Medicare payments.[7]

Price Transparency

On January 1, 2021, the Hospital Price Transparency Final Rule went into effect, wherein all U.S. hospitals are required to provide online pricing information in a clear, accessible manner and make the information available in two ways: "as a comprehensive machine-readable file with all items and services," *and* "in a display of shoppable services in a consumer-friendly format."[8] The Hospital Price Transparency Final Rule was prompted by provisions in the Patient Protection and Affordable Care Act (ACA) and an executive order from former President Trump on "Improving Price and Quality Transparency."[9] An economic report to the former president found that less than half of healthcare services are "shoppable," meaning consumers were likely not able to compare and choose providers based on price and quality or determine when and where they could receive care.[10] The opaque nature of

pricing and quality in the U.S. healthcare market has often been viewed as a market failure, preventing consumers from making an educated decision and consequently hindering competition.

Several months after the Hospital Price Transparency Final Rule took effect, current President Biden issued an executive order on "Promoting Competition in the American Economy" that addressed price transparency and increasing competition in the U.S. healthcare sector.[11] While the order did not change any current laws, it did direct the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) to address the lack of competition that has led to price increases and quality decreases.[12]

Consequently, in its CY 2022 proposed rule, CMS is taking into consideration not only Biden's executive order but also comments from patients that hospitals have not complied with the Hospital Price Transparency Final Rule since the beginning of 2021.[13] First, CMS explained their concern that hospitals may be embedding code in their web pages to prevent them from being indexed by search engines.[14] CMS proposes to prohibit the use of "blocking codes" or any methods that prevent search engines from displaying pricing in search results.[15] Second, due to numerous hospitals' noncompliance, CMS proposes to modify the civil monetary penalties (CMP) associated with the Hospital Price Transparency Final Rule.[16] The proposed approach would maintain the current CMP for smaller hospitals of 30 beds or less with a minimum fine of $300 per day for noncompliance, or a maximum annual charge of $109,500 per hospital.[17] However, larger hospitals of 30 beds or more may be charged $10 per bed per day (capped at $5,500 per day), or a maximum annual charge of $2,007,500 per hospital.[18] CMS also proposes including additional criteria that could increase or decrease a hospital's CMP, such as hospital revenue; the nature, scope, severity, and duration of noncompliance; and, the hospital's reason for noncompliance.[19] If finalized, the CMP for hospitals in violation of the Hospital Price Transparency Final Rule would take effect January 1, 2022.[20]

Elimination of the Inpatient-Only (IPO) List

In the CY 2021 OPPS final rule, CMS decided to eliminate the IPO list over a three-year period.[21] The IPO list was first established in 2000 alongside the OPPS to ensure Medicare would still pay for inpatient services that were too clinically complex to perform in an outpatient setting.[22] In 2021, the first phase of elimination sought to remove nearly 300 of the 1,740 services included in this list.[23] Due to numerous stakeholder comments opposing the elimination of the IPO list, CMS proposes to halt the elimination of the list and add back the 298 services that were removed in CY 2021.[24] Patient safety concerns are the primary reason for CMS's termination of the IPO list phase-out, as the change occurred without evaluating if each procedure could be safely removed from the list.[25] Among some of the procedures to be eliminated in the first phase were musculoskeletal procedures such as limb amputation, invasive spinal procedures, and repair of fractures for major joints.[26] While CMS proposes to add the eliminated procedures back to the IPO list for CY 2022, it is still looking to narrow the IPO list. CMS is asking for stakeholder feedback on whether to

maintain the initial objective to eliminate the list over a longer period, or to significantly scale back the list so that IPO-designated procedures align with current standards.[27]

Elimination of ASC-Covered Procedures

Similarly, CMS proposes to eliminate services from the ASC-covered procedure list (ASC CPL), reversing decisions that were implemented in the CY 2021 OPPS final rule. In the current final rule, CMS revised safety criteria and adopted a new notification process in which public suggestions were accepted for surgical procedures to be added to the ASC CPL.[28] Under the current criteria, 267 procedures have been added to the ASC CPL,[29] which has major impacts on merger and acquisition trends for hospitals that left the urgent care setting and acquired ASCs.[30] For CY 2022, CMS proposes to eliminate 258 of the 267 procedures added in 2021, update safety criteria, and change the notification process to a formal stakeholder nomination process that would begin in CY 2023.[31] Additionally, CMS requests stakeholder comments to reinstate the proposed 258 procedures if they meet the new safety criteria.[32]

Quality Reporting Changes

To improve measurement and reporting of quality of care, CMS proposes four actions for the Hospital Outpatient Quality Reporting (OQR) Program and two actions for the ASC Quality Reporting (ASCQR) Program. First, CMS proposes the Hospital OQR Program to adopt three new measures, remove two measures, mandate reports for two currently voluntary or suspended measures, and update Hospital OQR Program validation policies to reduce provider burden.[33] Notably, one of the new measures CMS proposes to adopt includes the measurement and reporting of the vaccination status of healthcare personnel for COVID-19.[34] Second, CMS proposes the ASCQR Program to adopt the same COVID-19 vaccination measurement mentioned previously, and mandate reports for six currently voluntary or suspended measures.[35] Additionally, CMS is seeking stakeholder feedback for several revisions and additional measurements for reporting health disparities and ways to address these social risk factors.

Stakeholder Responses

Stakeholders' reactions to the changes in the 2022 OPPS proposed rule were a mixed bag. Most stakeholders, including the American Hospital Association (AHA) and America's Essential Hospitals (AEH), agreed with CMS on the need to increase price transparency, but have conflicting opinions on enforcement regulations. Many stakeholders believe that CMS should not be increasing penalties for noncompliance with all the reversals they are proposing to implement in the CY 2022 rule. However, the AHA was "pleased that CMS…proposes to roll back two problematic policies it advanced last year," in regard to halting the elimination of the IPO list and adding back ASC-covered procedures that were removed last year.[36] Ambulatory Surgery Center Association (ASCA) CEO Bill Prentice similarly supported the reversal of the IPO list elimination and the re-addition of ASC procedures.[37] Additionally,

ASCA showed support for the new measures proposed for the ASCQR Program, such as the COVID-19 vaccination among healthcare personnel measure.[38]

Conclusion

For a majority of products and services in the U.S., consumers are aware of the actual price, which allows them to competently assess their options and make an educated decision. However, the U.S. healthcare sector does not operate under these standards because of the third party payor system and information asymmetry between providers and patients. The main theme of the CY 2022 OPPS proposed rule stems from President Biden's executive order to increase price transparency, access, and quality. While the potential impacts for the CY 2022 OPPS proposed rule have yet to be determined, monetary penalizations and payment cuts are likely to cause contention in the U.S. health industry in 2022. CMS will receive comments and information on requested topics until September 17, 2021.[39]

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1 "Healthcare News: Biden Administration Aims to Strengthen Competition Through Issuance of Sweeping Executive Order" By Brian Hayles and Najla Long, Bradley Arant Boult Cumming LLP, July 19, 2021, https://www.jdsupra.com/legalnews/healthcare-news-biden-administration-8371981/ (Accessed 7/21/21).

2 "CMS Proposes Rule to Increase Price Transparency, Access to Care, Safety & Health Equity" Centers for Medicare & Medicaid Services, July 19, 2021, https://www.cms.gov/newsroom/press-releases/cms-proposes-rule-increase-price-transparency-access-care-safety-health-equity (Accessed 7/20/21).

3 "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; etc." Centers for Medicare & Medicaid Services, July 19, 2021, unpublished version, https://public-inspection.federalregister.gov/2021-15496.pdf (Accessed 7/20/21), p. 12.

4 *Ibid.*

5 *Ibid.*

6 *Ibid*, p. 15.

7 While fee schedule factor increase, total payments still decreased by $20 million due to changes in enrollment, beneficiary utilization, and case-mix. *Ibid*, p. 12, 15.

8 "Hospital Price Transparency Final Rule, By Rhonda Sheppard and Terri Postma, Medicare Learning Networking, December 8, 2020, https://www.cms.gov/files/document/2020-12-08-hospital-presentation.pdf (Accessed 7/21/21), p. 4.

9 "Economic Report of the President: Together with the Annual Report of the Council of Economic Advisers" The White House, March 2019, https://www.govinfo.gov/content/pkg/ERP-2019/pdf/ERP-2019.pdf (Accessed 7/21/21), p. 205.

10 *Ibid*.

11 "FACT SHEET: Executive Order on Promoting Competition in the American Economy" The White House, July 9, 2021, https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/ (Accessed 7/26/21).

12 *Ibid*.

13 "Executive Order on Promoting Competition in the American Economy" The White House, July 9, 2021, https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/ (Accessed 7/21/21).

14 Centers for Medicare & Medicaid Services, July 19, 2021, unpublished version, https://public-inspection.federalregister.gov/2021-15496.pdf (Accessed 7/20/21), p. 749.

15 *Ibid*, p. 753.

16 *Ibid*, p. 743.

17 "CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1753-P)" Centers for Medicare & Medicaid Services, July 19, 2021, https://www.cms.gov/newsroom/fact-sheets/cy-2022-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center (Accessed 7/20/21).
18 *Ibid.*
19 Centers for Medicare & Medicaid Services, July 19, 2021, https://www.cms.gov/newsroom/press-releases/cms-proposes-rule-increase-price-transparency-access-care-safety-health-equity (Accessed 7/20/21).
20 *Ibid.*
21 *Ibid.*
22 "OPPS Final Rule Issued, Heralding Beginning of the End for Inpatient-Only List" By Mark Spivey, ICD10 Monitor, December 3, 2020, https://www.icd10monitor.com/opps-final-rule-issued-heralding-beginning-of-the-end-for-inpatient-only-list (Accessed 7/20/21).
23 Centers for Medicare & Medicaid Services, July 19, 2021, unpublished version, https://public-inspection.federalregister.gov/2021-15496.pdf (Accessed 7/20/21), p. 13.
24 Centers for Medicare & Medicaid Services, July 19, 2021, https://www.cms.gov/newsroom/fact-sheets/cy-2022-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center (Accessed 7/20/21).
25 *Ibid.*
26 Spivey, December 3, 2020.
27 Centers for Medicare & Medicaid Services, July 19, 2021, https://www.cms.gov/newsroom/press-releases/cms-proposes-rule-increase-price-transparency-access-care-safety-health-equity (Accessed 7/20/21).
28 Centers for Medicare & Medicaid Services, July 19, 2021, https://www.cms.gov/newsroom/fact-sheets/cy-2022-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center (Accessed 7/20/21).
29 Medicare outlines surgical procedures it will pay for surgical procedures in ASCs unless they meet certain exclusion criteria, such as inclusion on the IPO list, the surgery is requires monitoring overnight, or the surgery is emergent or life-threatening. "Medicare Payments: ASC List Exclusion Criteria" Ambulatory Surgery Center Association, updated January 1, 2021, https://www.ascassociation.org/asca/federalregulations/medicarepayments/facilityfee/exclusioncriteria (Accessed 7/222/21).
30 Centers for Medicare & Medicaid Services, July 19, 2021, unpublished version, https://public-inspection.federalregister.gov/2021-15496.pdf (Accessed 7/20/21), p. 16; "CMS proposes increasing penalties for hospitals not meeting price transparency rule" By Robert King, Fierce Healthcare, July 19, 2021, https://www.fiercehealthcare.com/hospitals/cms-proposes-increasing-penalties-for-hospitals-not-meeting-price-transparency-rule (Accessed 7/20/21).
31 Centers for Medicare & Medicaid Services, July 19, 2021, unpublished version, https://public-inspection.federalregister.gov/2021-15496.pdf (Accessed 7/20/21), p. 16.
32 *Ibid*.
33 *Ibid*, p. 607-611.
34 *Ibid*.
35 *Ibid*, p. 612.
36 "In OPPS rule, CMS proposes to boost payment rates by 2.3%, make modifications to price transparency rule" American Hospital Association, July 19, 2021, https://www.aha.org/news/news/2021-07-19-opps-rule-cms-proposes-boost-payment-rates-23-make-modifications-price (Accessed 7/21/21).
37 "2022 Proposed Medicare Payment Rule Released" Ambulatory Surgery Center Association, July 20, 2021, https://www.ascassociation.org/asca/aboutus/latestnews/newsarchive/newsarchive2021/july2021/202107medicare2022proposedpaymentrule (Accessed 7/21/21).
38 *Ibid.*
39 Centers for Medicare & Medicaid Services, July 19, 2021, https://www.cms.gov/newsroom/fact-sheets/cy-2022-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center (Accessed 7/20/21).

CMS Releases 2022 IPPS Final Rule

[Excerpted from the article published in August 2021.]

On August 2, 2021, the Centers for Medicare & Medicaid Services (CMS) released its finalized payment and policy updates for the Medicare Inpatient Prospective Payment System (IPPS) and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) for fiscal year (FY) 2022.[1] Notably, CMS determined in their final rule that it would be using FY 2019 data to determine inpatient hospital utilization for FY 2022 due to aberrations in the FY 2020 data stemming from the COVID-19 public health emergency (PHE).[2] The final rule authorized Medicare inpatient reimbursement increases for 2022, extended reimbursement for COVID-19 diagnostics and treatment, moved forward with improvements to quality measurement and data evaluations, but did not approve the addition of 1,000 new graduate medical education (GME) slots. This Health Capital Topics article will discuss the IPPS final rule and stakeholder reactions.[3]

IPPS and LTCH PPS Payment Rate Updates

The final rule includes a 2.5% payment increase for hospitals that report quality data through the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful users of electronic health records (EHRs).[4] This payment increase is 0.3% lower than the proposed payment rate.[5] CMS estimates hospital payments to increase by an adjusted total (after various decreases) of $2.3 billion in FY 2022.[6] Under the FY 2022 IPPS, hospitals may also see payment reductions for excessive readmissions, 1% payment reductions for the worst-performing quartile of hospitals, and neutral payment adjustments due to CMS suppressing many hospital value-based purchasing program measures during COVID-19.[7]

Additionally, CMS finalized LTCH-PPS payment increases of approximately 1.1%, or $42 million, a reversal from last year's decrease of 0.9%.[8] Further, for FY 2022, LTCH discharges paid the standard payment rate are expected to increase by 0.9%, a decrease of 0.3% from the proposed rate.[9] To be paid this rate upon discharge, a patient must have been directly admitted to the LTCH from an IPPS hospital after: (a) spending at least three days in an intensive or coronary care unit; or (b) having been on a ventilator for at least 96 hours, and must have not been assigned to psychiatric or rehabilitation services upon discharge.[10] Additionally, the proposed site-neutral payment rate for LTCH discharges was finalized at an increased rate of 3.0% for FY 2022.[11] The site-neutral payment rate is applied to all discharges that do not fit the criteria for the standard payment rate. For FY 2022, CMS estimates discharges paid the site-neutral payment will comprise 25% of all LTCH cases and 10% of all LTCH PPS payments, the same composition as 2021.[12]

These payment changes will affect inpatient discharges for approximately 3,200 acute care hospitals and 360 LTCHs.[13]

Extended Reimbursements for COVID-19 Treatments and Diagnosis

For FY 2022, CMS finalized 19 technologies that applied for new technology add-on payments (NTAP) and is continuing NTAP for the 23 technologies currently receiving the add-on payments.[14] NTAP is additional reimbursement that provides "add-on" payments (up to 65%) to hospitals for the use of technology that may not be included in the diagnosis related group (DRG) bundled payment due to the novelty of that technology.[15] Further, CMS proposed establishing the New COVID-19 Treatments Add-On Payment (NCTAP) to incentivize hospitals to provide new COVID-19 treatments and minimize any payment disruption for inpatient discharges through the end of the COVID-19 PHE.[16] In total, CMS has finalized 42 technologies that are eligible to receive NTAP for FY 2022, which will increase Medicare spending on NTAP by approximately $1.5 billion from FY 2021.[17]

Hospital Inpatient Quality-Reporting (IQR) Program

The Hospital IQR Program is a quality reporting program that may reduce payments to hospitals that fail to meet quality reporting requirements. CMS finalized several changes to the IQR Program, which adds five new measures to the program, including the COVID-19 vaccination rates among healthcare personnel, a metric targeting maternal morbidity, a hybrid hospital-wide-all-cause risk standardized mortality measure, and two medication-related adverse event electronic clinical quality measures (eCQMs).[18] CMS will also remove the exclusive breast milk feeding measure, the admit decision time to emergency department departure for admitted patients measure, and a discharge-related eCQM.[19]

Other Changes

Notably, CMS decided not to move forward with the increase of 1,000 GME positions to promote health equity under the Consolidated Appropriations Act, a trillion-dollar spending bill that seeks to provide economic relief from the COVID-19 PHE.[20] CMS had proposed to allow additional funding for residency positions added between FY 2023 and 2031, prioritizing underserved populations.[21] However, CMS said these issues would be addressed in future payment rules.[22]

Additionally, CMS will distribute $7.2 billion in uncompensated care payments for FY 2022, an approximately $1.1 billion decrease from FY 2021.[23] The finalized uncompensated care payments are lower than the $7.6 billion proposed payment, and a decrease of $660 million from FY 2021.[24] CMS is required to prospectively distribute payment equal to 75% of what would have otherwise been uncompensated care to disproportionate share hospitals.[25]

CMS will also move forward with its proposal to remove median payor-specific negotiated rates by Medicare severity-diagnosis related group (MS-DRG) with Medicare Advantage insurers.[26] CMS said this will reduce the administrative burden on hospitals by approximately 64,000 hours.[27]

Conclusion

While important health equity changes from the proposed rule, such as increases to GME slots, did not make the final rule, CMS still addressed many gaps that were highlighted by the COVID-19 PHE. Further, with this rule, CMS can improve how it measures and evaluates data while promoting high-quality care for Medicare beneficiaries. In an announcement following the release of the final rule, CMS expressed the importance of standardizing hospital quality data, with CMS Administrator Chiquita Brooks-LaSure asserting, "how Medicare pays for hospital care and evaluates quality, are integral pieces of achieving and addressing gaps in health equity and strengthening our health care system for a more sustainable future."[28] Additionally, stakeholders such as the American Hospital Association (AHA) and the Association of American Medical Colleges (AAMC) commented upon the release of the final rule, showing support for CMS helping inpatient hospitals during the COVID-19 PHE.[29] While these stakeholders did look forward to addressing health equity issues through additional GME slots, they appreciate that CMS will address this in future rules.[30] The final rule will take effect on inpatient discharges that take place on or after October 1, 2021.[31]

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1 Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) Rates Final Rule (CMS-1752-F)" Centers for Medicare & Medicaid Services, August 2, 2021, https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2022-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-0 (Accessed 8/3/21).

2 *Ibid*.

3 For more details on CMS's FY 2022 IPPS Proposed Rule, see the following Health Capital Topics article: "IPPS and LTCH PPS Proposed for 2022" Vol. 14, Issue 5 (May 2021), https://www.healthcapital.com/hcc/newsletter/05_21/HTML/IPPS/convert_2022-ipps-proposed-rule-5.19.21.php (Accessed 8/2/21).

4 "Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program" Federal Register Vol. 86, No. 154 (August 13, 2021), https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf (Accessed 8/13/21), p. 44790.

5 "Fiscal Year (FY) 2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Proposed Rule (CMS-1735-P)" Centers for Medicare & Medicaid Services, May 11, 2020 https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute (Accessed 8/4/21).

6 Federal Register Vol. 86, No. 154, August 13, 2021, p. 44783.

7 CMS, August 2, 2021.

8 *Ibid.*

9 *Ibid*; "Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Rates Proposed Rule (CMS-1752-P)" Centers for Medicare & Medicaid Services, April 27, 2021, https://www.cms.gov/newsroom/fact-shescal-year-fy-2022-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care (Accessed 8/3/21).

10 "Long Term Care Hospitals Payment Systems" Medicare Payment Advisory Commission, October 2018, http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_18_ltch_final_v2_sec.pdf?sfvrsn=0 (Accessed 8/3/21).
11 Federal Register Vol. 86, No. 154 (August 13, 2021), p. 45601.
12 CMS, August 2, 2021.
13 *Ibid.*
14 *Ibid.*
15 Federal Register Vol. 86, No. 154 (August 13, 2021), p. 44952.
16 *Ibid*, p. 44777-44778.
17 CMS, August 2, 2021.
18 *Ibid.*
19 *Ibid.*
20 *Ibid.*
21 "Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program" May 10, 2021, Federal Register Vol. 86, No. 88, https://www.govinfo.gov/content/pkg/FR-2021-05-10/pdf/2021-08888.pdf (Accessed 8/4/21), p. 25083.
22 CMS, August 2, 2021.
23 *Ibid.*
24 CMS, May 11, 2020.
25 CMS, August 2, 2021.
26 *Ibid.*
27 *Ibid.*
28 *Ibid.*
29 "AHA Summary of Hospital Inpatient PPS Final Rule for Fiscal Year 2022" American Hospital Association, August 3, 2021, https://www.aha.org/2021-08-03-aha-summary-hospital-inpatient-pps-final-rule-fiscal-year-2022 (Accessed 8/4/21).
30 *Ibid.*
31 CMS, August 2, 2021.

Bundled Payment Model Success Unaffected by Type of Participation

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Historically, Medicare has offered value-based payment models to healthcare organizations on both a voluntary and a mandatory participation basis. Because voluntary participants could self-select into programs to reduce spending, it was assumed that they achieved greater savings than mandated participants, but until recently, no data had tested this. However, a June 2021 study in the Journal of the American Medical Association (JAMA) found no difference in risk-adjusted episodic spending between voluntary and mandatory payment model participants.[1] This Health Capital Topics article will examine the bundled payment program observed in this study, discuss the methods and results of the study, and explore possible implications for Centers for Medicare and Medicaid Services (CMS) value-based payment programs going forward.

Background of Medicare Bundled Payment Programs

Traditional fee-for-service (FFS) Medicare makes separate payments to providers for each service or procedure they render to a beneficiary in treating or managing health conditions, which may drive up costs and spending, as this reimbursement scheme discourages cost-effective, coordinated care. In 2013, CMS launched a bundled payment program to test ways to improve care coordination and reduce costs for Medicare beneficiaries.[2] Bundled payments, in contrast to FFS reimbursement, consist of a single payment to a provider for a patient's entire episode of care. This payment strategy seeks to push providers to become more responsible for the comprehensive care of a patient by incentivizing the provider to provide services in a cost-efficient, high quality manner in order to realize a financial return.[3] The first Bundled Payments for Care Improvements (BPCI) Initiative developed by CMS was comprised of four models of care that linked a beneficiary's episode of care to the payments providers received for those services, which included hip and knee joint replacements.[4] The four models were differentiated by the setting in which the episode of care was provided.[5] The four models concluded in 2018, and remaining participants could choose to resign the program or move into the newer BPCI Advanced program.[6]

In 2016, CMS commenced the Comprehensive Care for Joint Replacement (CJR) model, which sought to test cost and quality measures for episodes of care related to hip and knee replacements, also referred to as lower extremity joint replacements (LEJR), under bundled payments.[7] Medicare beneficiaries account for a large proportion of LEJR, and recovery, rehabilitation, and complications (such as readmissions) alone account for more than $7 billion in annual Medicare spending.[8] The CJR model incentivizes participating hospitals to deliver comprehensive, cost-effective care from the time a patient is admitted for their surgical procedure until 90 days after discharge to ensure that patients have fully completed their recovery.[9] The CJR model is most similar to Model

4 of BPCI, wherein providers are paid prospectively for all services rendered during a patient's episode of care, including the inpatient stay in an acute care hospital, post-acute care, and all rehabilitation services up to 90 days post-discharge.[10]

The CJR model holds hospital participants financially responsible for effectively coordinating providers along the continuum of care, such as surgeons, post-acute care providers, and clinicians, and consequently reduce costs and improve quality.[11] Benchmarks on spending are set for providers, and if hospitals do not achieve cost and quality metrics, they may face repayments to Medicare.[12] Conversely, if providers are efficiently coordinating care, they may "earn" or keep the difference between their spending and benchmark payments.[13]

In July 2015, CMS originally planned to implement the CJR model in 75 MSAs, and use a control group consisting of the remaining 121 MSAs.[14] However, in November 2015, 8 MSAs were dropped due to an increase in participation in the BPCI model, making them ineligible for the CJR model.[15] Thus, CMS implemented the CJR model in 67 MSAs, and required hospitals within those MSAs to participate.[16] During 2018, the third performance year of the CJR model, CMS reduced mandatory participation to the lowest performing 34 MSAs with the highest average historical episodic payments, and began offering an opportunity to voluntarily opt-in to the model for the higher performing participants in the 33 MSAs with lower average episode payments.[17] Of the over 300 providers that were eligible for voluntary participation in the 33 voluntary MSAs, 86 providers opted-in to participate in CJR for its remaining performance years.[18]

Study Findings

The June 2021 JAMA study conducted by University of Pennsylvania researchers followed prior work that examined the spending differences between mandatory and voluntary participants in the CJR model, based on 2011-2017 data.[19] The researchers grouped CJR participants based on whether they participated in the BPCI program prior to their CJR model participation (i.e., the mandatory and voluntary participants), and then utilized hospitals in 121 MSAs that continued to receive traditional Medicare FFS payments as a "control," or comparison, group, as nonparticipating hospitals.[20]

The JAMA study found that after risk adjusting, episodic payment decreases after implementation of bundled payments for voluntary hospital participants versus mandatory hospital participants did not differ significantly, and non-participating hospitals performed slightly better than voluntary hospitals. Risk-adjusted episodic spending, after implementation of bundled payments, decreased approximately 12.8% for voluntary participants (from $21,182 to $18,452); 14.8% for mandatory participants (from $18,390 to $15,652); and 13.2% for non-participating hospitals (from $17,132 to $14,871).[21]

More Mandatory Programs to Come?

The JAMA study results, which showed lesser savings among voluntary participants, may provide support for future mandatory payment models. CMS has been foreshadowing more mandatory bundled payment models for some months, with the Center for Medicare and Medicaid Innovation (CMMI) director, Elizabeth Fowler, hinting at pivoting away from voluntary models. She reported to Health Affairs that voluntary models cannot generate system-level savings because providers tend to leave programs if they are not generating additional revenue, and those that do generate additional revenue tend to remain static and do not take on more risk.[22] Fowler wants to forge a path forward for organizations that are doing well under value-based care models, boost stragglers down the same path, and reach out to organizations that have not yet participated.[23]

In 2020, then–CMS Administrator Seema Verma made comments that CMS is planning to implement more mandatory payment models in the future because many are not generating statistically significant savings.[24] She additionally asserted that mandatory participation is vital to success, much to the chagrin of several medical groups and hospital associations. The Medical Group Management Association (MGMA), for example, stated that while they support efforts to improve value-based care, it is their position that it is unfair to require participation in payment models that lack evidentiary support.[25] Further, MGMA added that payment models are not one-size-fits-all, and that CMS should instead focus their attention to creating models that meet diverse needs.[26]

Additionally, hospitals have asked CMS to keep bundled payment models as voluntary initiatives. The Greater New York Hospital Association has argued that mandatory bundled payment initiatives pose a threat for safety net hospitals that primarily rely on Medicare payments.[27] The California Hospital Association and Missouri Hospital Association have echoed these frustrations by asking CMS to cancel any mandatory pay models because they place extreme hardships on providers' financial stability.[28]

Conversely, a population-based JAMA study in 2021 found that savings from the CJR program had dissipated between the second and fourth years of the program.[29] This study looked at 2014-2019 claims data to determine how changes in the program (i.e., the opportunity for hospitals to drop out of the program) affected episode spending.[30] Researchers suggested that the drop in episode spending savings is largely due to hospitals opting out of the CJR model.[31] To mitigate such issues, researchers suggested that future episode-based payment models be made mandatory, while changing some structural components (such as the risk adjustment changes in benchmarking) that may hamper savings and making models more flexible to evolve with clinical innovation.[32]

The CJR model was set to conclude on September 30, 2021, but a CMS final rule extended the payment model through December 31, 2024.[33] Additionally, CMS announced another round of changes to the BPCI Advanced model that

could make participation mandatory as early as 2024.[34] CMS is continually working to develop more bundled payment models that pay providers with minimal burden and push system-level change in cost and quality.[35]

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1 "Association Between Hospital Voluntary Participation, Mandatory Participation, or Nonparticipation in Bundled Payment and Medicare Episodic spending for Hip and Knee Replacements" By Joshua Liao, Atul Gupta, & Yueming Zhao, JAMA Network, June 16, 2021, https://jamanetwork.com/journals/jama/fullarticle/10.1001/jama.2021.10046?utm_campaign=articlePDF%26utm_medium=articlePDFlink%26utm_source=articlePDF%26utm_content=jama.2021.10046 (Accessed 6/23/21).

2 "Bundled Payments for Care Improvement (BPCI) Initiative: General Information" Centers for Medicare & Medicaid Services, May 4, 2021, https://innovation.cms.gov/innovation-models/bundled-payments (Accessed 6/24/21).

3 "Bundled Payment" American Hospital Association, October 2018, https://www.aha.org/bundled-payment (Accessed 6/24/21).

4 CMS, May 4, 2021.

5 *Ibid.*

6 *Ibid.*

7 "Comprehensive Care for Joint Replacement Model" Centers for Medicare & Medicaid Services, May 25, 2021, https://innovation.cms.gov/innovation-models/cjr (Accessed 6/24/21).

8 *Ibid.*

9 *Ibid.*

10 CMS, May 4, 2021; CMS, May 25, 2021.

11 CMS, May 25, 2021.

12 *Ibid.*

13 *Ibid.*

14 "Two-year evaluation of mandatory bundled payments for joint replacement, Supplementary Index A" Michael Barnett, et al., New England Journal of Medicine 380(3), updated April 18, 2019, https://www.nejm.org/doi/pdf/10.1056/NEJMsa1809010?articleTools=true (Accessed 6/30/21), p. 3-4.

15 *Ibid.*

16 CMS, May 25, 2021.

17 *Ibid.*

18 *Ibid.*

19 JAMA Network, June 16, 2021.

20 New England Journal of Medicine 2019;380:252-62, updated April 18, 2019.

21 JAMA Network, June 16, 2021.

22 "CMMI Exploring More Mandatory Models, Fowler Says" By Michael Brady, Modern Healthcare, June 3, 2021, https://www.modernhealthcare.com/payment/cmmi-exploring-more-mandatory-models-fowler-says (Accessed 6/24/21).

23 *Ibid.*

24 "MGMA Voices Displeasure With CMS' Talk of Mandated APMs" By Rajiv Leventhal, Healthcare Innovation, October 22, 2020, https://www.hcinnovationgroup.com/policy-value-based-care/alternative-payment-models/news/21159638/mgma-voices-displeasure-with-cms-talk-of-mandated-apms (Accessed 6/30/21).

25 *Ibid.*

26 *Ibid.*

27 "Hospitals call on Trump administration to end mandatory bundled pay programs" By Virgil Dickson, Modern Healthcare, April 24, 2017, https://www.modernhealthcare.com/article/20170424/NEWS/17

0429928/hospitals-call-on-trump-administration-to-end-mandatory-bundled-pay-programs (Accessed 6/30/21).

28 *Ibid.*

29 "Hospital responses to Incentives in Episode-Based Payment for Joint Surgery" By Andrew Wilcock, et al., JAMA Internal Medicine, May 17, 2021, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2779739?guestAccessKey=ba39f244-d8ff-4a54-b3e3-94bc48261c87&utm_source=silverchair&utm_medium=email&utm_campaign=article_alert-jamainternalmedicine&utm_content=etoc&utm_term=070621 (Accessed 7/8/21).

30 *Ibid.*

31 *Ibid.*

32 *Ibid.*

33 "Comprehensive Care for Joint Replacement (CJR) Model Frequently Asked Questions" Department of Health and Human Services, March 8, 2018, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cjr%20faqs%2003%2008%2018_2.pdf (Accessed 7/1/21), p 21; "Comprehensive Care for Joint Replacement Model" Centers for Medicare & Medicaid Services, May 25, 2021, https://innovation.cms.gov/innovation-models/cjr (Accessed 6/24/21).

34 Healthcare Financial Management Association, September 17, 2020.

35 Modern Healthcare, June 3, 2021.

III. REGULATORY TOPICS

Stark & Anti-Kickback Revisions Finalized: Changes to Stark's Big Three Provisions

[This is the first article in a three-part series regarding Stark & Anti-Kickback Revisions This installment was published in November 2020.]

On November 20, 2020, the *Centers for Medicare & Medicaid Services* (CMS) and the *Office of Inspector General* (OIG) of the *Department of Health and Human Services* (HHS) issued two final rules to modernize and clarify the *Stark Law* and the *Anti-Kickback Statute* (AKS).[1] The rule changes are part of the larger effort by HHS (of which CMS is part) to modernize and clarify fraud and abuse laws as part of the *Regulatory Sprint to Coordinated Care* initiative and CMS's *Patients over Paperwork* initiative, which are aimed at reducing regulatory barriers and accelerating the transformation of the healthcare system into one that better pays for value and promotes care coordination.[2] Recognizing the rapidly changing healthcare system, CMS and OIG established new rules, and rule changes, that are more consistent with emerging value-based healthcare delivery and payment models, and which may allow for better coordination of care.

This is the first installment in a *Health Capital Topics* series that will examine these final rules and discuss their impact on healthcare valuation going forward. This initial article will summarize the Stark Law final rule as relates to "The Big Three" Requirements – Commercial Reasonableness, the Volume or Value Standard and the Other Business Generated Standard, and Fair Market Value.

Overview of the Stark Law

The Stark Law governs those physicians (or their immediate family members) who have a financial relationship (i.e., an ownership investment interest or a compensation arrangement) with an entity, and prohibits those individuals from making Medicare referrals to those entities for the provision of *designated health services* (DHS).[3] Notably, the law contains a large number of *exceptions*, which describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.[4]

Goals of Definitional Revisions

Many of the exceptions to the Stark Law require that one or more of the following requirements be met: that the compensation arrangement be commercially reasonable, that the compensation methodology not be determined in a manner that takes into account the volume or value of referrals (or other business generated between the parties), and that the amount of compensation paid be *fair market value*.[5] Due to their pervasiveness, these requirements are often referred to as "The Big Three."

In its final rule, CMS explained its reasons for making changes to the definitions of these three terms, principally "*to establish bright-line, objective regulations for each of these fundamental requirements …*"[6]

Each of these requirements will be discussed in turn on the next pages.

Commercial Reasonableness

In its October 2019 proposed rule, CMS recognized that it has only addressed the concept once, in a 1998 proposed rule, interpreting the term "*commercially reasonable*" to mean an arrangement that appears to be:

"*...a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals*."[7]

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

(1) "*the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements*" [emphasis added]; or,
(2) "*the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty*."[8] [Emphasis added.]

CMS unequivocally noted that, no matter which of the alternative definitions were finalized, an arrangement would be *commercially reasonable* "*even if it does not result in profit for one or more of the parties*."[9] [Emphasis added.]

Based on the comments received as to these two alternative definitions, CMS ultimately chose to incorporate aspects of each of the proposed alternative definitions in its final definition:

"*Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties*."[10] [Emphasis added.]

In explaining its selection of the above definition, CMS acknowledged that if the agency had finalized the first alternative proposed definition, the regulation would have included "*the limitation that the arrangement [be] on similar terms and conditions as like arrangements*."[11] [Emphasis added.] Commenters expressed concern "*that parties to an arrangement would not have access to data to identify 'like arrangements' or be aware of their terms and conditions*" or that "*parties may enter into a novel compensation arrangement that bears minimal, if any, resemblance to existing arrangements against which it could be compared for 'similar terms*.'"[12] CMS ultimately agreed with Commenters that

"*requiring a compensation arrangement to be on similar terms as like arrangements in order to be commercially reasonable does not provide for the clarity that we and stakeholders seek and, in fact, could increase the burden on parties that must seek the expertise of outside organizations to ensure compliance with the requirement that their arrangement is commercially reasonable*."[13]

Further, CMS pointed out, the finalized definition "*is consistent with the guidance we provided in the 1998 proposed rule* [set forth above], *appropriately considers the characteristics of the parties to the actual arrangement being assessed for its commercial reasonableness, and will adequately ensure that parties cannot protect abusive arrangements under the guise of 'commercial reasonableness*.'"[14]

Commenters raised a number of questions and comments related to the phrase "*furthers a legitimate business purpose of the parties*" in the definition of *commercial reasonableness*, and CMS dedicated a sizable portion of the final rule to the discussion of this phrase.

While CMS acknowledged that "*identifying the business purpose of an arrangement may entail an inquiry into the parties' intent for the arrangement*," the requirement that the arrangement *further* a legitimate business purpose of the parties "*would be considered only after the determination that there actually exists a legitimate business purpose for the arrangement*."[15] According to CMS, some of the purposes that could "*qualify as 'legitimate business purposes' of the parties to an arrangement, depending on the facts and circumstances of the parties*," included:

(1) Addressing community need;
(2) Providing timely access to healthcare services;
(3) Fulfilling licensure or regulatory obligations, such as those under the *Emergency Medical Treatment and Labor Act* (EMTALA);
(4) Providing charity care; and,
(5) Improving quality and health outcomes.[16]

However, as CMS noted in its October 2019 proposed rule, "*arrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements*."[17]

As to the link between Commercial Reasonableness and the Volume or Value standard, CMS made note that, although many of the Stark Law exceptions require that an arrangement be commercially reasonable "*even if no referrals were made between the parties*" or "*even if no referrals were made to the employer*," this language was not included in the final *commercial reasonableness* definition. Nevertheless, CMS asserted, the *Volume or Value* standard (or *Other Business Generated* standard) "*remains an important constraint when determining whether an arrangement satisfies the requirements of an applicable exception*."[18]

Volume or Value Standard and the Other Business Generated Standard

Many Stark Law exceptions require that the compensation arrangement at issue "*not [be] determined in a manner that takes into account the volume or value of referrals by the physician...[or be] determined in a manner that takes into account other business generated between the parties*."[19] In response to Commenter concerns, CMS proposed in its October 2019 proposed rule "*objective tests for determining whether compensation takes into account the*

volume or value of referrals or the volume or value of other business generated by the physician,"[20] including "*narrowly-defined circumstances under which [the agency] would consider fixed-rate compensation...to be determined in a manner that takes into account the volume or value of referrals or other business generated.*"[21]

In its final rule, CMS finalized the objective tests for those payments that correlate with the volume or value of referrals or other business generated. However, the agency declined to finalize its proposed "*additional special rules outlining the circumstances under which we would consider fixed-rate compensation to be determined in a manner that takes into account the volume or value of referrals or other business generated by a physician for the entity paying the compensation*."[22] This decision was based upon CMS's agreement with Commenters who noted that "*fixed rate compensation (for example, $200,000 per year) qualifies as unit-based compensation*," which means that the proposed special rules regarding fixed-rate compensation would be effectively nullified by the unit-based compensation special rule.[23]

Perhaps the most significant statement made by CMS in this section was the finalization of its discussion in the October 2019 proposed rule regarding the Volume or Value standard and the Other Business Generated standard in light of fraud and abuse cases, such as *United States ex rel. Drakeford v. Tuomey*, which have held that, within the context of inpatient and outpatient hospital services, any *ancillary service and technical component* (associated with a physician's professional services, i.e., a "*facility fee*") services performed in connection with personally performed services constituted an impermissible referral.[24] In the proposed rule, CMS reaffirmed its previous position that "*[w]ith respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services...are billed each time the employed physician personally performs a service*."[25] Subsequently, in response to Commenter questions, CMS reiterated in the final rule that "*the fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement)*."[26] CMS reaffirmed the position it took in the Stark Phase II regulation, stating that "*with respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service*."[27] CMS also clarified that its guidance "*extends to compensation arrangements that do not rely on the exception for bona fide employment relationships [e.g., personal service arrangements]…and under which a physician is paid using a unit-based compensation formula for his or her personally performed services, provided that the compensation meets the conditions in the special rule [regarding unit-based compensation]*."[28]

Fair Market Value

Historically, the Stark Law has defined *fair market value* generally (with additional modifications of the definition as applies to equipment leases and office space leases[29]) as follows:

> "*the value in arm's-length transactions, consistent with the general market value....Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals*."[30]

In its October 2019 proposed rule, CMS proposed three separate *fair market value* definitions: (1) generally; (2) for the rental of equipment; and, (3) for the rental of office space.[31] However, the agency emphasized that "*the proposed structure of the definition merely reorganizes for clarity, but does not significantly differ from the [previous] statutory language*..."[32]

The three separate *fair market value* definitions were proposed as follows:

(1) **General**: The value in an arm's-length transaction –

  (a) With like parties and under like circumstances;
  (b) Of like assets or services; and,
  (c) Consistent with the general market value of the subject transaction.

(2) **Rental of Equipment**: With respect to the rental of equipment, the value in an arm's-length transaction –

  (a) With like parties and under like circumstances;
  (b) Of rental property for general commercial purposes (not taking into account its intended use); and,
  (c) Consistent with the general market value of the subject transaction.

(3) **Rental of Office Space**: With respect to the rental of equipment, the value in an arm's-length transaction –

  (a) With like parties and under like circumstances;
  (b) Of rental property for general commercial purposes (not taking into account its intended use);
  (c) Without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee; and,
  (d) Consistent with the general market value of the subject transaction.[33]

CMS finalized its proposed restructuring of the *fair market value* definitions, but revised the definitions for each:

(1) **General**: The value in an arm's-length transaction –
   (a) Consistent with the general market value of the subject transaction.

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

(3) **Rental of office space**: With respect to the rental of office space, the value in an arm's-length transaction –
   (a) Of rental property for general commercial purposes (not taking into account its intended use);
   (b) Without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee; and,
   (c) Consistent with the general market value of the subject transaction.[34]

As can be discerned from a reading of these above definitions, CMS ultimately chose not to finalize their proposed references in the definitions to "*like parties and under like circumstances*," but asserted that "*the structure of the final regulation merely reorganizes for clarity, but does not significantly differ from, the statutory language*"[35] of the Stark Law.[36]

Of note, the revised definition of *fair market value* (as well as the revised definition of *general market value*, discussed below) eliminates the connection to the *volume or value* standard, in line with the October 2019 proposed rule. CMS noted that "*a careful reading of the statute shows that the fair market value requirement is separate and distinct from the volume or value standard and the other business generated standard*," and thus there is no need to intertwine the discrete standards.[37]

Additionally, the Stark Law currently requires that *fair market value* "*be consistent with the general market value*," and defines the term as:

> "*...the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement*."[38]

In addition to the delineated definitions for *fair market value* set forth above, CMS suggested in the October 2019 proposed rule that *general market value* be defined separate and apart from *fair market value*.[39] Similar to *fair market*

value, CMS delineated the definitions based on whether it applies generally or to *rental of equipment or office space*,[40] as follows:

(1) **General**: "*the price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement*."[41] [Emphasis added.]

(2) **Rental of Equipment or Office Space**: "*the price that rental property would bring as the result of bona fide bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement*."[42] [Emphasis added.]

CMS finalized its proposal to define *general market value* separately from *fair market value*. However, the finalized definitions for *general market value* were further delineated, eschewing a "general" definition related to both assets and services (i.e., compensation) for specific definitions for each:

(1) **Assets**: "*the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other*." [Emphasis added.]

(2) **Compensation**: "*the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other*." [Emphasis added.]

(3) **Rental of Equipment or Office Space**: "*the price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other*."[43] [Emphasis added.]

Interestingly, CMS largely reverted back to its original definition of *general market value* for the finalized definitions, choosing to reference "*well-informed parties*" rather than the parties to the subject transaction.

The October 2019 proposed rule discussed the equivalence of *general market value* and "*'market value,' the term uniformly used in the valuation industry*."[44] However, in the final rule, CMS admitted that "*[o]ur use of the term 'market value' in our preamble discussion, although not carried into the proposed definition of 'general market value,' may have been inaccurate*."[45] In response to those Commenters that pointed out that *general market value* does not equate to the market value of a transaction, such terminology is used in the valuation industry, CMS did not finalize their proposed statements equating *general market value* with market value, reasoning that, "*if finalized, [our proposals] could have had an unintended limiting effect on the regulated community, as well as the valuation community*."[46]

In the October 2019 proposed rule, CMS spent a significant amount of the *fair market value* section reconciling the terms *fair market value* and *general*

market value, proposing clear guidance on the relationship, as well as the interplay, between the two terms. Specifically, CMS stated that it viewed *fair market value* as relating to "*the value of an asset or service to hypothetical parties in a hypothetical transaction (that is, typical transactions for like assets or services, with like buyers and sellers, and under like circumstances)*" [emphasis added], while *general market value* related to "*the value of an asset or service to the actual parties to a transaction*..."[47] CMS did not finalize its "*proposed analytical framework related to 'hypothetical' versus 'actual' transactions*" in its final rule, although the agency stated that it

> "*continue[s] to believe that the fair market value of a transaction—and particularly, compensation for physician services—may not always align with published valuation data compilations, such as salary surveys. In other words, the rate of compensation set forth in a salary survey may not always be identical to the worth of a particular physician's services*."[48]

In making its point, CMS reiterated the "*rock star*" physician scenario it set forth in the October 2019 proposed rule as an example of when "*extenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other valuation data compilations that are not specific to the actual parties to the subject transaction*."[49]

CMS delved further into the topic of salary surveys, responding to a number of comments on the reliance on salary surveys and dispelling any misunderstandings as to CMS's policies on this matter:

- "*It appears from the comments that stakeholders may have been under the impression that it is CMS policy that reliance on salary surveys will result, in all cases, in a determination of fair market value for a physician's professional services. It is not CMS policy that salary surveys necessarily provide an accurate determination of fair market value in all cases… Consulting 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*."[50]
- "*[W]e agree that a hospital may find it necessary to pay a physician above what is in the salary schedule, especially where there is a compelling need for the physician's services. For example, in an area that has two interventional cardiologists but no cardiothoracic surgeon who could perform surgery in the event of an emergency during a catheterization, a hospital may need to pay above the amount indicated at a particular percentile in a salary schedule to attract and employ a cardiothoracic surgeon*."[51]
- "*Parties do not necessarily fail to satisfy the fair market value requirement simply because the compensation exceeds a particular percentile in a salary schedule…We wish to be perfectly clear that nothing in our commentary was intended to imply that an independent valuation is required for all compensation arrangements*."[52]

- "*We are uncertain why the commenters believe that it is CMS policy that compensation set at or below the 75th percentile in a salary schedule is always appropriate, and that compensation set above the 75th percentile is suspect, if not presumed inappropriate. The commenters are incorrect that this is CMS policy*."[53]

Interestingly, CMS also addressed the "*practice loss postulate*" (also known as the "*practice loss theory*").[54] In response to a Commenter who suggested that "*the definition of 'fair market value' should include a statement that organizations compensating individuals at an ongoing loss may create risk that the compensation is not representative of fair market value*," CMS agreed that, "*in some circumstances, an entity's compensation of a physician at an ongoing loss may present program integrity concerns, but see no need to include the language requested by the commenter in regulation*."[55] CMS asserted that including the phrase "*not in a position to generate business*" in the *general market value* definition should at least partly assuage the commenter's concern, because it "*requires that the nature or identity of the purchaser of the items or services…[be] irrelevant to a determination of 'general market value' and, thus, 'fair market value.*"[56] CMS did, however, specifically note its disagreement with the Commenter's assertion that "*two hypothetical parties (that cannot consider the fact that one party can generate business for the other) would never enter into a situation in which the physician's compensation and benefits exceeded direct revenue*"[57] [emphasis added], noting that "*there are many valid reasons and legitimate business purposes for entering into an arrangement that will not result in profit for one or more of the parties to the arrangement*," as set forth in the commercial reasonableness definition and related guidance.[58]

Despite the revised definition and guidance, CMS reiterated its statements in prior rulemakings that in establishing

"*the fair market value (and general market value) of a transaction that involves compensation paid for assets or services, we intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions that are not in a position to refer to one another….Rather, as stated in Phase II and reiterated in Phase III, we will consider a range of methods of determining fair market value and that the appropriate method will depend on the nature of the transaction, its location, and other factors…*"[59]

Conclusion

While various definitions were changed from their proposed versions, the overall intent behind CMS's revisions remained the same. As with the October 2019 proposed rule, the most significant takeaways stem from CMS's acknowledgment that: not all physicians, or compensation arrangements, are the same; compensation arrangements may have qualitative benefits that outweigh quantitative costs, i.e., profitability; and, salary surveys are only a starting point in the valuation of a healthcare transaction.

The final revisions to the Stark Law's "Big Three" further demonstrate the need for valuation professionals in the healthcare industry who utilize an evidence-driven methodology that includes both *qualitative* and *quantitative* assessments of the specific facts and circumstances related to the transaction; document their consideration of these facts and circumstances; and, articulate their ultimate applicability to the transaction in support of their opinion.

Stark & Anti-Kickback Revisions Finalized: New Stark Exceptions Established

[This is the second article in a three-part series regarding Stark & Anti-Kickback Revisions This installment was published in December 2020.]

On November 20, 2020, the *Centers for Medicare & Medicaid Services* (CMS) and the *Office of Inspector General* (OIG) of the *Department of Health and Human Services* (HHS) issued two final rules to modernize and clarify the *Stark Law* and the *Anti-Kickback Statute* (AKS).[60] This is the second installment in a *Health Capital Topics* series examining these final rules and their impact on healthcare valuation going forward. The first article provided an overview of the Stark Law and summarized the law's final rule as relates to "The Big Three" Requirements – Commercial Reasonableness, the Volume or Value Standard and the Other Business Generated Standard, and Fair Market Value.[61] This second article will summarize the new Stark Law exceptions finalized by CMS.

New Value-Based Exceptions

CMS finalized a number of new, permanent exceptions to the Stark Law, most notably for *value-based arrangements* (VBAs).[62] As part of the new exceptions, CMS introduced a number of new definitions, including those for value-based activity, VBA, value-based enterprise (VBE), value-based purpose, VBE participant, and target patient population.[63]

Definitions

CMS finalized the definition of value-based activity as "*any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) The provision of an item or service; (2) The taking of an action; or (3) The refraining from taking an action*."[64] CMS made some revisions to this definition from the proposed rule, based on commenter suggestions. Notably, CMS did not finalize its proposed statement that the making of a referral is not a value-based activity, in response to commenters' concern that referrals are "*an integral part of a value-based health care delivery and payment system, especially with respect to care planning*."[65] Specifically, CMS stated that "*[c]are planning activities that meet the definition of 'referral'…will qualify as 'the taking of an action' for purposes of applying the definition of 'value-based activity.'*"[66] Despite

commenter requests, CMS declined to "*provide a list of items or services, actions, and ways to refrain from taking an action that qualify as value-based activities*" so as not to limit potential activities.[67] On the topic of whether a value-based activity is "*reasonably designed to achieve at least one value-based purpose*," CMS stated that such a determination is fact specific – "*[p]arties must have a good faith belief that the value-based activity will achieve or lead to the achievement of at least one value-based purpose...*"[68] [Emphasis added.] This does not mean, however, that the value-based purpose(s) must actually be achieved in order for the value-based arrangement to fall within an exception.[69] As to how to adequately memorialize value-based activities, CMS noted "*that contemporaneous documentation is a best practice, and we encourage parties to follow this practice*."[70] Further, CMS reminded stakeholders that the burden of proof to show compliance with an exception is on the parties asserting such an exception (i.e., those engaging in a value-based activity.[71]

CMS finalized the definition of value-based arrangement to mean "*an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are— (1) The value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise*."[72] [Emphasis added.] Notably, CMS finalized the emphasized language in this definition instead of its proposed language, "*between or among*," to clarify "*that all parties to the value-based arrangement must be VBE participants in the same VBE*."[73] Additionally, while CMS requested comment on requiring "*care coordination and management in order to qualify as a value-based arrangement*," the agency ultimately declined to include that requirement.[74] As to whom may participate in a value-based arrangement, CMS asserted that "*effectively, the parties to a value-based arrangement must include an entity…and a physician; otherwise the [Stark Law's] prohibitions would not be implicated*."[75] Further, "*…the value-based arrangement must be a compensation arrangement and not another type of financial arrangement…*"[76]

CMS finalized the definition of value-based enterprise (VBE) to mean "*two or more VBE participants— (1) Collaborating to achieve at least one value-based purpose; (2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and (4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).*"[77] Put another way, "*a value-based enterprise is a network of individuals and entities that are collaborating to achieve one or more value-based purposes of the value-based enterprise*."[78] Further, "*[i]f a value-based enterprise is comprised of only two VBE participants, they must have at least one value-based arrangement with each other...*"[79] VBEs can have multiple parties, or add parties later, to a contract, but CMS emphasized that "*each of the financial relationships that results from the contract must be analyzed separately under*" the Stark Law, as

they are "*separate and distinct compensation arrangement[s] that must be analyzed for compliance with an applicable exception*."[80] While a number of commenters urged CMS to not finalize the requirement that a VBE have "*an accountable body or person that is responsible for the financial and operational oversight of the enterprise*," CMS declined to remove the requirement, finalized the requirement as proposed, and "*maintain[ed] the requirement that the enterprise must have a governing document that describes the value-based enterprise and how its VBE participants intend to achieve its value-based purpose(s)*."[81] The agency assured stakeholders that it was not "*dictating particular legal or other structural requirements for a value-based enterprise; rather, the final regulations accommodate both formal and informal value-based enterprises*."[82] Consequently, "*the written agreements and contracts that parties enter into in the normal course of their business dealings could serve as the documentation required under the new exception for value-based arrangements*."[83]

CMS finalized the definition of VBE participant to mean "*a person or entity that engages in at least one value-based activity as part of a value-based enterprise*."[84] [Emphasis added.] In a departure from its proposed definition, CMS added "*person*" to the definition of VBE participant so as to: (1) bring the definition in line with that set forth in the AKS final rule; and, (2) not exclude any specific persons, entities, or organizations from the definition.[85] In adding this word, CMS noted that it intended for the phrase "*person or entity*" to refer to both natural and non-natural persons.[86] In making this change, CMS acknowledged commenters' assertions that "*laboratories and [Durable Medical Equipment, Prosthetics, Orthotics, and Supplies] DMEPOS suppliers may play a beneficial role in the delivery of value-based health care*."[87]

CMS finalized the definition of *value-based purpose* as "*any of the following: (1) Coordinating and managing the care of a target patient population; (2) Improving the quality of care for a target patient population; (3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population*."[88] Similar to the *value-based arrangement* definition, CMS did not finalize a definition for "*coordinating and managing care*," as that phrase is used in the first goal in the definition.[89] In discussing the "*four core goals related to a target patient population*,"[90] the agency agreed "*that [the 4th] value-based purpose shares certain aspects of the pre-participation waiver under the Shared Savings Program*"; however, CMS noted that the existing *accountable care organization* (ACO) fraud and abuse waivers will "*remain in place and are not affected by the existence of the value-based exceptions*."[91]

CMS finalized the definition of target patient population to mean "*an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that— (1) Are set out in writing in*

advance of the commencement of the value-based arrangement; and (2) Further the value-based enterprise's value-based purpose(s)."[92] While this definition was finalized by CMS as it was proposed,[93] CMS did seek comment on (but ultimately did not finalize) whether this definition should "*incorporate a requirement that patients in the target patient population have at least one chronic condition in order to align with [the Office of Inspector General's] OIG's proposals…*"[94] In its discussion of this term, CMS discussed instances "*…where a target patient population is ascribed to the value-based enterprise (or the VBE participants that are parties to the specific value-based arrangement) by the payor*" and noted that VBEs and VBE participants are still ultimately responsible for "*ensur[ing] that the requirements of the definition of 'target patient population' are satisfied.*"[95] CMS further stated that "*[i]t is not sufficient for the [VBE] or its VBE participants to merely state that the selection criteria will be determined by another party (in this case, the payor)…[they] may need to collaborate with the payor to ensure that the patient population attributed meets the definition of 'target patient population.* "[96]

Exceptions

CMS finalized new exceptions for three types of value-based arrangements:

(1) Full Financial Risk Arrangements;
(2) Value-Based Arrangements with Meaningful Downside Risk; and,
(3) Other Value-Based Arrangements.

In general, CMS stated that all three arrangements are "*aligned in nearly all respects with OIG's final value-based definitions*" in the AKS final rule. [97] Further, CMS finalized its proposal to *not* require that remuneration associated with a value-based arrangement: (1) be consistent with *Fair Market Value*; or, (2) not take into account the volume or value of a physician's referrals or the other business generated by the physician for the entity.[98] However, CMS is requiring that the compensation arrangements under these exceptions be commercially reasonable (although the agency noted that these arrangements are "*likely commercially reasonable*").[99]

Each of these arrangements are discussed in turn below.

Full Financial Risk Arrangements[100]

CMS finalized the exception for full financial risk arrangements, wherein "*the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time*," with one modification – the agency extended the "*pre-risk period* (the time prior to the commencement of the arrangement),[101] from 6 months to 12 months.[102] These arrangements do not have documentation requirements,[103] but a VBE's financial risk must be prospective.[104]

CMS discussed at length what remuneration under these arrangements may, or may not, include. As to what full financial risk arrangements *may* include, CMS noted that they may include "*risk mitigation terms such as risk corridors, global risk adjustments, reinsurance, or stop-loss provisions to protect against*

significant and catastrophic losses,"[105] meaning that payors may make payments "*to offset losses incurred by the enterprise above those prospectively agreed to by the parties. The payment of shared savings or other incentive payments for achieving quality, performance, or other benchmarks are also not prohibited*."[106] The exception requires the remuneration to be for, or result from, value-based activities, which is intended "*to be an objective standard; that is, the remuneration must, in fact, be for or result from value-based activities*…"[107] Additionally, "*if remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement [must] compl[y] with both of the following conditions:*

(A) *The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties; and*

(B) *the requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment*."[108]

Notably, "*[t]he final exception does not protect arrangements where one or both parties have made referrals or other business not covered by the value-based arrangement a condition of the remuneration*."[109] For example, "*the exception will not protect a value-based arrangement related to knee replacement services furnished to Medicare beneficiaries if the arrangement requires that the physician perform all his or her other orthopedic surgeries at the hospital*."[110]

Value-Based Arrangements with Meaningful Downside Risk[111]

In the final rule, CMS revised the definition of "*meaningful downside financial risk*" to mean "*that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement*," as opposed to the 25 percent that was proposed.[112] This change was in response to commenters who, in making this request, referenced "*a 2018 Deloitte Survey of U.S. physicians that surveyed 624 primary care and specialty physicians practicing in a variety of health care settings and found that most physicians are willing to tie approximately 10 percent of their compensation to quality and cost measures*."[113]

Similar to full financial risk arrangements, value-based arrangements with meaningful downside risk remuneration only relates to remuneration from an entity to a physician,[114] and may include *"[w]ithholds, repayment requirements, or incentive pay tied to meeting goals or outcome measures…provided that the physician's downside financial risk is tied to the achievement of the value-based purpose(s) of the value-based enterprise and not the goals of the parties or the arrangement (unless the parties alone comprise the value-based enterprise)*."[115]

However, unlike full financial risk arrangements, value-based arrangements with meaningful downside risk must set forth, in writing, the "*nature and extent of the physician's financial risk*,"[116] "*in advance of the undertaking of value-based activities for which the remuneration is paid*;"[117] however, "*[p]arties need not know the ultimate amount of remuneration under the value-based arrangement*."[118] [Emphasis added.]

Lastly, CMS specifically noted that this exception is not parallel with the substantial downside financial risk safe harbor under the AKS final rule.[119]

Other Value-Based Arrangements[120]

Other value-based arrangements, the definition of which is discussed above, included a number of additional requirements in order to fit within this exception. In the proposed rule, CMS required, among other things, that "…*the performance or quality standards against which the recipient of the remuneration will be measured, if any, are objective and measurable…*"[121] [Emphasis added.] However, "*[b]ecause commenters expressed concern regarding the term 'performance or quality standards,' and in an effort to reduce burden on stakeholders by aligning our terminology with OIG*" CMS removed the "*performance or quality standards*" language and replaced it with "*outcome measures*."[122] CMS defined "*outcome measure*" as "*a benchmark that quantifies:*

(A) *Improvements in or maintenance of the quality of patient care; or*

(B) *reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care*."[123]

CMS did note that "…*outcome measures may not be applicable to all value-based arrangements…*"[124] but, if "*the value-based arrangement does include outcome measures…[they] must be determined in advance of their implementation*."[125] [Emphasis added.] CMS considered "*whether to require that outcome measures be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery*," but ultimately declined to include this requirement.[126] CMS did make clear that outcome measures may be replaced or substituted, so long as those changes are set forth in writing and made prospectively.[127]

CMS also included an explicit monitoring requirement, wherein "*[p]arties…must monitor the value-based arrangement no less frequently than annually…to determine whether the parties have furnished the value-based activities required under the arrangement, and whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise.*"[128] If the parties' monitoring "*indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity*."[129] CMS did make clear that if a value-based arrangement is found to be ineffective, it will still be "*deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise during the entire period during which it was undertaken by the parties*," i.e., so long as the parties

monitor their activities, catch an ineffective activity, and timely (i.e., within 90 days) cease that activity, they will not run afoul of the Stark Law.[130]

The other change CMS made to this exception in the final rule was its expansion of the proposed requirement that remuneration not be "*conditioned on the volume or value of referrals of <u>any patients, including patients in the target patient population</u>, to the entity or the volume or value of any other business generated, including business covered by the value-based arrangement, by the physician for the entity*."[131] [Emphasis added.] The proposed rule spoke only to patients *not* part of target patient population or business *not* covered by the value-based arrangement.[132] In expanding this requirement, CMS reminded "*readers that the value-based purpose of the arrangement must relate to the value-based enterprise as a whole…the exception will not protect a 'side' arrangement between two VBE participants that is unrelated to the goals and objectives (that is, the value-based purposes) of the value-based enterprise…*"[133]

Significantly, similar to the Value-Based Arrangements with Meaningful Downside Risk exception, CMS changed the Other Value-Based Arrangements exception's contribution requirement for physicians. In the proposed rule, CMS "*considered whether to require the recipient of any nonmonetary remuneration under a value-based arrangement to contribute at least 15 percent of the donor's cost of the nonmonetary remuneration*."[134] For the final rule, CMS declined to include any contribution requirement for this exception.[135]

Further, CMS chose not to limit this exception to nonmonetary remuneration only.[136] Consequently, the other value-based arrangements exception may cover both monetary and nonmonetary compensation.[137]

Of note, this exception does require the arrangement to be set forth in writing (and signed by the parties) and include "*a description of the value-based activities to be undertaken under the arrangement; how the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; the target patient population for the arrangement; the type or nature of the remuneration; the methodology used to determine the amount of the remuneration; and the performance or quality standards against which the recipient of the remuneration will be measured, if any*."[138]

Other New and Revised Exceptions

Indirect Compensation Arrangements

The definition of an indirect compensation arrangement was revised to include value-based arrangements, and was finalized so that "*…an unbroken chain of financial relationships that includes a value-based arrangement could form an 'indirect compensation arrangement' for purposes of*" the Stark Law, provided that certain factors are met.[139] This definition was updated "*[t]o avoid a blanket prohibition on indirect compensation arrangements that enhance value-based health care delivery and payment…[and] to make additional exceptions available to certain indirect compensation arrangements that include a value-based arrangement in the unbroken chain of financial relationships*."[140] CMS

clarified that "*the link closest to the physician may not be an ownership interest; it must be a compensation arrangement that meets the definition of value-based arrangement*."[141]

Limited Remuneration to a Physician

In its proposed rule, CMS suggested a new exception for limited remuneration to a physician (without documentation) for items or services actually provided by the physician, on an "*infrequent or short-term basis*," in an aggregate amount not exceeding $3,500 per calendar year (as adjusted by inflation) if:

(1) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician;
(2) The compensation does not exceed the *Fair Market Value* of the items or services; and,
(3) Arrangements for the rental or use of office space or equipment do not violate the prohibitions on per-click and percentage-based compensation formulas.[142]

The final rule made multiple changes to this new exception:

(1) The annual aggregate remuneration limit was raised from $3,500 to $5,000 (as adjusted by inflation);[143]
(2) Physicians are allowed to provide these services or items through employees whom were hired for the purpose of providing these services or items; and,
(3) The arrangement must be commercially reasonable.[144]

Notably, as set forth in the proposed rule, this exception operates on a calendar year basis, and not on a trailing twelve month basis from the start/end of the arrangement.[145]

Cybersecurity Donations

CMS also proposed the establishment of a new exception for donations of cybersecurity technology and related services that are "*necessary to implement, maintain, or reestablish security*."[146] For the exception to apply, a number of conditions must be met, including that: (1) the volume or value of referrals not be considered;[147] and, (2) the receipt of such technology may not be a condition of doing business with the donor.[148] CMS believes that the cybersecurity exception will be widely used by physicians because it helps address the growing threat of cyberattacks on data systems and health records.[149] CMS also proposed allowing for the donation of cybersecurity hardware, but only if that hardware was determined to be "*reasonably necessary*" based on the donor's risk assessments of its organization, as well as of the potential donee.[150]

The final rule remained generally the same as proposed, but with one notable exception. In finalizing this exception, CMS included hardware in the category of "*cybersecurity technology*"; the proposed definition had specifically omitted hardware, and the final rule removed that explicit omission.[151]

Conclusion

While some modifications were made to the various new Stark exceptions, the overall intent behind these new exceptions remain the same – to catch up to the rapidly changing healthcare system, and accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination. However, because of the novelty of these new exceptions, putting these arrangements into practice may raise a number of questions that will need to be subsequently addressed by CMS. Either way, given the high number of new healthcare fraud and abuse enforcement actions over the past decade, the enforcement of the Stark Law will likely continue in its intensity going forward.

Stark & Anti-Kickback Revisions Finalized: New Safe Harbors

[This is the final article in a three-part series regarding Stark & Anti-Kickback Revisions This installment was published in January 2021.]

On November 20, 2020, the *Centers for Medicare & Medicaid Services* (CMS) and the *Office of Inspector General* (OIG) of the *Department of Health and Human Services* (HHS) issued two final rules to modernize and clarify the *Stark Law* and the *Anti-Kickback Statute* (AKS).[152] This is the third installment in a *Health Capital Topics* series examining these final rules and their impact on healthcare valuation going forward. The first article provided an overview of the Stark Law and summarized the law's final rule as relates to "The Big Three" Requirements – Commercial Reasonableness, the Volume or Value Standard and the Other Business Generated Standard, and Fair Market Value.[153] The second article summarized the new Stark Law exceptions finalized by CMS, particularly those related to *value-based arrangements* (VBAs).[154] This third article will summarize the new AKS Safe Harbors finalized by the OIG.

Similarity to, and Distinction from, Stark Exceptions

Similar to CMS, OIG finalized a number of new, permanent AKS safe harbors, most notably for VBAs. As part of the new safe harbors, OIG established several new definitions, including those for value-based activity, VBA, value-based enterprise (VBE), value-based purpose, VBE participant, and target patient population.

It is critical to note that not all of the AKS safe harbors are the same as the Stark Law exceptions for VBAs. Consequently, this article will note those safe harbors that are identical to their sister Stark Law exceptions, and expand on those safe harbors that diverge from their sister exceptions.

New Value-Based Safe Harbors

Definitions

OIG finalized the definition of value-based activity as "*any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) The provision of an item or service; (2) The taking of an action; or (3) The refraining from taking an action*."[155] This definition is identical to the Stark Law definition of the term, and similar to the Stark Law, referrals may not be considered value-based activities.[156]

OIG finalized the definition of value-based arrangement as "*an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are: (1) The value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise*."[157] [Emphasis added.] Just like CMS, OIG finalized the emphasized language in this definition instead of its proposed language, "*between or among*," to "*clarify that that only the value-based enterprise and one or more of its VBE participants, or VBE participants in the same value-based enterprise, may be parties to a value-based arrangement*."[158] While this definition is identical to the Stark Law definition of the term, the application of the definition necessarily differs – while Stark VBAs are limited to physicians and entities as well as to designated health services, the AKS version of the definition does not have such limitations.[159]

OIG finalized the definition of value-based enterprise (VBE) to mean "*two or more VBE participants: (i) Collaborating to achieve at least one value-based purpose; (ii) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (iii) that have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and (iv) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s)*."[160] This definition is identical to the Stark Law definition of the term.[161]

OIG finalized the definition of VBE participant to mean "*an individual or entity that engages in at least one value-based activity as part of a value-based enterprise, other than a patient acting in their capacity as a patient*."[162] This definition generally aligns with the CMS definition, but is not verbatim.[163] Where the OIG's interpretation of VBE participant does differ from CMS is in its application. While the definition itself does not exclude certain entity types, the various value-based safe harbors (discussed below) identify certain entities that are ineligible for a given safe harbor (e.g., pharmaceutical manufacturers, distributors, and wholesalers; pharmacy benefit managers, laboratory companies; compounding pharmacies; medical device/supply manufacturers; entities/individuals that sell/rent DMEPOS (other than a pharmacy or a provider); and, medical device distributors/wholesalers.[164]

OIG finalized the definition of *value-based purpose* as "*(i) Coordinating and managing the care of a target patient population; (ii) improving the quality of care for a target patient population; (iii) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (iv) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population*."[165] This definition is identical to the Stark Law definition of the term.

OIG finalized the definition of target patient population to mean "*an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that: (i) Are set out in writing in advance of the commencement of the value-based arrangement; and (ii) further the value-based enterprise's value-based purpose(s)*."[166] This definition is identical to the Stark Law definition of the term.

Exceptions

OIG finalized new safe harbors for three types of value-based arrangements:

(1) Value-Based Arrangements with Full Financial Risk;
(2) Value-Based Arrangements with Substantial Downside Financial Risk; and,
(3) Care Coordination Arrangements.

In general, OIG "*sought to align value-based terminology and safe harbor conditions with those [Stark Law exceptions] being adopted by CMS…wherever possible….However, complete alignment is not feasible because of fundamental differences in statutory structures and sanctions across the two laws…the [AKS] is an intent-based, criminal statute that covers all referrals of Federal health care program business…In contrast, the [Stark Law] is a civil, strict-liability statute that prohibits payment by CMS for a more limited set of services referred by physicians who have certain financial relationships with the entity furnishing the services. As a result, the value-based exceptions adopted by CMS do not need to contemplate the broad range of conduct that implicates the [AKS]*."[167]

Each of these arrangements are discussed in turn below.

Full Financial Risk Arrangements[168]

OIG finalized the safe harbor for full financial risk arrangements to be those where "*the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least 1 year*."[169] This definition is largely in alignment with its sister Stark Law exception – similar to CMS, OIG extended the "*pre-risk period*" (the time prior to the commencement of the arrangement) for such arrangements from 6 to 12 months.[170] However, there are a couple of differences in the wording of the definition itself. For example, OIG differed on the characterization of the "*items and services*" at issue – CMS specified these as "*patient care items and services*,"[171] while OIG made no such

stipulation. Additionally, instead of simply stating that the term must be a "*specified period of time*," as CMS did,[172] OIG quantified the term as being at least one year in length.

Substantial Downside Financial Risk Arrangements[173]

In the final rule, OIG finalized its "*substantial downside financial risk*" safe harbor to apply to a VBE if it falls under one of three methodologies:

(A) Financial risk equal to at least 30 percent of any loss, where losses and savings are calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a bona fide benchmark designed to approximate the expected total cost of such care;

(B) Financial risk equal to at least 20 percent of any loss, where:

1) Losses and savings are calculated by comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that are covered by the applicable payor to a bona fide benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care; and

2) The parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting; or

(C) The VBE receives from the payor a prospective, per-patient payment that is:

1) Designed to produce material savings; and

2) Paid on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services."[174] [Emphasis added.]

Further, under this safe harbor, VBE participants (unless they are the payor undertaking the risk) must be at risk for "*a meaningful share*" of the VBE's substantial downside financial risk. OIG defined "*meaningful share*" to mean:

"*the VBE participant:*

(A) Assumes two-sided risk for at least 5 percent of the losses and savings, as applicable, realized by the VBE pursuant to its assumption of substantial downside financial risk; or

(B) Receives from the VBE a prospective, per-patient payment on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services, and does not claim payment in any form from the payor for the predefined items and services."[175] [Emphasis added.]

This is significantly different from the Stark Law's Value-Based Arrangements with Meaningful Downside Risk exception,[176] which only requires "*that the physician is responsible to repay or forgo no less than 10 percent of the total*

value of the remuneration the physician receives under the value-based arrangement."[177]

Care Coordination Arrangements[178]

The Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency safe harbor allows for certain remuneration provided if 13 factors are met. Notably, the safe harbor only protects certain in-kind (but not monetary) remuneration (a departure from the comparable Stark Law exception, which covers both monetary and in-kind compensation[179]); the arrangement must be "*commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE*"; and, the recipient of the remuneration must pay "*15 percent of the offer's cost or 15 percent of the fair market value of the remuneration*" (also a departure from the comparable Stark Law exception, which does not include a contribution requirement).[180]

Of note, unlike CMS, OIG defined the term "*coordination and management of care*," stating it means "*the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population*."[181]

Other New Safe Harbors

CMS-Sponsored Models

OIG established a new safe harbor related to remuneration exchanged among CMS-sponsored model participants and to CMS beneficiaries treated under the model (i.e., patient incentives). Importantly, CMS must affirmatively determine that this safe harbor applies to a given CMS-sponsored model.[182] There are several criteria that must be satisfied for both remuneration among participants and remuneration to patients;[183] notably, the arrangement must be memorialized in advance in a signed writing, which must include, "*at a minimum the activities to be undertaken by the CMS-sponsored model parties and the nature of the remuneration to be exchanged under the CMS-sponsored model arrangement*."[184]

Patient Engagement and Support

Another new safe harbor established by OIG protects arrangements for patient engagement and support to improve quality, health outcomes, and efficiency. Specifically, remuneration by way of tools and supports furnished by VBE participants to those in a target patient population would be protected, provided that, among other things, no more than $500 worth of in-kind (i.e., nonmonetary) remuneration is provided to a given patient in a year.[185] This safe harbor is only available to VBE participants – pharmaceutical manufacturers, distributors, and wholesalers; pharmacy benefit managers; laboratories; compounding pharmacies; physician-owned medical device and supply manufacturers; medical device distributors and wholesalers; and sellers of

durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), are not eligible for this safe harbor.[186]

Cybersecurity Technology and Services

OIG also finalized a new safe harbor for donations of cybersecurity technology and related services donation, similar to the Stark Law's new exception,[187] "*to protect nonmonetary donations of certain cybersecurity technology and related services to help improve the cybersecurity posture of the health care industry*."[188] For the safe harbor to apply, a number of conditions must be met, including that: (1) the volume or value of referrals not be considered; and, (2) the receipt of such technology may not be a condition of future referrals.[189] Importantly, OIG included in the finalized safe harbor protection for certain cybersecurity hardware, which had previously been omitted in the proposed safe harbor.[190]

Conclusion

While some modifications were made to the various new AKS safe harbors, the overall intent behind these safe harbors remain the same – to catch up to the rapidly changing healthcare system, and accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination. However, because of the novelty of these safe harbors, as well as their interplay with the Stark Law exceptions, putting these arrangements into practice may raise a number of questions that will need to be subsequently addressed by OIG. Either way, given the high number of new healthcare fraud and abuse enforcement actions over the past decade, the enforcement of AKS will likely continue in its intensity going forward.

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1 "HHS Makes Stark Law and Anti-Kickback Statute Reforms to Support Coordinated, Value-Based Care" U.S. Department of Health & Human Services, November 20, 2020, https://www.hhs.gov/about/news/2020/11/20/hhs-makes-stark-law-and-anti-kickback-statute-reforms-support-coordinated-value-based-care.html (Accessed 11/24/20).

2 "Modernizing and Clarifying the Physician Self-Referral Regulations Final Rule (CMS-1720-F)" Centers for Medicare & Medicaid Services, November 20, 2020, https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-final-rule-cms-1720-f (Accessed 11/24/20).

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

4 *Ibid.*

5 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" CMS-1720-F, Unpublished Version, https://public-inspection.federalregister.gov/2020-26140.pdf (Accessed 11/24/20), p. 123.

6 *Ibid*, p. 124.

7 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55799 (citing "Medicare and Medicaid Programs; Physician Referrals to Health Care Entities With Which They Have a Financial Relationship: Proposed rule" Federal Register Vol. 63, No. 6 (January 9, 1998), p. 1700).

8 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55790, 55840.

9 *Ibid*, p. 55790, 55840.

10 "Definitions" 42 C.F.R. § 411.351; "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" CMS-1720-F, Unpublished Version, https://public-inspection.federalregister.gov/2020-26140.pdf (Accessed 11/24/20), p. 128.

11 CMS-1720-F, Unpublished Version, p. 129.

12 *Ibid.*
13 *Ibid*, p. 130.
14 *Ibid.*
15 *Ibid*, p. 135.
16 These purposes were also listed and discussed in the October 2019 proposed rule. "CMS-1720-F, Unpublished Version, p. 136.
17 *Ibid*, p. 135.
18 *Ibid*, p. 128-129.
19 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55791.
20 *Ibid.*
21 *Ibid*, p. 55794.
22 CMS-1720-F, Unpublished Version, p. 167.
23 *Ibid*, p. 166.
24 "United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc." Case No. 10-254 (4th Cir., September 20, 2010), Opposition of the United States of America to Petition by Tuomey Healthcare System, Inc. for Permission to Appeal Interlocutory Order, p. 8-9.
25 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55795.
26 CMS-1720-F, Unpublished Version, p. 154.
27 *Ibid.*
28 *See* "Financial relationship, compensation, and ownership or investment interest." 42 C.F.R. § 411.354(d)(2)
29 "Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55797.
30 "Definitions" 42 CFR § 411.351.
31 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55797.
32 *Ibid.*
33 *Ibid.*
34 CMS-1720-F, Unpublished Version, , p. 198.
35 *Ibid.*
36 The Stark Law defines *fair market value* as "*the value in arms length [sic] transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee*." Social Security Act § 1877(h)(3); 42 U.S.C. § 1395nn(h)(3).
37 CMS-1720-F, Unpublished Version, p. 197.
38 "Definitions" 42 CFR § 411.351.
39 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55840.
40 *Ibid.*
41 *Ibid.*
42 *Ibid*, p. 55798, 55840.
43 CMS-1720-F, Unpublished Version, p. 539.
44 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55798.
45 CMS-1720-F, Unpublished Version, p. 201-202.
46 *Ibid*, p. 201-202.
47 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55799.
48 CMS-1720-F, Unpublished Version, p. 202.
49 *Ibid.*
50 *Ibid*, p. 211.
51 *Ibid.*
52 *Ibid*, p. 211-212.
53 *Ibid*, p. 215.
54 For more information on this controversial concept, see "Practice Loss Postulate (PLP) Regulatory Trend Misapplies Economic Theory to Healthcare Integration" Health Capital Topics, Vol. 9, Issue 6 (June 2016), https://www.healthcapital.com/hcc/newsletter/06_16/HTML/PHP/9.6_hc_topics_june_16_plp_abstract_6.22.php (Accessed 11/24/20).
55 CMS-1720-F, Unpublished Version, p. 207-208.
56 *Ibid.*
57 Emphasis added to illustrate CMS's disagreement with the categorical statement, i.e., that such a situation would "never" happen. CMS-1720-F, Unpublished Version, p. 208.
58 *Ibid*, p. 207-208.
59 *Ibid*, p. 209-210.

60 "HHS Makes Stark Law and Anti-Kickback Statute Reforms to Support Coordinated, Value-Based Care" U.S. Department of Health & Human Services, November 20, 2020, https://www.hhs.gov/about/news/2020/11/20/hhs-makes-stark-law-and-anti-kickback-statute-reforms-support-coordinated-value-based-care.html (Accessed 11/24/20).
61 "Stark & Anti-Kickback Revisions Finalized: Changes to Stark's Big Three Provisions" Health Capital Topics, Vol. 13, Issue 11 (November 2020), https://www.healthcapital.com/hcc/newsletter/11_20/HTML/STARK/convert_stark-aks-final-rules-11.24.20a.php (Accessed 12/4/20).
62 "Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule" Centers for Medicare & Medicaid Services, October 9, 2019, https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-proposed-rule (Accessed 10/22/19).
63 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55773.
64 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations: Final rule" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77497.
65 *Ibid*, p. 77497, 77500.
66 *Ibid*, p. 77501.
67 *Ibid*, p. 77500.
68 *Ibid*.
69 *Ibid*.
70 *Ibid*.
71 *Ibid*.
72 *Ibid*, p. 77497.
73 *Ibid*.
74 *Ibid*, p. 77498.
75 *Ibid*.
76 *Ibid*.
77 *Ibid*, p. 77497.
78 *Ibid*, p. 77501.
79 *Ibid*, p. 77498.
80 *Ibid*, p. 77501.
81 *Ibid*, p. 77502.
82 *Ibid*.
83 *Ibid*.
84 *Ibid*, p. 77497.
85 *Ibid*, p. 77499.
86 *Ibid*, p. 77505.
87 *Ibid*, p. 77502.
88 *Ibid*, p. 77497.
89 *Ibid*, p. 77499.
90 *Ibid*, p. 77498.
91 *Ibid*, p. 77503, 77509.
92 *Ibid*, p. 77497.
93 *Ibid*, p. 77499.
94 *Ibid*, p. 77505.
95 *Ibid*.
96 *Ibid*.
97 *Ibid*, p. 77508.
98 "Medicare 55777; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55829; "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations: Final rule" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77510.
99 Federal Register, Vol. 85, No. 232, p. 77509.
100 42 C.F.R. § 411.357(aa)(1).
101 42 C.F.R. § 411.357(aa)(1)(vii).
102 Federal Register, Vol. 85, No. 232, p. 77510.
103 *Ibid*, p. 77512.
104 *Ibid*, p. 77511.
105 *Ibid*, p. 77513.
106 *Ibid*, p. 77512.
107 *Ibid*, p. 77511.

108 *Ibid*, p. 77514.
109 *Ibid*, p. 77512.
110 *Ibid*.
111 42 C.F.R. § 411.357(aa)(2)
112 Federal Register, Vol. 85, No. 232, p. 77515.
113 *Ibid*, p. 77515 (citing https://www2.deloitte.com/us/en/insights/industry/health-care/volume-to-value-basedcare.html (last accessed June 18, 2020)).
114 *Ibid*.
115 *Ibid*, p. 77517.
116 *Ibid*, p. 77515.
117 *Ibid*, p. 77518.
118 *Ibid*, p. 77518.
119 *Ibid*, p. 77517.
120 42 C.F.R. § 411.357(aa)(3).
121 Federal Register Vol. 84, No. 201, p. 55784.
122 Federal Register, Vol. 85, No. 232, p. 77519.
123 *Ibid*, p. 77519.
124 *Ibid*.
125 *Ibid*.
126 *Ibid*, p. 77519-77520.
127 *Ibid*, p. 77525.
128 *Ibid*, p. 77520.
129 *Ibid*.
130 *Ibid*.
131 *Ibid*, p. 77519.
132 *Ibid*.
133 *Ibid*.
134 *Ibid*, p. 77521.
135 *Ibid*.
136 *Ibid*.
137 *Ibid*, p. 77518.
138 *Ibid*, p. 77519.
139 *Ibid*, p. 77525.
140 *Ibid*, p. 77526.
141 *Ibid*.
142 Federal Register Vol. 84, No. 201, p. 55829.
143 Federal Register, Vol. 85, No. 232, p. 77624.
144 *Ibid*.
145 *Ibid*, p. 77627.
146 Federal Register Vol. 84, No. 201, p. 55835.
147 *Ibid*, p. 55847.
148 *Ibid*.
149 *Ibid*, p. 55839.
150 *Ibid*, p. 55834.
151 Federal Register, Vol. 85, No. 232, p. 77639.
152 "HHS Makes Stark Law and Anti-Kickback Statute Reforms to Support Coordinated, Value-Based Care" U.S. Department of Health & Human Services, November 20, 2020, https://www.hhs.gov/about/news/2020/11/20/hhs-makes-stark-law-and-anti-kickback-statute-reforms-support-coordinated-value-based-care.html (Accessed 11/24/20).
153 "Stark & Anti-Kickback Revisions Finalized: Changes to Stark's Big Three Provisions" Health Capital Topics, Vol. 13, Issue 11 (November 2020), https://www.healthcapital.com/hcc/newsletter/11_20/HTML/STARK/convert_stark-aks-final-rules-11.24.20a.php (Accessed 12/4/20).
154 "Stark & Anti-Kickback Revisions Finalized: New Stark Exceptions Established" Health Capital Topics, Vol. 13, Issue 12 (December 2020), https://www.healthcapital.com/hcc/newsletter/12_20/HTML/STARK/convert_stark-aks-final-rules---new-exceptions-12.18.20.php (Accessed 1/8/21).
155 "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: Final rule" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77703.
156 *Ibid*.
157 *Ibid*, p. 77700.

158 *Ibid*.
159 *Ibid*, p. 77695.
160 *Ibid*, p. 77705-77706.
161 *Ibid*, p. 77697.
162 *Ibid*, p. 77706.
163 The CMS definition of VBE participant is: "*a person or entity that engages in at least one value*-based activity as part of a value-based enterprise." [Emphasis added.] The emphasized language differs from the OIG definition of the term. "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77497.
164 Federal Register, Vol. 85, No. 232, p. 77706.
165 *Ibid*, p. 77720.
166 *Ibid*, p. 77702.
167 *Ibid*, p. 77689.
168 42 C.F.R. § 1001.952(gg).
169 42 C.F.R. § 1001.952(gg)(10)(i). Federal Register, Vol. 85, No. 232, p. 77770-77771.
170 Federal Register, Vol. 85, No. 232, p. 77771.
171 *Ibid*, p. 77510.
172 *Ibid*.
173 42 C.F.R. § 1001.952(ee).
174 42 C.F.R. § 1001.952(ee)(i).
175 42 C.F.R. § 1001.952(ee)(ii).
176 42 C.F.R. § 411.357(aa)(2).
177 Federal Register, Vol. 85, No. 232, p. 77515.
178 42 C.F.R. § 1001.952(ee).
179 *Ibid*.
180 Federal Register, Vol. 85, No. 232, p. 77724, 77731.
181 *Ibid*, p. 77748.
182 42 C.F.R. § 1001.952(ii)(1)(i).
183 Federal Register, Vol. 85, No. 232, p. 77809.
184 42 C.F.R. § 1001.952(ii)(1)(iv).
185 Federal Register, Vol. 85, No. 232, p. 77781.
186 42 C.F.R. § 1001.952(hh)(1).
187 Federal Register, Vol. 85, No. 232, p. 77630.
188 *Ibid*, p. 77814-77815.
189 42 C.F.R. § 1001.952(jj)(1).
190 Federal Register, Vol. 85, No. 232, p. 77814-77815.

Methodist Healthcare Accused of Paying Kickbacks to Oncologists

[Excerpted from the article published in October 2020.]

Methodist Le Bonheur Healthcare (MLH), a non-profit healthcare system consisting of five hospitals as well as outpatient and ancillary services, has been accused of paying kickbacks in exchange for patient referrals.[1] Between 2012 and 2018, over $400 million was allegedly paid by MLH for referrals from physicians at The West Clinic, a Memphis, Tennessee based, for-profit private physician group of medical oncologists, gynecologic oncologists, radiologists, and other physician specialists.[2] The relators, a former MLH executive leadership team member and the former CEO for Methodist University Hospital, claim that MLH induced the referrals of cancer patients to their facility through kickback payments made to The West Clinic, in violation of numerous fraud and abuse laws.[3]

On October 28, 2011, MLH and The West Clinic announced that beginning January 1, 2012, MLH would enter into a partnership with five of The West Clinic's eight locations "*to transform cancer care in the [local region]*."[4] The complaint alleges that this arrangement was "*not a legal partnership, but rather an alliance to enter into business agreements*" and carry out business practices in violation of the Stark Law, Anti-Kickback Statute, and the Fair Claims Act.[5] These alleged business practices include entering into an agreement in which The West Clinic would exclusively refer patients to MLH (rather than to Baptist Healthcare, a competitor of MLH to which The West Clinic physicians had historically referred patients), and in exchange, MLH would reward The West Clinic physicians with: (1) compensation per work relative value unit (wRVU) in excess of fair market value (FMV); (2) "management" service fees largely determined by the volume and value of referrals; (3) sharing of 340B drug profits based on referrals; and, (4) a $7 million payment to The West Clinic for patient referrals, disguised as an investment in The West Clinic's research company.[6]

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

The Anti-Kickback Statute (AKS) makes it a felony for any person to "*knowingly and willfully*" solicit or receive, or to offer or pay, any "*remuneration*", directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[10] Similar to the Stark Law, the AKS contains several *safe harbors*, including protections for personal services and management contracts, which may shield an arrangement from regulatory liability if some or all of the requisite criteria is met.[11] Failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[12] However, as with the Stark Law, for a payment to meet the requirements of many AKS *safe harbors*, the compensation must: (1) be consistent with FMV; (2) be *commercially reasonable*; and, (3) not *take into account the value or volume of any referrals* provided by the group practice physicians.[13]

Violations of the Stark Law and/or AKS can trigger a violation of the False Claims Act (FCA).[14] The FCA imposes civil monetary penalties in an amount between $5,000 to $10,000 per claim, as well as treble damages, upon any individual who knowingly submits a false or fraudulent claim to, or uses false records to induce payment from, the U.S. government.[15] The FCA is a potent fraud and abuse enforcement tool, as it allows private individuals, also known as *qui tam* relators or *whistleblowers*, to bring suits on behalf of the government.[16]

The lawsuit alleges that Methodist compensated The West Clinic physicians an above-FMV and commercially unreasonable amount.[17] During the partnership between MLH and The West Clinic (2012-2018), most physicians at The West Clinic were medical oncologists.[18] The relators allege that each oncologist at The West Clinic was compensated over $1 million annually, while senior oncologists received an annual income of over $3 million, exceeding the Medical Group Management Association (MGMA) national 90th percentile annual compensation benchmark for oncology specialties, which averaged $760,600 during the time period in question.[19]

The relators alleged that concerns over proving that the demanded compensation packages were not in excess of FMV were discussed internally.[20] Allegations in the lawsuit indicate that the then-MLH CEO and CFO made an effort to find a compensation consultant that would support the level of compensation The West Clinic was demanding.[21] The relators allege that once a company was found that agreed that the extraordinarily-high compensation packages to be awarded to The West Clinic physicians were FMV, the then-MLH CEO and CFO "*admitted they would probably never be able to get such an opinion again*."[22] The alleged above-FMV compensation paid to The West Clinic physicians was composed of three components: (1) compensation per wRVU; (2) payments for "co-management" services; and, (3) shared 340B profits.[23]

The first type of compensation that The West Clinic physicians received from MLH was compensation per wRVU.[24] The agreement between The West Clinic and MLH allegedly specified that The West Clinic physicians would be paid

$120 per wRVU, regardless of the physician's experience or performance.[25] This level of compensation was slightly higher (1.24%) than the MGMA national 90th percentile for medical oncologists in 2012.[26] To support their claims of Stark Law violations, the relators allege that MLH leadership was aware that $120 per wRVU was a commercially unreasonable level of compensation considering that almost half of The West Clinic's patients were Medicare beneficiaries, which reimbursed at a rate of $34-35 per wRVU during the seven-year period of the West Clinic-MLH partnership.[27] MLH executives allegedly knew that without consideration of the $120 million in revenues from The West Clinic's referrals, compensation of $120 per wRVU would lead to significant financial loss.[28]

The second component of The West Clinic physicians' compensation package was payments for co-management services provided by the physicians.[29] The lawsuit alleges that as a part of the West Clinic-MLH partnership, The West Clinic entered into a management agreement with MLH requiring The West Clinic physicians to manage the oncology service lines at the four MLH hospitals located in the Memphis area.[30] However, the relators allege that communication within MLH and between The West Clinic and MLH indicates that The West Clinic physicians did not actually manage the oncology service line as their agreement required, and that this agreement was simply another way to disguise kickback payments to The West Clinic physicians.[31] To support their claims of Stark Law violations, the relators allege that management fees were paid to The West Clinic during time periods in which The West Clinic was not contractually required to perform management services under their agreement and that fluctuations in management fees can be traced to fluctuations in oncology service line revenues, largely influenced by referrals from The West Clinic physicians.[32]

The third component of The West Clinic physicians' compensation package was payments from shared 340B profits.[33] MLH generated between $100 million and $700 million in 340B profits as a direct result of The West Clinic physicians' referrals to MLH.[34] In exchange for The West Clinic physicians' referrals for chemotherapy and oral cancer drugs, MLH allegedly agreed to share their increased profits with The West Clinic, as evidenced by inconsistencies in Form 990 line items.[35] It is reported that in 2012, 2013, and 2014, total compensation for wRVUs and co-management fees only accounted for 67% to 69% of the total amount paid to The West Clinic physicians for physician services, suggesting that the additional 31% to 33% came from distributions of 340B profit savings to The West Clinic physicians.[36]

In addition to physician compensation in excess of FMV, the lawsuit alleges that MLH induced referrals from The West Clinic through a $7 million investment in Vector Oncology, a for-profit research entity controlled by The West Clinic physicians.[37] The $7 million investment is alleged to have been a condition made by The West Clinic for entering into the partnership with MLH. Half of the investment made by MLH was allocated to paying off Vector Oncology's debts, which debts were personally financed by The West Clinic

physicians.[38] The relators allege that Vector Oncology was unable to generate self-sustaining revenue, had no intellectual property of value, and had no viable business strategy; thus, there was no legitimate business reasoning for MLH to invest in Vector Oncology.[39] When concerns about the financial performance of Vector Oncology were expressed, MLH executives allegedly responded that MLH's investment was "*the cost of doing business*" with The West Clinic.[40] The relators emphasize that because The West Clinic physicians were personally liable for Vector Oncology's debts, $3.5 million of the investment made by MLH was a direct kickback to The West Clinic physicians for their agreement to refer patients to MLH.[41]

The complaint alleges that through the illegal inducement of referrals from The West Clinic physicians, MLH received over $1.5 billion in increased revenues from 2012 to 2018,[42] with over half of these increased revenues estimated to have been paid by Medicare and Medicaid.[43]

In response to the relators' allegations, MLH and The West Clinic deny any wrongdoing.[44] MLH said in a statement that, "*[o]ur payments for the services provided were appropriate. We cooperated fully in the government's investigation of these allegations, and we are pleased the government has decided not to intervene in the lawsuit at this time. The lawsuit lacks merit, and we will continue to vigorously defend ourselves*."[45]

The suit, originally filed in 2017, is currently in the discovery phase.[46] The defendants have filed a motion to dismiss the plaintiff's Second Amended Complaint, but the court has yet to rule on the motion.[47] Interestingly, as noted by MLH, the U.S. Attorney's Office has declined to intervene in the case thus far, but has stated that they will "*continue to monitor the case*."[48]

As mentioned in the March 2020 *Health Capital Topics* article entitled, "*DOJ Recovers Over $3 Billion in False Claims Act Cases*," there has been a significant number of FCA suits brought by whistleblowers, as well as by the *Department of Justice* (DOJ), in recent years.[49] Despite the Trump Administration's actions to deregulate the healthcare industry during the last three years, the high number of new healthcare fraud and abuse enforcement actions suggest that regulatory scrutiny of healthcare transactions will continue in its intensity going forward.

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1 "United States and State of Tennessee ex rel. Jeffery H. Liebman and David M. Stern v. Methodist Le Bonheur Healthcare, et al." Case No: 3:17-cv-00902 (M.D. Tenn., December 13, 2019), Second Amended Complaint, p. 4 and 12

2 *Ibid.*

3 *Ibid*, p. 4.

4 "Methodist and The West Clinic Form Partnership," Methodist Le Bonheur Healthcare, October 28, 2011, https://www.methodisthealth.org/articles/methodist-and-the-west-clinic-form-partnership/ (Accessed 10/20/20).

5 Case No: 3:17-cv-00902 (M.D. Tenn., December 13, 2019), Second Amended Complaint, p. 12.

6 *Ibid*, p. 26 and 36.

7 "Prohibition on certain referrals by physicians and limitations on billing" 42 C.F.R. § 411.353.
8 "Exceptions to the referral prohibition related to compensation arrangements" 42 C.F.R. § 411.357.
9 *Ibid*.
"Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).
11 "Exceptions" 42 C.F.R. §§ 1001.952(d) (2016).
12 "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 10/2/19), p. 1.
13 "Exceptions" 42 CFR §§ 1001.952(d).
14 "False claims" 31 U.S.C. § 3729(a)(1).
15 *Ibid*.
16 *Ibid*.
17 Case No: 3:17-cv-00902 (M.D. Tenn., December 13, 2019), Second Amended Complaint, p. 94.
18 *Ibid*.
19 *Ibid*, p. 94-95. The national 90th percentile compensation for medical oncologists was $777,940 in 2013, $922,244 in 2014, $762,970 in 2015, $693,452.28 in 2016, and $646,226.73 in 2017 according to MGMA Physician Compensation and Production Survey Data.
20 *Ibid*, p. 95.
21 *Ibid*.
22 *Ibid*.
23 *Ibid*, p. 96.
24 *Ibid*.
25 *Ibid*.
26 *Ibid*, p. 96-97.
27 *Ibid*, p. 96.
28 *Ibid*.
29 *Ibid*.
30 *Ibid*, p. 80.
31 *Ibid*, p. 87.
32 *Ibid*.
33 *Ibid*, p. 96. Section 340B of the Public Health Service Act (340B) allows healthcare organizations that care for a large low income or uninsured population to purchase outpatient drugs at significantly discounted prices from pharmaceutical manufactures participating in Medicaid and Medicare Part B programs. "340B Drug Pricing Program," Health Resources & Services Administration, October 2020, https://www.hrsa.gov/opa/index.html (Accessed 10/22/20).
34 *Ibid*, p. 48 and 113.
35 *Ibid*, p. 48, 53.
36 *Ibid*, p. 53.
37 *Ibid*, p. 88-89
38 *Ibid*, p. 89.
39 *Ibid*, p. 92-93.
40 *Ibid*, p. 93.
41 *Ibid*.
42 *Ibid*, p. 6.
43 *Ibid*.
44 "Methodist Le Bonheur accused of paying kickbacks to physicians" By Alex Kacik, Modern Healthcare, October 16, 2020, https://www.modernhealthcare.com/legal/methodist-le-bonheur-accused-paying-kickbacks-physicians (Accessed 10/20/20).
45 *Ibid*.

46 Case No: 3:17-cv-00902 (M.D. Tenn., December 13, 2019), Civil Docket (Accessed 10/19/20).
47 *Ibid*.
48 "Lawsuit: Methodist, West Clinic defrauded healthcare programs through kickback arrangement" By Max Garland, Memphis Commercial Appeal, October 14, 2020, https://www.commercialappeal.com/story/money/business/2020/10/14/methodist-le-bonheur-healthcare-west-clinic-lawsuit-alleged-kickbacks/3649942001/ (Accessed 10/20/20).
49 "DOJ Recovers Over $3 Billion in False Claims Act Cases" Health Capital Topics, Vol. 13, Issue 3 (March 2020), available at: https://www.healthcapital.com/hcc/newsletter/03_20/HTML/DOJ/convert_hc_topics_doj_2019_settlements.php.

CMS Final Rule Brings Transparency to Healthcare Industry

[Excerpted from the article published in November 2020.]

On October 29, 2020, the *Centers for Medicare & Medicaid Services* (CMS) released the *Transparency in Coverage* final rule.[1] This long-anticipated final rule stems from President Donald Trump's June 2019 executive order on "*Improving Price and Quality Transparency*"[2] and builds upon the hospital *Outpatient Prospective Payment System* (OPPS) price transparency requirements released in November 2019.[3] These requirements came under fire in a lawsuit filed by the *American Hospital Association* (AHA), *Association of American Medical Colleges* (AAMC), *Children's Hospital Association* (CHA), and *Federation of American Hospitals* (FAH), against the *Department of Health and Human Services* (HHS); the requirements were upheld by the courts in June 2020 and the lawsuit is being appealed by the plaintiffs.[4] Perhaps emboldened by this win, HHS and CMS have now passed a new final rule focusing on transparency for private health insurers, which includes ways for beneficiaries to estimate their out-of-pocket expenses and "*shop*" for services.[5]

This newly-announced final rule makes several changes and steps toward price transparency. Beginning January 1, 2021, group and individual health plans and insurers must disclose cost-sharing information for covered items and services from providers as requested by beneficiaries.[6] This information is to be available online and in paper form and should allow beneficiaries to estimate their own out-of-pocket expenses.[7] The final rule requires the disclosure of negotiated rates, historically allowed amounts for out-of-network providers, and drug prices.[8] The goal of this final rule is to create better-informed consumers who could then shop for services more efficiently and is meant to slow the rise of healthcare spending.[9]

CMS's reasoning in requiring transparency stems from the *Rational Actor Theory*, which posits that rational consumers will choose, among a number of options, that option which maximizes their utility, based upon "*extensive information, a coherent preference ordering, and a commitment to the principles of self-interest...*"[10] For most consumer products and services in the U.S., the buyer (consumer) of those products and services is aware of the actual price, which allows them to competently assess their options and make an educated decision. However, the U.S. healthcare system does not operate under these principles because prices for healthcare services and cost-sharing information are not typically known to the consumer (i.e., the patient). The consequences of this information asymmetry are numerous. First, patients often pay more out of pocket when they are not provided with price information sufficient to comparison shop.[11] In fact, many studies have cited secrecy around pricing as a primary reason for increasing healthcare costs.[12] Second, information asymmetry leads patients to accept medical care that is often unnecessary and to not seek the care that is necessary; this cycle of uninformed patients demanding unnecessary treatments due to a lack of information consequently leads to market failure.[13] Ways to correct this market failure could

include increasing healthcare choice and competition as well as remedying the opaque nature of pricing in healthcare, which could subsequently enhance competition as consumers are able to make more educated pricing decisions.

Research has found that informing patients as to the price structure of their healthcare services could allow more patients to knowledgeably shop for their medical expenditures, which may subsequently drive down prices, foster high-value care, lower costs, and increase competition in the healthcare marketplace.[14] The hypothesis that price transparency may lead to positive market outcomes is substantiated by a study of New Hampshire's price transparency efforts, which found not only that patients who utilized the state's website comparison tool to compare medical imaging procedure prices paid less out of pocket, but also that the price transparency led to lower prices for *all* patients (even those who did not utilize the website).[15] This New Hampshire case study is corroborated by economic analysis which indicates that if healthcare consumers have pricing information, providers face pressure to lower prices or provide better quality healthcare.[16]

It is important to note that not all studies show a consensus about the benefits of price transparency,[17] and many also point to low price tool utilization rates as an issue facing this movement toward transparency.[18] This shows the importance of education regarding these tools as well as the need to ensure that they are user-friendly and freely available. A 2009 study in California further found that the price transparency rules in that state were not sufficient for comparison shopping if one did not have insurance, indicating a need for additional price transparency legislation to enable consumers to be fully informed of their options.[19] Accordingly, some have claimed that the CMS price transparency final rule will not actually benefit consumers. Matt Eyles, President and CEO of *America's Health Insurance Plans* (AHIP), cited the high number of commercial health insurers who already offer price transparency tools to the more than one-third of Americans that they serve.[20] He also says that disclosing rates that are privately negotiated by insurers will reduce incentives to offer low rates, creating a quasi-price-floor for prices that providers will accept.[21] Eyles cites *Federal Trade Commission* (FTC) guidance that "*too much transparency can harm competition in any market, including in health care markets*."[22] The FTC has similarly warned legislators that, while increased access to information can spur competition and counter information asymmetries, as discussed above, disclosing information such as "*prices, costs, output, and contract terms*" may result in coordination or collusion among competitors.[23] This information could also reduce providers' incentives to negotiate discounts and lead to less aggressive bidding for contracts.[24]

Whether this final rule makes healthcare pricing more accessible, fosters competition, and lowers prices (as CMS and others claim), or reduces incentives for competitive negotiations from providers (as critics claim), has yet to be seen. The final rule goes into effect on January 1, 2021, but many of its provisions, such as a detailed pricing using historical payment information and an initial list of 500 "*shoppable*" services will not be required to be made

available until later years (in 2022 and 2023).[25] As more states and insurers implement their own price transparency rules and legislation, this coverage transparency rule will serve as a federal benchmark that builds off of CMS's existing OPPS price transparency final rule. Implementing additional measures on a federal level may also allow for more research to be conducted on the true effects of price transparency in different areas. The positive or negative effects on healthcare costs and competition as a consequence of this final rule will inform future policy as many push for greater transparency and look for solutions to intervene on continually rising healthcare costs.

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1 "Transparency in Coverage" Centers for Medicaid & Medicare Services, October 30, 2020, https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CMS-Transparency-in-Coverage-9915F.pdf (Accessed 11/3/20).

2 "Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First" The White House, June 24, 2019, https://www.whitehouse.gov/presidential-actions/executive-order-improving-price-quality-transparency-american-healthcare-put-patients-first/ (Accessed 11/3/20).

3 "Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; etc." Federal Register Vol. 84, No. 218 (November 12, 2019), p. 61142-61146

4 American Hospital Association, et al. v. Alex M. Azar II, Secretary of Health & Human Services, (D.D.C. December 4, 2019), available at: https://www.aha.org/system/files/media/file/2019/12/hospital-groups-lawsuit-over-illegal-rule-mandating-public-disclosure-individually-negotiated-rates-12-4-19.pdf%20.pdf (Accessed 11/3/20), p. 1-9; Court Upholds CMS' Hospital Price Transparency Final Rule" By John Commins, HealthLeaders Media, June 24, 2020, https://www.healthleadersmedia.com/strategy/court-upholds-cms-hospital-price-transparency-final-rule (Accessed 11/3/20).

5 Centers for Medicaid & Medicare Services, October 30, 2020, p. 2

6 *Ibid.*

7 *Ibid.*

8 *Ibid.*

9 *Ibid.*

10 "21st century political science: A reference handbook" By John T. Ishiyama & Marijke Breuning, Thousand Oaks, CA: SAGE Publications, Inc., 2011, p. 7.

11 Finding that when patients are provided the right comparison tools and information on how to use them to offset mistakes they will make superior healthcare spending choices. "Price Transparency: Not a Panacea for High Health Care Costs" By Kevin G. Volpp, Journal of the American Medical Association, Vol. 315, Issue 17 (May 2016), p. 1842-1847.

12 "The Disruptive Innovation of Price Transparency in Health Care" By Uwe Reinhardt, Journal of the American Medical Association, Vol. 310, No. 18 (November 13, 2013), p. 1927

13 As applied to the used car market, the authors define *market failure* as occurring when "*bad cars drive out the good because they sell at the same price as good cars...the bad cars sell at the same price as good cars since it is impossible for a buyer to tell the difference...only the seller knows*." "When Healthcare is a "Lemon": Asymmetric Information and Market Failure" By David W. Johnson, March 3, 2015, 4sightHealth, https://www.4sighthealth.com/when-healthcare-is-a-lemon-asymmetric-information-and-market-failure/ (Accessed 11/3/20) (finding that George Akerlof's "lemon" theory applies to healthcare markets due to a lack of information on the part of patients and health insurance companies (i.e., adverse selection)). For more information on the "lemon" theory, refer to: "The Market for "Lemons": Quality Uncertainty and the Market Mechanism" By

George Akerlof, The Quarterly Journal of Economics, Vol. 84, No. 3 (August 1970), available at: https://www.jstor.org/stable/1879431?seq=1 (Accessed 11/3/20).

14 Centers for Medicare & Medicaid Services, November 15, 2019; "Price Transparency For MRIs Increased Use Of Less Costly Providers And Triggered Provider Competition" By Sze-jung Wu, Gosia Sylwestrzak, Christiane Shah, and Andrea DeVries, Health Affairs, Vol. 22, No. 8 (2014), p. 1394-1395; "Association Between Availability of Health Service Prices and Payments for These Services" By Christopher Whaley, Jennifer Schneider Chafen, Sophie Pinkard, Gabriella Kellerman, Dena Bravata, Robert Kocher, and Neeraj Sood, Journal of the American Medical Association, Vol. 312, No. 16 (October 2014), p. 1670.

15 "An Empirical Model of Price Transparency and Markups in Health Care" Zach Y. Brown, August 2019, http://www-personal.umich.edu/~zachb/zbrown_empirical_model_price_transparency.pdf (Accessed 11/3/20), p. 2-4.

16 "Shopping For Price in Healthcare" By Paul B. Ginsburg, Health Affairs, Vol. 26, No. 2 (February 6, 2007), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.26.2.w208 (Accessed 11/3/20), p. w209.

17 "Association Between Availability of a Price Transparency Tool and Outpatient Spending" By Sunita Desai, Laura A. Hatfield, Andrew L. Hicks, Michael E. Chernew, and Ateev Mehrotra, Journal of the American Medical Association, Vol. 315, No. 17 (May 3, 2016), p. 1874.

18 Journal of the American Medical Association, Vol. 315, No. 17 (May 3, 2016), p. 1874; "Examining A Health Care Price Transparency Tool: Who Uses It, And How They Shop For Care" By Anna D. Sinaiko and Meredith B. Rosenthal, Health Affairs, Vol. 35, No. 4 (2016), p. 665, 668; "Americans Support Price Shopping For Health Care, But Few Actually Seek Out Price Information" By Ateev Mehrotra, Katie M. Dean, Anna D. Sinaiko, and Neeraj Sood, Health Affairs, Vol. 36, No. 8 (August 2017), p. 1394-1397.

19 "Does Price Transparency Legislation Allow the Uninsured to Shop for Care?" By Kate Stockwell Farrell, Leonard J. Finocchio, Amal N. Trivedi, and Ateev Mehrotra, Journal of General Internal Medicine, Vol. 25, No. 2 (November 21, 2009), p. 110.

20 "Public Disclosure of Privately Negotiated Rates Will Lead to Less Affordable Health Care for Americans" America's Health Insurance Plans, October 29, 2020, https://www.ahip.org/public-disclosure-of-privately-negotiated-rates-will-lead-to-less-affordable-health-care-for-americans/ (Accessed 11/3/20).

21 *Ibid.*

22 "Price transparency or TMI?" By Tara Isa Koslov and Elizabeth Jex, Federal Trade Commission, July 2, 2015, https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi (Accessed 11/3/20).

23 "Re: Amendments to the Minnesota Government Data Practices Act Regarding Health Care Contract Data" By Marina Lao, Deborah L. Feinstein, and Francine Lafontaine, Letter to Joe Hoppe and Melissa Hortman of the Minnesota House of Representatives, June 29, 2015, https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care/150702minnhealthcare.pdf (Accessed 11/3/20) p. 4-6.

24 *Ibid*, p. 7.

25 "Transparency in Coverage Final Rule Fact Sheet (CMS-9915-F)" Centers for Medicare and Medicaid Services, October 29, 2020, https://www.cms.gov/newsroom/fact-sheets/transparency-coverage-final-rule-fact-sheet-cms-9915-f (Accessed 11/3/20).

DOJ Recoveries for False Claims Act Cases Fall in 2020

[Excerpted from the article published in January 2021.]

On January 14, 2021, the *U.S. Department of Justice* (DOJ) announced their recovery of $2.2 billion in settlements and judgments from civil cases involving fraud and false claims for *fiscal year* (FY) 2020.[1] Approximately $1.8 billion was recouped from the healthcare industry for federal losses alone, and included recoveries from drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians.[2] This figure is significantly lower than healthcare-related recoveries during FY 2019, which totaled $2.6 billion.[3] Settlements received from the healthcare industry (nearly 82% of the total recovery amount) far outstripped recoveries from defense, energy, construction, and other industries.[4] In addition to the $1.8 billion recovered for federal losses, the DOJ also recovered tens of millions of dollars for state and Medicaid programs in FY 2020.[5]

As seen in years past, the largest healthcare recoveries were obtained from the drug industry. One of the largest settlements involved kickbacks paid to physicians by Novartis Pharmaceuticals Corporation to incentivize them to prescribe the company's pharmaceuticals.[6] This case alone accounted for approximately one-third of 2020 healthcare recoveries.[7] Similarly, Novartis and Gilead Sciences were also prosecuted for illegally subsidizing patient copays for their own products through the use of independent foundations,[8] which allowed these companies to inflate the costs of their drugs.[9] In addition, four of those foundations paid $13 million for their involvement in the kickback schemes with Novartis and Gilead. Universal Health Services also paid $117 million to settle allegations that its psychiatric and behavioral facilities submitted false claims to the government.[10] Additionally, the Oklahoma Center for Orthopaedic and Multi-Specialty Surgery paid $72 million to settle a case on improper remuneration in exchange for physician referrals.[11] As in previous years, the DOJ pursued cases related to opioids as well, including an *electronic health record* (EHR) misrepresentation case related to OxyContin.[12] One settlement case involved a contractor with the *Veterans Administration* (VA), who allegedly failed to offer timely appointments and falsified outpatient clinic wait times.[13]

Several laboratory, testing, and medical device cases and complaints, such as those involving companies such as Logan Laboratories, Inc., Tampa Pain Relief Centers Inc., SpineFrontier Inc., ResMed Corp., and UTC Laboratories Inc., were filed or settled in 2020.[14] All cases, except for the one involving Logan Laboratories, Inc. and Tampa Pain Relief Centers Inc., involved kickback allegations.[15] The Logan Laboratories and Tampa Pain Relief Centers case involved the ordering of urine drug tests for all patients without a showing of medical necessity.[16]

Of note, the totals for 2020 do not include two major cases, including the largest healthcare fraud and opioid enforcement case in DOJ history, which was announced on September 30, 2020.[17] This case involved 345 defendants and

more than $6 billion in alleged losses.[18] The defendants in this case were charged with submitting fraudulent claims connected to telemedicine, substance abuse treatment facilities, opioid distribution, and other fraud.[19] All three areas of the case involved false claims made to both public and private insurance companies.[20] Of $6 billion in alleged losses, $4.5 billion is related to telemedicine fraud, including paying physicians and nurse practitioners to order unnecessary durable medical equipment (DME), diagnostic testing, and pain medications.[21] The *Centers for Medicare & Medicaid Services* (CMS) Center for Program Integrity has separately taken action against this fraud by revoking the Medicare billing privileges of an additional 256 medical professionals for their involvement in telemedicine fraud.[22] In recognition of the necessity and increased utilization of telemedicine during the COVID-19 pandemic, payors rapidly expanded coverage of, and reimbursement for, telemedicine services during 2020. While the past year has proven the potential of telemedicine to foster efficient, high-quality care for future medical practice,[23] fraud in telemedicine may become a more prevalent issue as well. The second case not included in the 2020 totals involved an $8 billion settlement with Purdue Pharma LP on October 21, 2020.[24] $2.8 billion of this settlement was related to False Claims Act allegations that Purdue aggressively lobbied physicians to prescribe opioids even when they were not medically necessary.[25]

As in 2019, the DOJ's FY 2020 press release included an additional section entitled, "*Holding Individuals Accountable*," wherein it reviewed several cases in which the DOJ obtained substantial judgments from individuals, illustrating its continued commitment to the 2015 memorandum authored by then-Deputy Attorney General Sally Yates regarding holding individuals accountable for corporate wrongdoing (often referred to as the "Yates Memo").[26]

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.[27] Since 1986, recoveries made under civil FCA suits total more than $64 billion.[28] Over the past five years, there has been a significant uptick in the number of FCA suits brought on by both *whistleblowers* (also known as *qui tam* lawsuits) and the DOJ, with 672 qui tam cases and 250 *non*-qui tam cases initiated in FY 2020 alone.[29] The number of qui tam cases in 2020 is very similar to 2019, but over 100 more non qui tam cases were initiated in 2020 than in 2019, potentially indicating the government's decreasing reliance on whistleblower activity.[30] Despite the Trump Administration's actions to deregulate the healthcare industry over the past four years, the number of new cases enforcing healthcare fraud and abuse laws in 2020 appears to be on par with figures from previous years and would have been higher if cases settled after September 30, 2020, were included,[31] suggesting that FCA enforcement will remain high going forward.

1 "Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020," Department of Justice, Office of Public Affairs, Press Release, January 14, 2021, https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020 (Accessed 1/19/21).
2 *Ibid.*
3 "Justice Department Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019," Department of Justice, Office of Public Affairs, Press Release, January 9, 2020, https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019 (Accessed 3/2/20); "Fraud Statistics – Overview" Department of Justice, https://www.justice.gov/opa/press-release/file/1233201/download (Accessed 3/2/20).
4 Department of Justice, Office of Public Affairs, Press Release, January 14, 2021.
5 *Ibid.*
6 *Ibid.*
7 *Ibid.*
8 *Ibid.*
9 "Novartis Agrees to Pay Over $51 Million to Resolve Allegations that It Paid Kickbacks Through Co-Pay Foundations" Department of Justice, U.S. Attorney's Office: District of Massachusetts, July 1, 2020, https://www.justice.gov/usao-ma/pr/novartis-agrees-pay-over-51-million-resolve-allegations-it-paid-kickbacks-through-co-pay (Accessed 1/22/21); "Gilead Agrees To Pay $97 Million To Resolve Alleged False Claims Act Liability For Paying Kickbacks" Department of Justice, Office of Public Affairs, Press Release, September 23, 2020, https://www.justice.gov/opa/pr/gilead-agrees-pay-97-million-resolve-alleged-false-claims-act-liability-paying-kickbacks (Accessed 1/22/21).
10 Department of Justice, Office of Public Affairs, Press Release, January 14, 2021.
11 *Ibid.*
12 *Ibid.*
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
16 *Ibid.*
17 "National Health Care Fraud and Opioid Takedown Results in Charges Against 345 Defendants Responsible for More than $6 Billion in Alleged Fraud Losses" Department of Justice, Office of Public Affairs, Press Release, September 30, 2020, https://www.justice.gov/opa/pr/national-health-care-fraud-and-opioid-takedown-results-charges-against-345-defendants (Accessed 1/19/21).
18 *Ibid.*
19 *Ibid.*
20 *Ibid.*
21 *Ibid.*
22 *Ibid.*
23 "HHS Issues New Report Highlighting Dramatic Trends in Medicare Beneficiary Telehealth Utilization amid COVID-19" Department of Health and Human Services, July 28, 2020, https://www.hhs.gov/about/news/2020/07/28/hhs-issues-new-report-highlighting-dramatic-trends-in-medicare-beneficiary-telehealth-utilization-amid-covid-19.html (Accessed 1/19/21); Department of Justice, Office of Public Affairs, Press Release, September 30, 2020.
24 "Purdue Pharma Pleads Guilty to Criminal Charges for Opioid Sales" By Jan Hoffman and Katie Benner, December 17, 2020, https://www.nytimes.com/2020/10/21/health/purdue-opioids-criminal-charges.html (Accessed 1/22/21).
25 *Ibid.*; "False Claim Act Recoveries During 2020: A Strong Year for the Department of Justice" Polsinelli, January 21, 2021, https://www.polsinelli.com/intelligence/false-claim-act-recoveries-during-2020 (Accessed 1/22/21).
26 Department of Justice, Office of Public Affairs, Press Release, January 14, 2021; "Individual Accountability for Corporate Wrongdoing" By Sally Quillian Yates, Letter to Assistant U.S. Attorneys General and All United States Attorneys, September 9, 2015.
27 Department of Justice, Office of Public Affairs, Press Release, January 14, 2021.
28 *Ibid.*
29 "Fraud Statistics – Overview" Department of Justice, https://www.justice.gov/opa/press-release/file/1354316/download (Accessed 1/19/21).
30 *Ibid.*
31 *Ibid*; Polsinelli, January 21, 2021.

Healthcare Provisions in the American Rescue Plan

[Excerpted from the article published in March 2021.]

Introduction

On March 11, 2021, President Joe Biden signed into law the *American Rescue Plan Act of 2021* (ARPA).[1] Biden first announced this $1.9 trillion relief package on January 20, 2021, as part one of a two-step COVID-19 rescue and recovery plan.[2] In addition to another round of stimulus checks and extended unemployment benefits, ARPA includes several provisions related to insurance subsidies and coverage as well as healthcare providers.[3] The law looks to alleviate the burden felt by the millions of people who lost their employer-sponsored health insurance over the first six months of the pandemic and assist the hardest-hit communities through the extension of the *Patient Protection & Affordable Care Act* (ACA) and *Consolidated Omnibus Budget Reconciliation Act* (COBRA) subsidies, expanding Medicaid coverage, increasing funding for behavioral health, ramping up COVID-19 vaccines and testing, providing financial relief for rural providers, and enacting other individual and healthcare system protections.[4]

Coverage and Subsidy Expansions for Public Insurance

ARPA provisions related to state Medicaid programs span several areas: encouraging states that have yet to expand their Medicaid programs to expand; increasing coverage for COVID-19 patients and pregnant women; and, providing additional funding and support for home and community services as well as nursing facilities, among other temporary or emergency provisions.[5] In order to encourage Medicaid expansion in the 12 states that have not yet expanded, the ARPA increases the *Federal Medical Assistance Percentage* (FMAP), the share of Medicaid expenses paid by the federal government, by 5% for two years after the state's expansion.[6] This increase is in addition to the current 6.2% FMAP increase in place for the duration of the COVID-19 *public health emergency* (PHE); notably, the extra funds received from the increased FMAP will not apply to *disproportionate share hospital* (DSH) payments or the *Children's Health Insurance Program* (CHIP).[7]

Any state that expands Medicaid will be required to cover COVID-19 vaccines and treatments without cost sharing, in order to receive the increased FMAP.[8] The costs associated with COVID-19 vaccines will be matched at a rate of 100% FMAP until one year after the end of the PHE.[9] The new law also provides states with the option to provide COVID-19 vaccines and treatments to the uninsured without cost sharing and receive reimbursement for those otherwise uncompensated services at Medicaid rates.[10]

The law also provides for one-year increases in FMAP for home-based and community-based services and those services provided through the Urban Indian Organizations and Native Hawaiian Health Care Systems.[11] To account for the increased FMAP during COVID-19, the law calls for a recalculation of DSH payment allotments for each year in which the temporary FMAP increases

apply in order to reconcile what the state would have made without those FMAP increases.[12]

Increased Access to Individual Insurance Coverage

ARPA seeks to further expand insurance coverage through reducing the costs of Marketplace coverage and expanding COBRA coverage. Through tax year 2022, individuals who make between 100 and 150% of the *federal poverty level* (FPL) will not pay Marketplace premiums.[13] Households above the previous eligibility threshold of 400% FPL may also now be eligible for Marketplace tax credit subsidies.[14] Additionally, individuals who receive unemployment benefits during 2021 are eligible for Marketplace coverage.[15]

COBRA gives workers (and their families) the ability to maintain their group health coverage for limited periods of time after a life event such as job loss, job transition, divorce, or death.[16] However, those individuals are typically obliged to pay the entire premium for coverage during that time (in contrast to sharing that premium with the employer).[17] In an attempt to provide coverage to out-of-work individuals as a result of the pandemic, ARPA requires the federal government to fully subsidize COBRA premiums for eligible individuals and families through September 30, 2021.[18]

Mental and Behavioral Health Funding

Studies have shown that anxiety, depression, and substance use have all skyrocketed during the COVID-19 pandemic.[19] Research indicates a fourfold increase in anxiety and depression symptoms between January to June 2019 and December 2020 to January 2021, from 11% to over 40%.[20] Isolation, stress, and worry, stemming (for many) from isolation, job loss, and other pandemic-related changes, have had far-reaching effects.[21]

ARPA seeks to address these pandemic consequences through the allocation of $3.5 billion for behavioral health and substance abuse programs, $3 billion of which will go toward mental health and substance use disorder block grants.[22] The new law also provides $15 million for states to develop mobile service programs for individuals experiencing mental health or substance abuse crises for five years, as well as $80 million for pediatric mental health services.[23] The remaining funds will be given out as grants to:

(1) Clinics participating in the Certified Community Behavioral Health Clinic program;
(2) Behavioral health workforce education and training programs;
(3) Certain institutions for training in decreasing mental health disorders among healthcare personnel and for encouraging good health behaviors among staff;
(4) Overdose prevention and harm prevention programs;
(5) Education for healthcare staff and first responders in identifying and preventing behavioral health disorders; and,
(6) Community-based programs addressing child and adolescent mental health.[24]

Relief for Rural Providers

The law allocated a further $8.5 billion to rural healthcare providers.[25] These funds will be distributed once the *Department of Health and Human Services* (HHS) creates a process for eligible providers to apply.[26] This provision is meant to reimburse these rural providers for both additional expenses and lost revenues related to COVID-19.[27] Rural providers have been previously targeted by executive orders and legislation[28] because of their vulnerability, which was exacerbated by the COVID-19 PHE, as well as their importance in providing healthcare access to rural populations. Approximately 20% of rural Americans depend on local hospitals for their care, but even in early 2020 (prior to the pandemic), 25% of rural hospitals were at risk of closing; a total of 20 rural hospitals closed in 2020.[29] For an industry that comprises approximately 1,800 rural hospitals, a double-digit number of closures in a one-year span, and a 7% closure rate over the past 10 years, is not insignificant.[30] Whether more hospitals will close before the end of the pandemic period remains to be seen, but ARPA has attempted to thwart these vulnerable providers by targeting them with greater funding and relief.

Other Emergency Protections

ARPA also allows for $250 million to create strike teams that will specifically focus on the health and safety of nursing facility residents and employees and be responsible for tasks such as aiding in clinical care, infection control, and staffing, both during, and for one year after, the current PHE.[31] In total, there have been over 1.3 million COVID-19 cases and nearly 175,000 COVID-19 deaths across the more than 33,000 long-term care facilities in the U.S.[32] As of March 2021, despite only representing 1% of the nation's population, 34% of COVID-19 deaths had occurred in these facilities.[33] Because of the disproportionate burden of cases and deaths on nursing facilities, much of the COVID-19 response and infection prevention focus has been, and continues to be, focused on these entities. Some experts have even called for infection prevention staff to be hired permanently at nursing and other residential facilities,[34] and the creation of these strike forces may serve to answer these calls.

Conclusion

The long-term effects of ARPA remain to be seen. It is, however, giving relief to myriad areas in the healthcare industry, on both the patient and provider side, identified as having the most urgent needs: rising uninsured rates, individual financial struggles, behavioral health and substance use disorders, vulnerable rural providers, and residents of long-term care facilities. As mentioned briefly above, this law was only step one of President Biden's two-step plan for rescue and recovery. The next step is currently being deliberated by the president's advisors and is expected to be presented to government leaders in April 2021.[35] This $3 trillion plan will address economic inequality, infrastructure, reducing carbon emissions, and other measures to boost the economy in order to "*[build] back better than before [the pandemic]*."[36] The legislation is also expected to include measures specifically targeting pharmaceutical industry and drug

pricing reform, which draws from the *Elijah E. Cummings Lower Drug Costs Now Act* that was passed by the U.S. House of Representatives at the end of 2019.[37] However, with no official announcements from the president, how this new legislation will build upon healthcare reform and relief included in the recently-passed ARPA remains to be seen.

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1 "Summary of American Rescue Plan Act of 2021 and Provisions Affecting Hospitals and Health Systems" American Hospital Association, March 17, 2021, https://www.aha.org/advisory/2021-03-17-summary-american-rescue-plan-act-2021-and-provisions-affecting-hospitals-and (Accessed 3/23/21).

2 *Ibid*; "President Biden Announces American Rescue Plan" The White House, January 20, 2021, https://www.whitehouse.gov/briefing-room/legislation/2021/01/20/president-biden-announces-american-rescue-plan/ (Accessed 3/23/21).

3 American Hospital Association, March 17, 2021; "The $1.9 Trillion American Rescue Plan Offers Great News On Health Insurance; Here Are The Provisions That Cut Insurance Costs" By Deb Gordon, Forbes, March 12, 2021, https://www.forbes.com/sites/debgordon/2021/03/12/the-19-trillion-american-rescue-act-offers-great-news-on-health-insurance-here-are-the-provisions-that-cut-insurance-costs/?sh=76db45d81fe5 (Accessed 3/23/21).

4 American Hospital Association, March 17, 2021; Gordon, March 12, 2021; The White House, January 20, 2021.

5 "American Rescue Plan Act of 2021" H.R. 1319, 117th Cong. § 9811-9819 (March 11, 2021).

6 "Status of State Medicaid Expansion Decisions: Interactive Map" Kaiser Family Foundation, March 23, 2021, https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/ (Accessed 3/23/21); H.R. 1319, 117th Cong. § 9814 (March 11, 2021); American Hospital Association, March 17, 2021.

7 H.R. 1319, 117th Cong. § 9814 (March 11, 2021); American Hospital Association, March 17, 2021.

8 *Ibid.*

9 *Ibid.*

10 *Ibid.*

11 *Ibid.*

12 *Ibid.*

13 *Ibid.*

14 *Ibid.*

15 American Hospital Association, March 17, 2021.

16 "Continuation of Health Coverage (COBRA)" U.S. Department of Labor, https://www.dol.gov/general/topic/health-plans/cobra (Accessed 3/24/21).

17 *Ibid.*

18 H.R. 1319, 117th Cong. § 9501 (March 11, 2021); American Hospital Association, March 17, 2021.

19 "The Implications of COVID-19 for Mental Health and Substance Use" By Nirmita Panchal, Rabah Kamal, Cynthia Cox, and Rachel Garfield, Kaiser Family Foundation, February 10, 2021, https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/ (Accessed 3/23/21); "COVID's mental-health toll: how scientists are tracking a surge in depression" By Alison Abbott, Nature, February 3, 2021, https://www.nature.com/articles/d41586-021-00175-z (Accessed 3/23/21).

20 *Ibid.*

21 Panchal, Kamal, Cox, and Garfield, February 10, 2021.

22 H.R. 1319, 117th Cong. § 2701-2702 (March 11, 2021); American Hospital Association, March 17, 2021.

23 H.R. 1319, 117th Cong. § 2708, 2710, 2712 (March 11, 2021); American Hospital Association, March 17, 2021.

24 H.R. 1319, 117th Cong. § 2703-2707, 2709, 2711, 2713 (March 11, 2021); American Hospital Association, March 17, 2021.
25 H.R. 1319, 117th Cong. § 1150C (March 11, 2021).
26 H.R. 1319, 117th Cong. § 1150C (March 11, 2021); American Hospital Association, March 17, 2021.
27 "American Rescue Plan Act of 2021" H.R. 1319, 117th Cong. § 1150C (March 11, 2021).
28 See the August 2020 Health Capital Topics article "Executive Order Expands Telemedicine and Eases Burden on Rural Providers" available at: https://www.healthcapital.com/hcc/newsletter/08_20/HTML/EXEC/convert_executive_telemedicine_access_expansion_8.20.20.php (Accessed 3/23/21).
29 "180 Rural Hospital Closures: January 2005 – Present (136 since 2010)" The Cecil G. Sheps Center for Health Services Research, https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/ (Accessed 3/23/21); "1 In 4 Rural Hospitals Are At Risk Of Closure And The Problem Is Getting Worse" By Clary Estes, Forbes, February 24, 2020, https://www.forbes.com/sites/claryestes/2020/02/24/1-4-rural-hospitals-are-at-risk-of-closure-and-the-problem-is-getting-worse/?sh=43d29f9b1bc0 (Accessed 3/23/21).
30 Estes, Forbes, February 24, 2020.
31 H.R. 1319, 117th Cong. § 9818 (March 11, 2021).
32 "The Long-Term Care COVID Tracker" The COVID Tracking Project, March 4, 2021, https://covidtracking.com/nursing-homes-long-term-care-facilities (Accessed 3/23/21).
33 *Ibid.*
34 "COVID-19 drives nursing homes to overhaul infection control efforts" By Christine Kilgore, CHEST Physician, June 10, 2020, https://www.mdedge.com/chestphysician/article/223619/coronavirus-updates/covid-19-drives-nursing-homes-overhaul-infection?sso=true (Accessed 3/23/21).
35 "Biden Team Prepares $3 Trillion in New Spending for the Economy" By Jim Tankersley, The New York Times, March 23, 2021, https://www.nytimes.com/2021/03/22/business/biden-infrastructure-spending.html (Accessed 3/23/21).
36 *Ibid*; "President Biden Announces American Rescue Plan" The White House, January 20, 2021, https://www.whitehouse.gov/briefing-room/legislation/2021/01/20/president-biden-announces-american-rescue-plan/ (Accessed 3/23/21).
37 "Democrats see a pathway for their ambitious drug pricing bill" By Paige Winfield Cunningham and Alexandra Ellerbeck, The Washington Post, March 23, 2021, https://www.washingtonpost.com/politics/2021/03/23/health-202-democrats-see-pathway-their-ambitious-drug-pricing-bill/ (Accessed 3/23/21). "Elijah E. Cummings Lower Drug Costs Now Act" H.R. 3, 116th Cong. (December 12, 2019).

The Rise of Unregulated Convenience Care

[Excerpted from the article published in April 2021.]

Convenience care clinics, including *urgent care centers* (UCCs) and retail health clinics, have seen increasing popularity and attention in recent years. As the number of UCCs and retail health clinics in the U.S., as well as the number of patients they serve, grow, some experts have called for stronger state regulation and oversight in order to ensure that these convenience care centers are providing access to all, including vulnerable communities, without discrimination.

During the COVID-19 *public health emergency* (PHE), UCCs and retail health clinics have been central providers of COVID-19 testing and are likely to play an important role in COVID-19 vaccination.[1] In fact, CVS Health alone gave out 6 million tests in the first six months of the COVID-19 PHE.[2] A large proportion – approximately 70% – of those tests were given to new CVS Health patients, an indication of the massive influx of business that these centers have seen because of the PHE.[3] The *Centers for Medicare and Medicaid Services* (CMS) further broadened the list of acceptable ambulance destinations to include UCCs during the pandemic.[4] This regulatory change allowed for patients to be brought to UCCs, among other alternative destinations, in the event that transporting a patient to a hospital emergency room was not medically appropriate because of the conditions in that hospital.[5]

Even before the PHE, however, these convenience care clinics were growing at high rates. Only 700 retail health clinics existed in 2013, compared with more than 2,700 in 2019 (a nearly 286% increase); similarly, the number of UCCs increased from 6,100 in 2013 to 9,616 by late 2019 (about a 58% increase).[6] Additionally, in 2019, UCCs generated nearly $28 billion in revenue.[7] The growth in UCCs has been partially attributed to a better work-life balance for physicians, as urgent care work comes with no on-call scheduling or night or weekend shifts.[8] Patients also do not expect, or make appointments, to see particular physicians at a UCC, meaning that physicians are not expected to work during any off hours.[9]

Demand for convenience care services has also increased because of the cost-saving benefits and efficiency of these clinics.[10] Reducing the burden of health costs has become a strong focus over the past several years, as national health expenditures continue to increase year after year.[11] Studies have shown, in fact, that UCCs may be up to ten times less expensive on average, even for patients who receive the same diagnosis.[12] A growing number of consumers on high-deductible insurance plans has also likely contributed to the rise of cheaper options like retail health clinics or UCCs.[13] Further, fewer Americans have a primary care provider, and these clinics may provide a desired alternative for affordable care for those individuals.[14] Beyond affordability, retail health centers and UCCs are more convenient, with 70% of patients waiting less than 20 minutes at UCCs and nearly 94% being served within 30 minutes.[15] By

contrast, patients admitted to a hospital wait over 100 minutes for a hospital room on average.[16]

Though they have existed for many years, UCCs present unique challenges to regulators. Because these enterprises can range from a single office, to practices integrated with a hospital or multi-specialty groups, to an extension of a physician office, the size, reach, and needed infrastructure vary greatly from clinic to clinic.[17] In 2015, most state regulations in place for UCCs focused primarily on defining urgent care via naming conventions, included services, and accreditation standards.[18] Still, as of the date of publication, most states do not issue facility licenses for convenience care entities, with these centers instead operating under an individual physician's license or hospital license.[19] Only five states currently issue licenses to UCCs, with five additional states issuing licenses only in certain cases.[20] This lack of regulation means that there is often no charity care policy offered to consumers, so patients whose insurance is not accepted may receive unexpected medical bills.[21] Further, there is concern about restrictions on reproductive and sexual health services and coverage at centers operated by health systems with religious affiliations, as well as equitable access, as convenience care centers are still largely absent from low-income areas and instead populate areas with higher rates of private insurance coverage.[22]

With the recently-passed legislation that provides more protections from surprise billing (which bill takes effect in 2022)[23] and the increased attention given to convenience health centers as a result of the COVID-19 pandemic, it is likely that regulation in this industry will be addressed in the coming years. Some advocates suggest that state *certificate of need* (CON) programs be updated to include UCCs and retail clinics as a way to ensure that these entities are equitably distributed to meet the needs of all individuals in a given community.[24] What future regulatory processes around these clinics looks like remains to be seen, but encouraging nondiscrimination policies, continuum of care coordination with other health services, and equitable services to low-income neighborhoods are top priority for regulation advocates.[25] Providers who would consider entering the area of convenience care, in order to provide more time- and cost-effective care to their patients will want to stay abreast of any new regulatory developments that are likely to affect UCCs and retail health clinics in the near future.

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1 "Making "Convenient Care" the Right Care for All: Improving State Oversight of Urgent Care Centers and Retail Health Clinics" By Tess Solomon, Kelly Jo Popkin, Amy Chen, Lois Uttley, and Susannah Baruch, National Health Law Program, March 31, 2021, available at: https://healthlaw.org/resource/making-convenient-care-the-right-care-for-all-improving-state-oversight-of-urgent-care-centers-and-retail-health-clinics/ (Accessed 4/1/21).

2 *Ibid.*

3 *Ibid.*

4 "CMS: URGENT CARE CENTERS ARE OK AS DESTINATIONS FOR AMBULANCE TRANSPORT DURING PANDEMIC" The Journal of Urgent Care Medicine,

https://www.jucm.com/cms-urgent-care-centers-are-ok-as-destinations-for-ambulance-transport-during-pandemic/ (Accessed 4/1/21).

5 *Ibid.*

6 Solomon, Popkin, Chen, Uttley, and Baruch, March 31, 2021; "Now more than 9,000 urgent care centers in the U.S., industry report says" By Joanne Finnegan, Fierce Healthcare, February 26, 2020, https://www.fiercehealthcare.com/practices/now-more-than-9-000-urgent-care-centers-u-s-industry-report-says (Accessed 4/1/21).

7 "Industry Report OD5458: Urgent Care Centers" By Anna Miller, IBISWorld, November 2019, p. 8

8 "What's behind the growth of urgent care clinics?" By Cheryl Alkon, Medical Economics, August 29, 2018, https://www.medicaleconomics.com/view/whats-behind-growth-urgent-care-clinics (Accessed 4/1/21).

9 *Ibid.*

10 "How the growth of the urgent care industry business model is changing the healthcare market in 2021" By Shelagh Dolan, Business Insider, January 29, 2021, https://www.businessinsider.com/urgent-care-industry-trends (Accessed 4/1/21).

11 "National Health Care Spending In 2019: Steady Growth For The Fourth Consecutive Year" By Anne B. Martin, Micah Hartman, David Lassman, and Aaron Catlin, Health Affairs, Vol. 40, No. 1 (December 16, 2020), https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.02022 (Accessed 4/1/21).

12 Dolan, January 29, 2021.

13 Alkon, August 29, 2018.

14 "Declining numbers of Americans have a primary care provider" By Linda Carroll, Reuters, December 16, 2019, https://www.reuters.com/article/us-health-pcp-trends/declining-numbers-of-americans-have-a-primary-care-provider-idUSKBN1YK1Z4 (Accessed 4/1/21).

15 Dolan, January 29, 2021.

16 "10 States With the Longest Emergency Room Waits" By Casey Leins, U.S. News, March 17, 2020, https://www.usnews.com/news/best-states/articles/2020-03-17/10-states-with-the-longest-emergency-room-wait-times (Accessed 4/1/21).

17 "STATES GRAPPLE WITH THEIR OWN REGULATORY APPROACH TO URGENT CARE" By Alan A. Ayers, The Journal of Urgent Care Medicine, https://www.jucm.com/states-grapple-with-their-own-regulatory-approach-to-urgent-care/ (Accessed 4/1/21).

18 *Ibid.*

19 Solomon, Popkin, Chen, Uttley, and Baruch, March 31, 2021.

20 *Ibid.*

21 *Ibid.*

22 *Ibid.*

23 "Surprise Medical Bills: New Protections for Consumers Take Effect in 2022" Kaiser Family Foundation, February 4, 2021, https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/ (Accessed 4/1/21).

24 Solomon, Popkin, Chen, Uttley, and Baruch, March 31, 2021

25 *Ibid.*

Supreme Court Leaves ACA in Place

[Excerpted from the article published in June 2021.]

On June 17, 2021, the Supreme Court of the United States (SCOTUS) rejected, for the third time, a legal challenge to the *Patient Protection and Affordable Care Act* (ACA). A 7-2 majority found that the two individual and 18 state plaintiffs did not have standing, stating, *"the plaintiffs…failed to show a concrete, particularized injury fairly traceable to the defendants' conduct in enforcing the specific statutory provision they attack as unconstitutional*."[1] The Court ruled only on the standing issue and thus declined to proceed and rule on the constitutionality of the Individual Mandate. This *Health Capital Topics* article will discuss the background and procedural history of the case, as well as the analysis contained in the Court's decision.

Background

The ACA's Individual Mandate[2] was previously litigated in the 2012 case, *National Federation of Independent Business* (NFIB) *v. Sebelius*, in which a 5-4 decision found the provision constitutional.[3] Chief Justice Roberts concluded that the Individual Mandate produced "*at least some revenue for the Government*," and was found to be valid under Congress's authority to tax and spend.[4] However, in 2017, Congress passed the *Tax Cuts and Jobs Act* (TCJA), which among other things, reduced the Individual Mandate penalty to zero dollars ($0) effective January 2019.[5] Setting the penalty to zero dollars under the TCJA arguably rendered the Individual Mandate unconstitutional because "*the Individual Mandate no longer carries a noncompliance penalty that produces revenue.*"[6]

Procedural History

In February 2018, Texas Attorney General Ken Paxton and a group of 20 Republican state attorneys general and governors sued the federal government asserting they had been harmed by the increased number of beneficiaries they had to support on state insurance.[7] The Texas Federal District Court deemed the ACA unconstitutional in its entirety.[8] The decision was then appealed to the U.S. Court of Appeals for the Fifth Circuit, which also found the Individual Mandate unconstitutional, but remanded the case to the district court for further review to determine which parts of the ACA could survive without the Individual Mandate.[9] The ruling to uphold the lower court's decision did not come as a surprise after the Trump Administration's Department of Justice (DOJ) filed a letter in the case in 2019,[10] arguing the Individual Mandate could not be severed from the rest of the ACA if the mandate was declared unconstitutional.[11]

The saga then continued with an appeal to SCOTUS to determine:

(1) The constitutionality of the Individual Mandate with its penalty of zero dollars for not purchasing health insurance; and,
(2) Whether the Individual Mandate, if determined to be unconstitutional, is severable from the rest of the ACA.[12]

Oral arguments for the case were heard by the justices in November 2020.[13] The questions asked of counsel during oral arguments indicated that the justices seemed to take issue with the fact that a mandate without a penalty could not be enforced; therefore, invalidating the Individual Mandate would not address the alleged injuries at hand.[14] Additionally, several justices expressed skepticism that the entire ACA must be invalidated if the Individual Mandate was determined unconstitutional. The main argument for severability came from Chief Justice Roberts, who noted that the 2017 Congress left the rest of the law intact when it passed legislation reducing the Individual Mandate's penalty to zero.[15] From the oral arguments, legal experts predicted that even if SCOTUS would have found the Individual Mandate unconstitutional, they would have still held that the mandate was severable from the rest of the ACA.[16]

In February 2021, the DOJ (now under President Biden) submitted a letter to SCOTUS wherein the agency retracted its previous opposition to the ACA and argued *for* the validity of the ACA's Individual Mandate. [17] The letter also supported the severability of the Individual Mandate from the rest of the ACA, in the event that SCOTUS found the provision unconstitutional.[18]

SCOTUS Ruling

The long-awaited fate of the ACA was decided by SCOTUS on June 17, 2021, with a 7-2 majority finding that none of the plaintiffs had faced any "cognizable" injury from the removal of the Individual Mandate's monetary penalties. The Court's decision reversed the Fifth Circuit's judgment, which had previously declared the ACA unconstitutional.[19]

The majority opinion, written by Justice Breyer (with Chief Justice Roberts and Justices Sotomayor, Kagan, Kavanaugh, and Barrett joining, and with Justice Thomas concurring), found that none of the plaintiffs lacked legal standing to bring the lawsuit. In order to have standing to sue in federal court, plaintiffs must show that they have: "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision."[20] The two individual plaintiffs claimed that their injury was "in the form of payments they have made and will make each month to carry the minimum essential coverage" required by the Individual Mandate.[21] The majority found that, even assuming the individual plaintiffs incurred this "pocketbook injury" (i.e., the first element of standing), they did not prove that this injury is traceable to the Individual Mandate, because the $0 penalty rendered the Mandate unenforceable.[22] Therefore, if the individual plaintiffs simply canceled their health insurance, there would be no repercussions, i.e., there is no government action (such as a penalty) that is traceable to the plaintiff's alleged injury of paying for insurance.

Further, the majority stated that the 18 state plaintiffs did not show any "past or future injury" surrounding the enforcement of the Individual Mandate without that monetary penalty.[23] The state plaintiffs claimed "pocketbook injuries" stemming from the increased use of Medicaid by state residents attempting to comply with the Mandate, which in turn resulted in more costs to the states.[24] However, the majority determined that the states did not demonstrate a clear

link between the (unenforceable) Mandate and increased Medicaid enrollments.[25]

Because the majority concluded that none of the plaintiffs had legal standing, they were able to sidestep opining on the constitutionality of the Individual Mandate itself.

Justice Thomas, who wrote the dissenting opinion in the 2012 NFIB case, issued a concurring opinion in this case, agreeing with the dissent's opinion that the Mandate is unconstitutional because it goes beyond Congress's taxing power if there are no financial consequences.[26] However, Justice Thomas did not agree with the theory proffered by the dissent on the issue of standing (which theory is discussed further below), and thus agreed with the ultimate opinion reached by the majority.[27]

Justices Alito and Gorsuch dissented in the case, arguing that the plaintiffs do have standing sufficient to move onto analyzing the constitutionality of the Individual Mandate specifically, and the ACA as a whole. In a theory characterized by Justice Thomas as "standing through inseverability," the dissent argued that there are several provisions of the ACA (in addition to the Individual Mandate) that impose burdensome reporting and financial requirements, and because the Individual Mandate cannot be separated from the rest of the ACA, those provisions may also be taken into consideration in assessing standing. Upon a finding that the plaintiffs have standing, Justice Alito, the dissent's author, moved on to the merits of the plaintiffs' claims. The dissent argued that even if the Mandate was constitutional under Congress's taxing power prior to the TCJA (although Justice Alito dissented from this decision in the previous ACA cases), it is constitutional no longer, as it is no longer "produc[ing] at least some revenue for the Government," an "essential feature of any tax," as its tax penalty is now $0.[28] Further, citing to the reasoning set forth in the dissent within the 2012 NFIB case decision, the dissent asserted that, "to the extent the provisions of the ACA that burden the States are inextricably linked to the individual mandate, they too are unenforceable."[29]

Conclusion

The plaintiffs' lawsuit against the ACA is the "third installment in our epic Affordable Care Act trilogy"[30] since the 2010 passage of the law (in addition to the 70 times that Republicans have attempted to "repeal and replace" the ACA[31]). While most commentators assume this decision to be the ultimate end of this long-running saga, others have speculated as to other potential future legal challenges, considering the current conservative tilt of SCOTUS, and the Court's hints in the decision as to how to demonstrate standing in future legal challenges.[32] However, with the SCOTUS decision now in the rearview mirror, to ensure the ACA's security, President Biden and Congress are already looking to take steps to strengthen the ACA and close gaps in coverage,[33] shoring up the landmark healthcare law for decades to come.

1 "California, et al. v. Texas, et al." Case No. 19-840, June 17, 2021, available at: https://www.supremecourt.gov/opinions/20pdf/19-840_6jfm.pdf (Accessed 6/17/21), Majority, p. 19.
2 The ACA's Individual Mandate was a tax penalty of either $695.00 or 2.5% of a household's income (whichever was greater) on individuals who did not to have health insurance for at least 9 months during a calendar year, unless they were exempted. "National Federation of Independent Business v. Sebelius" 567 U.S. 519 (2012), p. 3.
3 "National Federation of Independent Business v. Sebelius" 567 U.S. 519 (2012), p. 64-65.
4 "Texas, et al. v. United States of America, et al." Case No. 4:18-CV-00167-O (N.D. Tex. December 14, 2018), Memorandum Opinion and Order, available at: https://oag.ca.gov/system/files/attachments/press-docs/211-texas-order-granting-plaintiffs-partial-summary-judgment.pdf (Accessed 6/9/21), p. 5-8.
5 "Tax Cuts and Job Act" Pub. L. No. 115-97, § 11081, 131 Stat. 2054, (December 12, 2017), p. 39; "Judge Strikes Down ACA Putting Law In Legal Peril – Again" By Julie Rovner, Kaiser Health News, December 14, 2018, https://khn.org/news/texas-judge-puts-aca-in-legal-peril-again/ (Accessed 6/7/21); "Federal Judge Strikes Down Entire ACA; Law Remains In Effect" By Katie Keith, Health Affairs, December 15, 2018,https://www.healthaffairs.org/do/10.1377/hblog20181215.617096/full/?utm_source=Newsletter&utm_medium=email&utm_content=Federal+Judge+Strikes+Down+ACA%3B+Expanding+The+Serious+Illness+Care+Team%3B+Telehealth+Policy&utm_campaign=HAT (Accessed 6/7/21).
6 Case No 19-10011, p. 10.
7 "Texas Judge Strikes Down Obama's Affordable Care Act as Unconstitutional" By Abby Goodnough and Robert Pear, The New York Times, December 14, 2018, https://www.nytimes.com/2018/12/14/health/obamacare-unconstitutional-texas-judge.html (Accessed 6/9/21); "Democrats Vow Rapid Action After Obamacare Tossed by Judge" By Tom Korosec and Kartikay Mehrotra, Bloomberg, December 14, 2018, https://www.bloomberg.com/news/articles/2018-12-15/obamacare-core-provisions-ruled-unconstitutional-by-judge (Accessed 6/9/21).
8 Case No 19-10011, p. 10.
9 "Judge Strikes Down ACA Putting Law In Legal Peril – Again" By Julie Rovner, Kaiser Health News, December 14, 2018, https://khn.org/news/texas-judge-puts-aca-in-legal-peril-again/ (Accessed 6/7/21); Keith, December 15, 2018; Case No 19-10011, p. 3.
10 "The Trump DOJ has taken an unexpected and unworkable position on the ACA" By Christen Linke Young, Brooking, September 18, 2019, https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/09/18/the-trump-doj-has-taken-an-unexpected-and-unworkable-position-on-the-aca/ (Accessed 6/17/21).
11 *Ibid*.
12 Keith, December 15, 2018.
13 "California, et al. v. Texas, et al. and Texas, et al. v. California, et al." Oral Argument Transcript, November 10, 2020, p. 1.
14 "Supreme Court Arguments: Even If Mandate Falls, Rest of Affordable Care Act looks Likely to Be Upheld" By Katie Keith, Health Affairs, November 11, 2020, https://www.healthaffairs.org/do/10.1377/hblog20201111.916 623/full/ (Accessed 6/9/21).
15 "California, et al. v. Texas, et al. and Texas, et al. v. California, et al." Oral Argument Transcript, November 10, 2020, p. 62-63.
16 "Thoughts on Today's Oral Argument in California v. Texas—the Obamacare Severability Case" By Ilya Somin, Reason, November 10, 2020, https://reason.com/volokh/2020/11/10/thoughts-on-todays-oral-argument-in-california-v-texas-the-obamacare-severability-case/ (Accessed 6/9/21).
17 "Biden admin changes DOJ's position pending in Supreme Court ACA case" By Paige Minemyer, FierceHealthcare, February 10, 2021, https://www.fiercehealthcare.com/payer/biden-admin-changes-doj-s-position-pending-supreme-court-aca-case (Accessed 6/9/21); "Re: California, et al. v. Texas, et al., No. 19-840, and Texas, et al., v. California, et al., No. 19-1019" U.S. Department of Justice, February 10, 2021, accessible at: https://www.supremecourt.gov/DocketPDF/19/19-

840/168649/20210210151147983_19-840%2019-1019%20CA%20v%20TX.pdf (Accessed 6/9/21), Majority, p. 1-2.

18 *Ibid*.

19 Case No. 19-840, p. 19.

20 "Spokeo v. Robins" 136 S. Ct. 1540, 1547 (2016).

21 *Ibid*, p. 5.

22 *Ibid*.

23 *Ibid*, p. 1.

24 The states presented two types of evidence in furtherance of their injury: (1) 21 declarations from states "about how new enrollees will increase the costs of state health insurance programs; and, (2) a 2017 Congressional Budget Office (CBO) report. The Court found that: (1) only four of the states' statements even alleged that the increased costs were attributable to the Mandate, and all four referred to that provision as it existed when the penalty was still enforceable; and, (2) the CBO report's statement that reducing the penalty to $0 would result in "only a small number of people" continuing to obtain health insurance out of a "willingness to comply with the law" was "predictive" in nature, and not sufficient to prove a link between the unenforceable Mandate and additional Medicaid beneficiaries. "California, et al. v. Texas, et al." Case No. 19-840, June 17, 2021, available at: https://www.supremecourt.gov/opinions/20pdf/19-840_6jfm.pdf (Accessed 6/17/21), Majority, p. 11-13 (citing "Repealing the Individual Health Insurance Mandate: An Updated Estimate" Congressional Budget Office, November 2017, p. 1).

25 Case No. 19-840, p. 3, 10-11.

26 *Ibid*, p. 3-5.

27 *Ibid*, p. 5-6.

28 *Ibid*, p. 32 (citing *NFIB*, 567 U.S., at 564).

29 *Ibid*, p. 4 (citing NFIB, 567 U.S., at 564).

30 *Ibid*, p. 1.

31 Republicans have led an estimated 70 attempts to repeal, modify, replace, or differently restrain the ACA since it became law in 2010. "Judge Strikes Down ACA Putting Law In Legal Peril – Again" By Julie Rovner, Kaiser Health News, December 14, 2018, https://khn.org/news/texas-judge-puts-aca-in-legal-peril-again/ (Accessed 6/17/21).

32 "The Supreme Court saved the ACA, again. It may not be the last word on challenges." By Samantha Liss, MedTechDive, June 21, 2021, https://www.medtechdive.com/news/the-supreme-court-saved-the-aca-again-it-may-not-be-the-last-word-on-chal/602133/ (Accessed 6/22/21).

33 "Affordable Care Act survives Texas' Supreme Court challenge" By Jessie Hellmann, Michael Brady, & Nona Tepper, Modern Healthcare, June 17, 2021, https://www.modernhealthcare.com/legal/affordable-care-act-survives-texas-supreme-court-challenge?utm_source=modern-healthcare-daily-finance-thursday&utm_medium=email&utm_campaign=20210617&utm_content=article3-headline (Accessed 6/21/21); "After ACA's Third Supreme Court Challenge, Voters Remain Divided on 2010 Law" By Gaby Galvin, Morning Consult, June 21, 2021, https://morningconsult.com/2021/06/21/obamcare-approval-supreme-court-polling/ (Accessed 6/23/21).

U.S. Supreme Court to Hear 340B Case

[Excerpted from the article published in July 2021.]

On July 2, 2021, the Supreme Court of the United States agreed to hear a case between the hospital industry and federal government disputing cuts to the 340B Drug Discount Program (340B program) in the term beginning October 2021.[1] The case, entitled *American Hospital Association v. Becerra*, reached the Court after a series of legal battles that began in 2017, when the Centers for Medicare & Medicaid Services (CMS) published a final rule cutting Medicare Part B and state Medicaid payments in the 340B program by an estimated $1.6 billion.[2] This Health Capital Topics article will review the history of the 340B program,[3] the procedural history of the case, and reactions from hospital industry stakeholders on the Court's undertaking of the case.

Congress created the 340B program in 1992 to help vulnerable or uninsured patients access prescription medication at safety-net hospitals, i.e., hospitals that serve a large population of vulnerable or uninsured patients.[4] The intent of the program was to create a ceiling on how much drug manufacturers could charge safety-net hospitals for medications; in turn, hospitals would pass these savings on to low-income patients through providing prescription medications at no cost or at heavily discounted rates.[5] In 1994, the Health Resources and Services Administration (HRSA) released guidance that extended the 340B program to hospital-owned outpatient clinics, and in 1996 it allowed hospitals and their clinics without an on-site pharmacy to contract with one off-site pharmacy.[6] In 2010, HRSA extended its guidance even further, allowing covered entities to have an unlimited number of contract pharmacies, including for-profit drug store chains, such as Walgreens and CVS.[7] 340B was most recently expanded under the Patient Protection and Affordable Care Act (ACA) to include critical access hospitals, sole community hospitals, rural referral centers, and cancer centers.[8] These expansions have resulted in the proliferation of contract pharmacies – in January 2010 (two months before the passage of the ACA), the number of contract pharmacies was less than 1,300; that number has jumped to nearly 28,000 as of July 2020, a more than 2,000% increase in slightly over a decade.[9]

As early as 2015, the Secretary of the Department of Health and Human Services (HHS) warned the Senate Finance Committee that the 340B program "ha[d] expanded beyond its bounds," and asserted that the number of 340B participants had grown to an unsustainable number.[10] With nearly half of U.S. hospitals purchasing pharmaceuticals under the 340B program, the out-of-control spending prompted the nonpartisan Government Accountability Office (GAO) to publish a report calling for the need to reduce financial incentives for over-prescribing.[11] While HHS believed that the unbounded number of contract pharmacy arrangements was fostering numerous violations and causing financial strain against the 340B program, hospital lobbyists pushed back on behalf of safety-net hospitals serving vulnerable or uninsured populations.[12] Ultimately, HHS found a significant gap between the discounted payment rates

for prescription drugs at which providers were buying and the much higher rates at which the providers were reimbursed, began taking steps in 2017 to reduce reimbursements and close that gap.[13]

In November 2017, CMS released their 2018 Hospital Outpatient Prospective Payment System (OPPS) final rule, which included significant reimbursement cuts to the 340B program.[14] Under the final rule, CMS changed its coverage of outpatient drugs and biologicals to the drug's average sales price (ASP)[15] *minus* 22.5%, a significant change from the previous rate of ASP *plus* 6%.[16] Subsequently, the American Hospital Association (AHA), Association of American Medical Colleges (AAMC), and America's Essential Hospitals (AEH) filed a lawsuit against HHS in the D.C. District Court as an attempt to prevent CMS from enacting the reduced reimbursements under the 2018 OPPS.[17] Although CMS's rule sought to reduce overall prescription drug spending, it resulted in significantly higher drug expenditures for 340B hospitals.[18] The associations argued that HHS did not establish an average-price metric, and the agency lacked the authority to reduce payments by nearly 30%, which is too large of a change to qualify as an "adjustment."[19] However, CMS's chosen ASP-minus-22.5% rate was based on the Medicare Payment Advisory Commission's estimate of the average minimum discount that eligible hospitals received for drugs acquired under the 340B program.[20] Further, certain drugs prescribed in exempt settings under 340B could still receive the original ASP-plus-6% payment rate.[21] The lower court sided with the HHS, and the plaintiffs appealed to the U.S. Court of Appeals for the D.C. Circuit; however, the appellate court upheld the lower court's decision and allowed the payment cuts for 2018 to continue, under the reasoning that the associations filed the suit prematurely, as hospitals had not yet experienced the payment cuts (and had not yet exhausted their administrative remedies by first formally filing complaints with HHS).[22]

In July 2018, CMS proposed to further reduce 340B spending by expanding the reduced payment rate to non-excepted off-campus provider-based departments.[23] After hospitals served vulnerable or uninsured patients for more than six months under the new payment rate (ASP minus 22.5%), AHA, AAMC, and AEH refiled in the D.C. District Court; in December 2018, the court ruled in favor of the hospital associations, finding that HHS overstepped its authority.[24] HHS appealed the lower court's decision in July 2019, and continued these cuts in its 2020 OPPS final rule.[25] One year later, the appellate court reversed the lower court's decision and found in favor of HHS, arguing that the agency's lower drug reimbursement rate "rests on a reasonable interpretation of the Medicare statute."[26] Shortly after the appellate court released their decision, CMS released their 2021 OPPS proposed rule, which proposed increasing 340B reimbursement cuts to a net rate of ASP minus 28.7%.[27] However, in their final rule released on December 2, 2020, CMS reverted back to the previous ASP-minus-22.5% rate and proposed to maintain that rate in the 2022 OPPS rule, which was release on July 19, 2021.[28]

The hospital associations appealed the federal appellate court's decision to the Supreme Court, and on July 2, 2021, the Court agreed to pick up the case in their next term, beginning October 2021.[29] The Court's decision to hear the case was met with excitement and anticipation from several stakeholders. AHA's general counsel, Melinda Hatton, commented she is hopeful the Supreme Court will reject the lower court's decision as their interpretation of Medicare statutes puts the sustainability of 340B participants and the important services they provide at risk.[30] Maureen Testoni, CEO of the advocacy group 340B Health, hopes the Supreme Court will rule in favor of the hospitals that treat patients with low incomes.[31] Additionally, she added that 340B Health will continue to urge the Biden Administration to abandon the harmful payment cuts in the 2022 OPPS and beyond.[32] AAMC CEO and President, David Skorton, added that the payment cuts are not only harmful to low-income, uninsured patients, but also to the future physician workforce, as many hospitals are safety-net providers in addition to teaching hospitals.[33] Further, he stated that "[a] reversal of the cuts will ensure that low-income, rural, and other underserved patients and communities are able to access the vital services they need."[34] As of the date of publication, neither HHS nor CMS has commented on the Supreme Court's decision to hear the case.

While the Trump Administration's HHS defended many of the cases that supported drug cuts, the Biden Administration will likely approach the lawsuits in their own way, albeit with the same intent. President Biden is concerned with lowering drug prices, and has asserted his desire to give Medicare the power to negotiate lower drug prices to provide to covered entities at discounted rates.[35] However, many fear that the 340B covered entities are using the discount to increase their profit, instead of passing the savings on to low-income patients.[36] If covered entities are not passing the discounts to patients, Congress believes that the entities should not continue to receive discounted drugs while also receiving higher reimbursement rates.[37] Hospitals have fought back on these assertions, arguing that the discounts provide the funds needed to improve the overall health of communities with large numbers of vulnerable or uninsured patients; thus, reimbursement cuts will affect their ability to deliver care to patients.[38] The Supreme Court will hear the 340B reimbursement cuts case in their new term beginning October 2021, with a decision expected by July 2022.[39]

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1 "Supreme Court to hear cases on Medicare and 340B payments" By Jessie Hellmann, Modern Healthcare, July 2, 2021, https://www.modernhealthcare.com/law-regulation/supreme-court-hear-cases-medicare-and-340b-payments (Accessed 7/6/21).

2 "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 7/6/21).

3 For more details on the history of the 340B program, see the following Health Capital Topics articles: "340B's Uphill Legal Battle for Hospital Associations" Vol. 11, Issue 8 (August 2018), https://www.healthcapital.com/hcc/newsletter/08_18/HTML/340B/convert_final_340b_topi

cs_8.21.18.php (Accessed 7/6/21); "Massive Cuts Made to 340B Drug Discount Program" Vol. 10, Issue 12 (December 2017), https://www.healthcapital.com/hcc/newsletter/12_17/HTML/340B/10.12_formatted_hc_topics_340b_12.22.17.php (Accessed 7/6/21).

4 "The Legislative and Regulatory History of the Evolution of 340B program" PhRMA, February 2017, https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/340B_Timeline_Handout_FINAL-Feb2017.pdf (Accessed 7/6/21).

5 "Overview of the 340B Drug Pricing Program" 340B Health, February 8, 2021, https://www.340bhealth.org/members/340b-program/overview/ (Accessed 7/8/21).

6 PhRMA, February 2017.

7 *Ibid.*

8 *Ibid.*

9 "Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?" By Adam Fein, Drug Channels Institute, July 14, 2020, https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html (Accessed 7/6/21).

10 PhRMA, February 2017.

11 "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals" United States Government Accountability Office, June 2015, https://www.gao.gov/assets/gao-15-442.pdf (Accessed 7/7/21), p. 11.

12 *Ibid*, p. 38.

13 *Ibid.*

14 Centers for Medicare & Medicaid Services, November 1, 2017.

15 ASP is a market-based pricing mechanism used by Medicare Part B to reimburse providers through payments that reflect the weighted average of all manufacturer sale prices. It includes all rebates and discounts that are privately negotiated between manufacturers and purchasers, with limited state and federal exceptions. ASP is used to determine the payment limit for all drugs covered by Medicare Part B as outlined by the OPPS, and is based on data submitted to the CMS by drug manufacturers. "Medicare Part B Drug Average Sales Price (ASP) User Manual" Centers for Medicare & Medicaid Services, April 15, 2019, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/Medicare-Part-B-ASP-Data-Collection-User-Guide.pdf (Accessed 7/7/21); "Medicare Monday: What is ASP?" By Kelsey Lang, PhRMA, September 28, 2015, https://catalyst.phrma.org/medicare-monday-what-is-asp (Accessed 7/7/21).

16 Centers for Medicare & Medicaid Services, November 1, 2017.

17 *Ibid*; "Heated and Deep-Pocketed Battle Erupts Over 340B Drug Discount Program" By Sarah Jane Tribble, Kaiser Health News, November 28, 2017, https://khn.org/news/heated-and-deep-pocketed-battle-erupts-over-340b-drug-discount-program/ (Accessed 7/6/21).

18 "Fact Sheet: The 340B Drug Pricing Program," American Hospital Association, March 2021, https://www.aha.org/system/files/media/file/2019/03/fact-sheet-340b-drug-pricinig-program-0119.pdf (Accessed 7/6/21).

19 Tribble, November 28, 2017.

20 Centers for Medicare & Medicaid Services, November 1, 2017.

21 Centers for Medicare & Medicaid Services, November 1, 2017.

22 "Appeals court rejects hospitals' challenge to 340B cuts" By Susannah Luthi, Modern Healthcare, July 17, 2018, https://www.modernhealthcare.com/article/20180717/NEWS/180719927/appeals-court-rejects-hospitals-challenge-to-340b-cuts (Accessed 7/2/21).

23 Rural sole community hospitals, critical access hospitals, children's hospitals, and cancer hospitals were still exempt from the cut. "CMS proposes Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System changes for 2019 (CMS-1695-P)" Centers for Medicare & Medicaid Services, July 25, 2018, https://www.cms.gov/newsroom/fact-sheets/cms-proposes-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center (Accessed 7/7/21).

24 "American Hospital Association, et al. v. Azar, Case No.19-5048 (D.C. Cir. 2020), available at:

https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/$file/19-5048-1854504.pdf (Accessed 7/7/21), p. 2.

25 "Federal Appeals Court Upholds Payment Reduction to 340B Hospitals" By Jeffrey Davis, Baker Donelson Health Law, August 2020, https://www.bakerdonelson.com/federal-appeals-court-upholds-payment-reduction-to-340b-hospitals (Accessed 7/9/21).

26 "American Hospital Association, et al. v. Azar, Case No.19-5048 (D.C. Cir. 2020), p. 2.

27 Davis, August 2020; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals" Federal Register Vol. 85, No. 156, August 12, 2020, https://www.govinfo.gov/content/pkg/FR-2020-08-12/pdf/2020-17086.pdf (Accessed 7/9/21), p. 48880.

28 "CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1736-FC)" Centers for Medicare & Medicaid Services, December 2, 2020, https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0 (Accessed 7/9/21); "CMS Proposes Rule to Increase Price Transparency, Access to Care, Safety & Health Equity" Centers for Medicare & Medicaid Services, July 19, 2021, https://www.cms.gov/newsroom/press-releases/cms-proposes-rule-increase-price-transparency-access-care-safety-health-equity (Accessed 7/20/21).

29 "Supreme Court to hear cases on Medicare and 340B payments" By Jessie Hellmann, Modern Healthcare, July 2, 2021, https://www.modernhealthcare.com/law-regulation/supreme-court-hear-cases-medicare-and-340b-payments (Accessed 7/6/21).

30 "AHA Statement on Decision by U.S. Supreme Court to Hear AHA Case on 340B Payment Cuts" Melinda Hatton, Press Release, American Health Association, July 2, 2021, https://www.aha.org/press-releases/2021-07-02-aha-statement-decision-us-supreme-court-hear-aha-case-340b-payment-cuts (Accessed 7/7/21).

31 "Statement on U.S. Supreme Court Order in 340B Medicare Cuts Lawsuit" Maureen Testoni, Press Release, 340B Health, July 2, 2021, https://www.340bhealth.org/newsroom/statement-on-u.s-supreme-court-order-in-340b-medicare-cuts-lawsuit/ (Accessed 7/7/21).

32 *Ibid*.

33 "AAMC Statement on Supreme Court Decision to Hear Arguments in 340B Drug Pricing Cuts Case" David Skorton, Press Release, Association of American Medical Colleges, July 2, 2021, https://www.aamc.org/news-insights/press-releases/aamc-statement-supreme-court-decision-hear-arguments-340b-drug-pricing-cuts-case (Accessed 7/721).

34 *Ibid*.

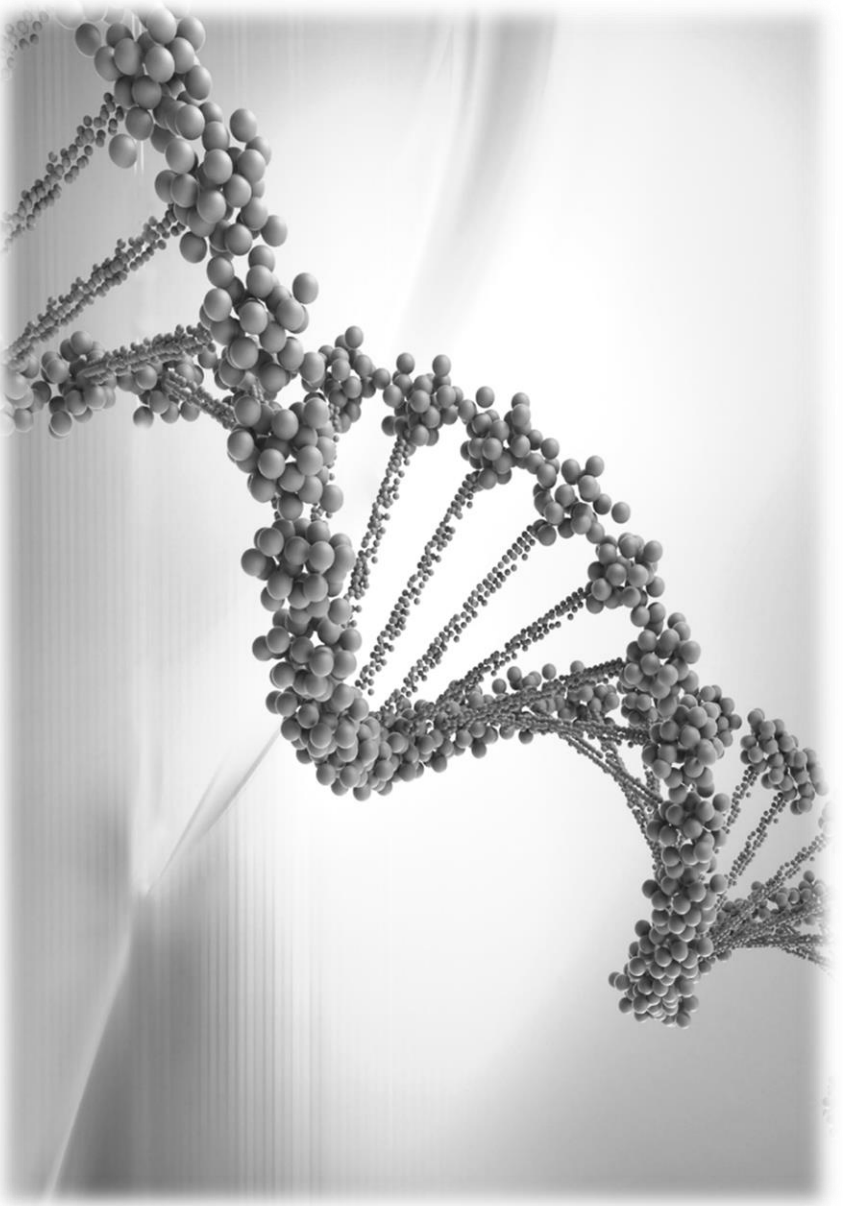
35 "The Case for Drug-Pricing Reform — The Cost of Inaction" By Lovisa Gustafsson and Rachel Nuzum, The Commonwealth Fund, May 26, 2021, https://www.commonwealthfund.org/blog/2021/case-drug-pricing-reform-cost-inaction (Accessed 7/7/21).

36 "Overview of the 340B Drug Pricing Program" 340B Health, February 8, 2021, https://www.340bhealth.org/members/340b-program/overview/ (Accessed 7/8/21).

37 Gustafsson and Nuzum, May 26, 2021.

38 340B Health, February 8, 2021.

39 Hellmann, Modern Healthcare, July 2, 2021.



IV. COMPETITION TOPICS

New Study Examines PE's Impact on Hospital Performance

[Excerpted from the article published in September 2020.]

In recent years, private equity investments in the healthcare sector have been on the rise. From 2008 to 2018, the number of private equity healthcare deals in the U.S. soared from 325 deals in 2008 to 788 deals in 2018, totaling more than $100 billion in value.[1] Private equity firms use capital from investors to purchase assets, such as hospitals, with the goal of increasing the value of the asset before selling off the asset, typically within three to seven years, at a profit and returning the profits to the investors.[2] Private equity firms generally look for underperforming yet stable targets, wherein costs can be cut and operational efficiencies can be realized to increase value.[3]

The healthcare sector has become an increasingly attractive target for private equity firms for several reasons. First, the fragmented nature of the healthcare industry provides private equity firms with ample opportunities to acquire and consolidate businesses to increase market power and negotiate higher reimbursement from payors.[4] Second, up to 25% of healthcare costs can be attributed to wasteful spending, largely attributable to administrative complexity.[5] The excess of waste in the healthcare system provides private equity firms with substantial opportunities to increase value through realized operational efficiencies.[6] Finally, revenue streams in the healthcare industry are reliable and represent a large portion of U.S. spending. Historically, demand for healthcare services has remained stable even through economic downturns.[7] Moreover, since the federal government accounts for approximately 40% of total healthcare spending, there is confidence in a secure cash flow for services.[8] Consequently, private equity firms may view healthcare assets as a less risky investment.

However, controversy remains as to whether private equity firms' increased interest in the healthcare industry is beneficial to consumers. Proponents assert that private equity firms have a unique capability to help reduce healthcare costs, improve efficiencies, and provide much needed capital to update IT systems and upgrade facilities.[9] Still, many remain concerned that the very nature of the private equity business model and the substantial pressure placed on providers to increase revenue and decrease costs will result in significant sacrifices in quality.[10]

In an effort to address these concerns, researchers from Harvard's School of Public Health and Medical School published a study in *JAMA Internal Medicine* in August 2020, evaluating the impact of private equity hospital acquisitions on several metrics, including hospital income, profitability, use, and quality.[11] The study revealed that post-acquisition, private-equity-owned hospitals experienced increased annual net income, hospital charges, charge-to-cost ratios, and case mix.[12] Additionally, these hospitals realized some improvement in certain quality metrics.[13]

To evaluate the impact of private equity acquisition on quality in acquired hospitals, the study aggregated the scores for quality-of-care process measures from the *Centers for Medicare & Medicaid Services'* (CMS's) Hospital Compare dataset for three conditions: heart failure, acute myocardial infarction (AMI), and pneumonia.[14] Analysis of these aggregated scores post-acquisition revealed an increase of 3.3 and 2.9 percentage points in the aggregate quality-of-care process scores for AMI and pneumonia, respectively.[15] These increases suggest better care for patients.[16] While this data is seemingly encouraging, other study results raise new concerns surrounding private equity's involvement in healthcare.

Post-acquisition, private-equity-acquired hospitals experienced an average increase of $2.3 million in net income relative to peer hospitals.[17] To explain this increase, the study also reported an increase of $407 in total charge per inpatient day, as well as increases of 0.61 and 0.31 in emergency and total charge-to-cost ratio, respectively.[18] These increases in charges and charge-to-cost ratios have many possible explanations.

First, patients who are commercially-insured provide higher reimbursement to hospitals.[19] As a result, if a hospital is to increase the percentage of commercially-insured patients served, it can increase its average charges, thus resulting in higher net income. As reported in the study, in private-equity-acquired hospitals, the percentage of Medicare patients comprising the total patient population decreased by 0.96% relative to peer hospitals.[20] It is possible that this change in payor mix is the result of strategic tactics to increase the number of commercially-insured patients, a common strategy used by hospitals – even nonprofit hospitals.[21] Hospitals can "*improve*" their payor mix through a variety of strategies, including marketing to commercially-insured patients and prioritizing commercially-insured patients for non-emergent care.[22]

Another possible explanation for private-equity-acquired hospitals' increase in charges and charge-to-cost ratio is that, post-acquisition, these hospitals are receiving higher diagnosis-related group (DRG) payments on average.[23] According to the study, post-acquisition, private-equity-owned hospitals exhibited an increase of 0.02 in their case mix index relative to peer hospitals (the sum of DRG weights for all Medicare discharges divided by the number of Medicare discharges), suggesting that post-acquisition, these hospitals saw sicker patients.[24] However, the study's authors also assert that the case mix increase could be indicative of changes in coding practices.[25] The study explains that the increase in case mix index could be the result of more complete coding if the hospital was previously assigning a code with too low of a DRG weight to represent the actual complexity of the procedure or diagnosis performed or diagnosed.[26] Alternatively, the authors suggest that the appearance of sicker patients could be the result of upcoding, a type of fraud in which the code submitted by the provider for billing is for a more serious and expensive diagnosis or procedure than was actually diagnosed or performed.[27]

In response to their findings, the study's authors call for further government oversight of the practices of private-equity acquired hospitals, asserting that "*[a]lthough further research is needed, our findings suggest that policy makers should consider monitoring or thoughtful oversight of changes in care delivery and billing practices in hospitals acquired by private equity firms to ensure proper stewardship of societal resources and the prioritization of patient interests*."[28]

These concerns are likely to be amplified both during and after the COVID-19 pandemic. The *American Hospital Association* (AHA) has projected that hospitals will lose a total of $323 billion in 2020 as a result of the pandemic.[29] The revenue losses being experienced by hospitals makes them more vulnerable to private equity acquisition, which in turn may garner increased concern and scrutiny regarding their post-acquisition practices.[30]

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1 "Private equity sees ripe opportunity in healthcare this year" By Samantha Liss, HealthCare Dive, March 25, 2019, https://www.healthcaredive.com/news/private-equity-sees-ripe-opportunity-in-healthcare-this-year/548831/ (Accessed 9/11/20).

2 "Changes in Hospital Income, Use, and Quality Associated with Private Equity Acquisition" By Joseph D. Bruch, Suhas Gondi, and Zirui Song, MD, PhD, JAMA Internal Medicine (August 24, 2020), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2769549#:~:text=Conclusions%20and%20Relevance%20Hospitals%20acquired,acquisition%20relative%20to%20nonacquired%20controls (Accessed 9/11/20).

3 "Private Equity Buyouts in Healthcare: Who Wins, Who Loses?" By Eileen Appelbaum and Rosemary Batt, Center for Economic Policy and Research, Institute for New Economic Thinking, March 15, 2020, https://www.ineteconomics.org/uploads/papers/WP_118-Appelbaum-and-Batt-2-rb-Clean.pdf (Accessed 9/14/20), p. 16; Bruch, Gondi, and Song, August 24, 2020.

4 *Ibid.*

5 "Waste in the US Health Care System Estimated Costs and Potential for Savings" By William H. Shrank, MD, MSHS, Teresa L. Rogstad, MPH, Natasha Parekh, MD, MS, JAMA, Vol. 322, No. 15 (October 15, 2019), accessed via: https://jamanetwork.com/journals/jama/article-abstract/2752664, (Accessed 9/17/20); Bruch, Gondi, and Song, August 24, 2020.

6 *Ibid.*

7 Bruch, Gondi, and Song, August 24, 2020.

8 Appelbaum and Batt, March 15, 2020, p. 16.

9 *Ibid*, p. 4.

10 *Ibid*, p. 5.

11 Bruch, Gondi, and Song, August 24, 2020.

12 *Ibid*.

13 *Ibid*.

14 *Ibid*.

15 *Ibid*.

16 *Ibid*.

17 *Ibid*.

18 *Ibid*.

19 *Ibid*.

20 *Ibid*.

21 *Ibid*; "Cherry-Picking Patients May Be Business as Usual for Not-for-Profits Like Mayo" By Elizabeth Whitman, Modern Healthcare, March 23, 2017,

https://www.modernhealthcare.com/article/20170323/NEWS/170329955/cherry-picking-patients-may-be-business-as-usual-for-not-for-profits-like-mayo (Accessed 9/17/20).

22 "Caught In The Competitive Crossfire: Safety-Net Providers Balance Margin And Mission In A Profit-Driven Health Care Market" By Peter J. Cunningham, Gloria J. Bazzoli, and Aaron Katz, Health Affairs, Vol. 27, No. 1 (August 12, 2008), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.27.5.w374 (Accessed 9/17/20).

23 Bruch, Gondi, and Song, August 24, 2020.

24 *Ibid.*

25 *Ibid.*

26 *Ibid.*

27 *Ibid*; "What Is Upcoding in Medical Billing?" By Trisha Torrey, Verywell Health, February 24, 2020, https://www.verywellhealth.com/what-is-upcoding-2615214 (Accessed 9/17/20).

28 Bruch, Gondi, and Song, August 24, 2020.

29 "Private Equity-Acquired Hospitals Charge More for Common Services" By Jacqueline LaPointe, Revcycle Intelligence, August 27, 2020, https://revcycleintelligence.com/news/private-equity-acquired-hospitals-charge-more-for-common-services (Accessed 9/17/20).

30 Bruch, Gondi, and Song, August 24, 2020.

M&A Activity Slowed in 2020, But is Poised to Accelerate in 2021

[Excerpted from the article published in February 2021.]

The COVID-19 pandemic undoubtedly had a strong influence on the healthcare *merger and acquisition* (M&A) market in 2020, as clearly seen from differences in activity between the first quarter and subsequent quarters of 2020, after the pandemic fully infiltrated the U.S. in March 2020. The COVID-19 pandemic represents a unique shock to the healthcare system, as it has directly affected acute care delivery. Revenues declined precipitously as: many lucrative, elective procedures were cancelled; occupancy rates in many hospitals decreased; and, new demands of staff related to the virus and infection prevention created greater burdens on hospital costs and clinical workers.[1] In fact, estimates indicate that extra costs and lower revenues led to more than $200 billion in lost funds for hospitals and health systems between March and June of 2020.[2] This article focuses on the data from several reports that outline the M&A activity in 2020, compares the transactional market volume to past years, and explores possible future trends.

Prior to the pandemic, the healthcare M&A market had seen steady increases throughout the previous decade. The number of M&A transactions peaked at 117 in 2017, then dropped to 90 in 2018 before rising slightly to 92 in 2019.[3] It may have realistically been expected that 2020 would follow this same trend, and first quarter 2020 M&A activity indicated a strong start to the year. During this quarter, 29 transactions were announced, the second highest amount in the first quarters of the previous five years.[4] It quickly became apparent, however, that this trend would likely not continue for the rest of 2020. Both greater financial burden on providers and an increased focus on short-term operations hampered healthcare executives' ability to implement strategic initiatives, including M&A deals.[5] Being unable to conduct business face-to-face led to differences in negotiations. Especially for organizations that are not well-acquainted with each other, conducting intensive meetings with boards, committees, physicians, leadership staff, and stakeholders – such as those required for M&A discussions – can be challenging.[6] Hospital executives have cited difficulties in understanding an organization's culture when meetings are conducted remotely, which can hinder effective relationship building.[7] In fact, one proposed merger between Advocate Aurora Health and Beaumont Health, which was one of the largest deals announced during the pandemic and would have created a $17 billion health system, was called off in October 2020, in part because of the difficulties of working remotely.[8]

Despite the unprecedented circumstances of 2020, the year closed at 79 announced transactions, still higher than the 74 transactions announced in 2010.[9] In fact, even in the midst of the worst declines in hospital operating earnings before interest, taxes, depreciation, and amortization (EBITDA) margins in April and May 2020, M&A activity did not experience declines to nearly the same degree.[10] Experts hypothesize that, while transactions

decreased for the reasons listed above, the pandemic also brought about a need for change in building business strengths, including resiliency to market changes; in creating partnerships; and, in strengthening intellectual capital resources.[11] In other words, 2020 numbers may have otherwise been lower, but the public health emergency accelerated the need for strategic initiatives, including transactions and partnerships, in order to drive change, create more efficient operations, improve quality, and fill in gaps and weakness in existing organizations.[12]

Some previous transactional trends continued into 2020. Overall, the size of the smaller partner in M&A deals (as measured by that partner's annual revenue) has been increasing over the years, at a compound annual growth rate (CAGR) of 6.2%.[13] In 2020, nearly 9% of transactions included a smaller partner having revenues exceeding $1 billion, the highest proportion since 9.4% in 2017 and a significant increase from 3.3% in 2019.[14] Consistent with 2019, the majority of acquisitions in 2020 (59%) occurred between two not-for-profit organizations. Approximately one-quarter of transactions involved a rural or urban/rural seller in 2020, compared to a little over one-third in 2019.[15] Curiously, more transactions in 2019 included a financially distressed seller (20%), than in 2020 (16%).[16] Even the number of M&A transactions among hospitals remained generally in line with historical numbers, although there was a decline in 2019.[17] After declines in the first two quarters of 2020, post-acute care M&As, including those for home health, hospice, and personal care services, experienced increases from 2019 by the third quarter of 2020, likely due to government financial aid.[18] Physician offices saw similar patterns, with expected returns to normal levels at the end of 2020 and beginning of 2021, with *private equity* (PE) buyers leading this activity.[19] Further, managed care, pharmacy, and *ambulatory surgery centers* (ASCs) all saw their fair share of M&A activity in 2020.[20]

Notwithstanding the large market fluctuations, in the form of declines in the first half of 2020 and increases by the end of the year, the 2020 M&A market looked different than previous years. One area where M&A saw strong growth was in behavioral health, which experienced a significant increase in demand throughout the pandemic.[21] Many of these transactions were made by PE buyers and were connected to technological benefits.[22] Investments in healthcare information technology, digital assets, and virtual healthcare tools similarly increased as healthcare providers began to implement these technologies at greater rates in order to improve services, outcomes, and compliance with social distancing guidelines.[23] In fact, one of the largest M&A deals of 2020 occurred in this sector of the healthcare industry – closing on October 30, 2020, the telehealth company Teladoc acquired Livongo, a company that provides tools for chronic disease management, for $18.5 billion.[24]

Telemedicine and healthcare technology will undoubtedly be a strong focus for M&A activity in 2021. A 2021 survey of healthcare *chief financial officers* (CFOs) indicated that 44% predict that the pandemic will drive an increase in partnerships and 42% believe it will drive increased consolidation across the

healthcare industry.[25] Half of CFOs are also focused on digital transformation, with 47% and 41% focused on product or service expansion and geographic expansion, respectively.[26] Further, 31% indicated that they plan to acquire physician practices, 28% plan to merge with another organization, 24% plan to enter a joint venture, 20% plan to sell to another organization, and 17% plan to acquire another organization.[27] Similarly, a Bain & Company report found that half of hospital administrators were very likely to make one or more acquisitions within the next two years.[28] This research also found that nearly 70% of independent physician practices were open to merging with or being acquired by another organization.[29] Chad Beste, a Principal at accounting firm BDO, summarized the situation as follows: "*2021 will be all about making the most of newly-formed partnerships…From seeking to address financial distress, to building up scale, to capitalizing on innovation and research, strategic and financial deals will help the industry on its path to better care for patients and continued financial recovery.*"[30]

While uncertainty, financial pressures, virtual communication, and rapid changes resulting from the pandemic led to decreases in M&A activity early in 2020, these elements may also be what led to an upswing at the end of the year and what will lead to increases in 2021. In fact, the number of announced transactions in the fourth quarter of 2020 is the highest since that same quarter in 2017.[31] As healthcare providers look to diversify; expand; increase quality of care and outcomes; focus more on primary care and eliminating social disparities; and, invest in new technologies, the number of M&As is likely to increase.[32] Further, evidence from executives indicates that private offices and hospitals alike are open to, and even planning on, participating in M&As in the coming years.[33] While the pandemic may have temporarily delayed this activity, it has likely had the ultimate effect of accelerating it, and the effects will likely be felt throughout the U.S. healthcare system for years to come.

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1 "2020 M&A In Review: Covid-19 as Catalyst for Transformation" Kaufman, Hall & Associates, LLC, 2021, https://www.kaufmanhall.com/sites/default/files/documents/2021-01/2020-Mergers-Acquisitions-Review_KaufmanHall.pdf (Accessed 2/11/21), p. 3.

2 "COVID-19, Market Consolidation, And Price Growth" By Laura Tollen and Elizabeth Keating, Health Affairs, August 3, 2020, https://www.healthaffairs.org/do/10.1377/hblog20200728.592180/full/ (Accessed 2/11/21).

3 Kaufman, Hall & Associates, LLC, 2021, p. 3.

4 Note: 2018 saw the highest number of announced transactions (30) in the first quarters of 2015 to 2020. "Healthcare Mergers & Acquisitions Activity Report: Q1 2020" Kaufman, Hall & Associates, LLC, https://www.kaufmanhall.com/ideas-resources/article/healthcare-mergers-acquisitions-activity-report-q1-2020 (Accessed 2/11/21).

5 Kaufman, Hall & Associates, LLC, 2021, p. 3.

6 "Zoom, pandemic complicating healthcare M&A" By Tara Bannow, Modern Healthcare, February 5, 2021, https://www.modernhealthcare.com/mergers-acquisitions/zoom-pandemic-complicating-healthcare-ma (Accessed 2/12/21).

7 *Ibid.*

8 *Ibid.*

9 "Kaufman, Hall & Associates, LLC, 2021, p. 3.

10 "Healthcare Transactions: Year in Review" Bass, Berry & Sims, January 2021, https://www.jdsupra.com/legalnews/healthcare-transactions-year-in-review-4050463/ (Accessed 2/19/21), p. 3.
11 Kaufman, Hall & Associates, LLC, 2021, p. 3-4, 8.
12 *Ibid*, p. 3-4; 12 "Pandemic, changes in health care spur practice consolidation" By Casey Tingle, Healio, February 17, 2021, https://www.healio.com/news/orthopedics/20210216/pandemic-changes-in-health-care-spur-practice-consolidation?utm_medium=social&utm_source=linkedin&utm_campaign=sociallinks (Accessed 2/19/21).
13 Kaufman, Hall & Associates, LLC, 2021, p. 7.
14 *Ibid*, p. 6.
15 *Ibid*, p. 5; "2019 M&A in Review: In Pursuit of the New Bases of Competition" Kaufman, Hall & Associates, LLC, 2020, https://www.kaufmanhall.com/sites/default/files/documents/2020-01/2019_mergers_and_acquisitions_report_kaufmanhall.pdf (Accessed 2/11/21), p. 5.
16 Kaufman, Hall & Associates, LLC, 2021, p. 5; "2019 M&A in Review: In Pursuit of the New Bases of Competition" Kaufman, Hall & Associates, LLC, 2020, https://www.kaufmanhall.com/sites/default/files/documents/2020-01/2019_mergers_and_acquisitions_report_kaufmanhall.pdf (Accessed 2/11/21), p. 5.
17 Bass, Berry & Sims, January 2021, p. 3.
18 *Ibid*, p. 5.
19 *Ibid*, p. 6.
20 *Ibid*, p. 8, 10-11.
21 *Ibid*, p. 9.
22 *Ibid*.
23 *Ibid*, p. 12.
24 "Teladoc snaps up Livongo" By Heather Landi, Fierce Healthcare, December 7, 2020, https://www.fiercehealthcare.com/special-report/list-most-interesting-health-tech-m-a-deals-2020/teladoc-snaps-up-livongo (Accessed 2/11/21).
25 "2021 BDO Healthcare CFO Outlook Survey" BDO USA, LLP, 2021, https://www.bdo.com/BDO/media/CFO-Outlook-Survey/IND_2021_HC_CFO-Survey_WEB.pdf (Accessed 2/12/21), p. 3.
26 *Ibid*, p. 5.
27 *Ibid*, p. 6.
28 "Preparing for a Post-Pandemic Boom in Healthcare Consolidation" By Michael Brookshire, Joshua Weisbrod, and Erin Ney, Bain & Company, Inc., September 15, 2020, https://www.bain.com/insights/preparing-for-a-post-pandemic-boom-in-healthcare-consolidation/ (Accessed 2/12/21).
29 "Preparing for a Post-Pandemic Boom in Healthcare Consolidation" By Michael Brookshire, Joshua Weisbrod, and Erin Ney, Bain & Company, Inc., September 15, 2020, https://www.bain.com/insights/preparing-for-a-post-pandemic-boom-in-healthcare-consolidation/ (Accessed 2/12/21).
30 "2021 BDO Healthcare CFO Outlook Survey" BDO USA, LLP, 2021, https://www.bdo.com/BDO/media/CFO-Outlook-Survey/IND_2021_HC_CFO-Survey_WEB.pdf (Accessed 2/12/21), p. 6.
31 "Zoom, pandemic complicating healthcare M&A" By Tara Bannow, Modern Healthcare, February 5, 2021, https://www.modernhealthcare.com/mergers-acquisitions/zoom-pandemic-complicating-healthcare-ma (Accessed 2/12/21).
32 "2020 M&A In Review: Covid-19 as Catalyst for Transformation" Kaufman, Hall & Associates, LLC, 2021, https://www.kaufmanhall.com/sites/default/files/documents/2021-01/2020-Mergers-Acquisitions-Review_KaufmanHall.pdf (Accessed 2/11/21), p. 12; "2021 BDO Healthcare CFO Outlook Survey" BDO USA, LLP, 2021, https://www.bdo.com/BDO/media/CFO-Outlook-Survey/IND_2021_HC_CFO-Survey_WEB.pdf (Accessed 2/12/21), p. 7.
33 "Preparing for a Post-Pandemic Boom in Healthcare Consolidation" By Michael Brookshire, Joshua Weisbrod, and Erin Ney, Bain & Company, Inc., September 15, 2020, https://www.bain.com/insights/preparing-for-a-post-pandemic-boom-in-healthcare-consolidation/ (Accessed 2/12/21); "2021 BDO Healthcare CFO Outlook Survey" BDO USA, LLP, 2021, https://www.bdo.com/BDO/media/CFO-Outlook-Survey/IND_2021_HC_CFO-Survey_WEB.pdf (Accessed 2/12/21), p. 6.

SPAC Popularity Soaring in Healthcare

[Excerpted from the article published in April 2021.]

The popularity of *special purpose acquisition companies* (SPACs) has been soaring in recent years. There are 35 times as many SPACs operating in 2020 as in 2010, and these companies seem poised for greater exponential growth in the future.[1] While many experts are predicting a continued, rapid increase in SPACs, this article will also examine the factors that could possibly slow SPAC growth and diminish their future prospects.

SPACs are companies set up by investors that do not produce or sell their own products.[2] Instead, these companies, also termed "*blank check companies*," are set up solely to raise money through their *initial public offering* (IPO) and the future acquisition of other companies.[3] SPACs typically have a deadline of two years after the IPO to find an acquisition deal, and shareholders vote to approve these deals.[4] SPACs span several market areas, including biotechnology and healthcare; this article will review SPAC trends generally as well as healthcare SPACs in particular.

As noted above, overall SPAC activity has soared over the last decade. In 2010, there were seven SPAC IPOs with a little over $500 million in proceeds in the U.S., while in 2020, there were 248 SPAC IPOs with over $83 billion in proceeds.[5] While the number of total IPOs also increased during this period, the share of SPACs grew at a much faster rate, from 4% of total IPOs in 2010 to 55% in 2020.[6] Similarly, SPAC IPO proceeds made up only 1% of all IPO proceeds in 2010, but comprised 46% of all IPO proceeds a decade later.[7] Interestingly, unlike during the Great Recession, where the growth of SPAC IPOs plummeted from 66 in 2007 to 1 in 2009,[8] the number and share of SPAC IPOs have increased exponentially amid the current *public health emergency* (PHE) and resulting economic market volatility, from 59 SPACs in 2019 (28% of the total IPO market) to 248 in 2020 (55%), the first year of the PHE.[9]

SPACs in the healthcare sector saw similar booms in 2020, as well as in the first three months of 2021. Overall healthcare merger and acquisition activity is projected to increase in 2021,[10] and healthcare SPAC activity is expected to follow that trend. The number of healthcare-focused SPAC IPOs increased on a monthly basis throughout 2020, and peaked in October 2020 and again in January 2021.[11] Overall, there were 36 healthcare SPAC IPOs in 2020, with a total of $8.8 billion dollars raised, compared with only two healthcare SPAC IPOs in 2019.[12] As of March 2021, there were 53 SPACs actively searching for target companies in healthcare and life sciences.[13] In fact, the funds raised in the first quarter of 2021 alone is almost double the amount raised in all of 2020.[14] Healthcare, which comprises 20% of the U.S. *gross domestic product* (GDP), has been subject to significant disruption through the COVID-19 PHE.[15] Consequently, investors have looked to SPACs as a way to combat this market volatility and uncertainty, while pursuing promising new companies that can fill in the gaps in healthcare highlighted by COVID-19.[16]

Despite SPACs' status as arguably the most popular asset class in American equity markets, a study from the *Financial Times* found that the majority of SPACs organized between 2015 and 2019 were below the standard starting share sale price to the public of $10 per share.[17] This evidence consequently indicates that SPACs may be a risky investment as "*only half of them are shown to be value creating*."[18] SPACs also struggle with a reputation for fraud and other suspicious business dealings where financiers used the model to unload dubious companies onto unsuspecting investors.[19] Another emerging and growing concern is the strong incentives given to SPAC founders, also called sponsors.[20] SPAC founders are usually given a 20% share in the acquired company for free, as a way to compensate these individuals for their efforts in locating the target company. However, these terms can also lower the incentive to find quality businesses.[21]

Nevertheless, SPACs hold certain advantages over traditional IPOs, and some have seen wild success, with valuations for two of these companies (DraftKings and Nikola) currently over $10 billion.[22] The process for a business to create a traditional IPO is long and tedious.[23] SPACs have filled in the gap left by the worsening underpricing of IPOs to create an easier and faster process for start-ups to bring their business to market.[24] SPACs may present less risk for companies by allowing them to coordinate with the SPAC founder for a fixed amount of money and negotiated price.[25] This concept is essentially the difference between traditional IPOs and SPACs: IPOs involve companies looking for funders to invest in them, while SPACs are funders looking for a company in which to invest. Further, the one-on-one deals involved with SPACs may also be more conducive to the remote work environment brought about by the COVID-19 PHE than the typical meetings and "*roadshows*" that are part of traditional IPOs.[26] For pre-revenue companies, SPACs also hold the appeal of lower liability risk for mistakes or omissions to investors and more flexibility on future earnings projections.[27]

Accordingly, some experts have voiced concerns about the long-term viability and trends related to SPACs. Some speculate that the huge growth seen over the past year cannot continue at the same rate.[28] In the end, each SPAC that is formed is looking for a company to acquire. Too many SPACs in the market could mean that SPACs will begin to compete with each other on a greater scale for a limited number of start-ups available for acquisition.[29]

SPACs are often formed by experienced investors, high-profile CEOs, Wall Street professionals with private equity or hedge fund experience, or other major players, in order to grant them some legitimacy and attract investors.[30] Healthcare SPACs, for which biotechnology and health information technology (HIT) are two main areas of focus, are no exception to this general practice.[31] In fact, a study of HIT SPACs showed that few of these organizations' leaders had industry knowledge – rather than having healthcare experience, leaders were largely experts in investments and deal-making.[32] This may be a cause for concern in the long-term and calls into question the sustainability of healthcare (and other) SPACs. Evidence has shown that many SPACs have not performed

well post-merger, and not having leadership that is familiar with the industry may continue this trend for healthcare SPACs.[33]

Despite the various potential drawbacks, the continued popularity of SPACs both in and outside of healthcare cannot be denied. One recent notable healthcare SPAC is Jackson Acquisition, whose board includes former Florida governor Jeb Bush and former *Centers for Medicare & Medicaid Services* (CMS) administrator Marilyn Tavenner.[34] This SPAC aims to raise $300 million through its coming IPO and is following the precedent of similar SPACs who are taking this opportunity to get in on a growing market, albeit with a board laden with healthcare industry experience. The willingness of high-profile individuals to join the boards of SPACs may lend further credibility to these organizations and present an additional transactional opportunity for healthcare start-ups and investors alike.

The future prospects and sustainability of SPACs are currently based solely on speculation, but evidence has also shown that as more high-profile figures and well-regarded companies get involved with SPACs, new entrants are more likely to choose to pursue this method over traditional IPOs.[35]

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1 "SPAC and US IPO Activity" SPAC Analytics, https://spacanalytics.com/ (Accessed 3/30/21).
2 "What is a SPAC? Explaining one of Wall Street's hottest trends" By Tom Huddleston Jr., CNBC, February 23, 2021, https://www.cnbc.com/2021/01/30/what-is-a-spac.html (Accessed 3/30/21).
3 *Ibid.*
4 *Ibid.*
5 SPAC Analytics, (Accessed 3/30/21).
6 *Ibid.*
7 *Ibid.*
8 *Ibid.*
9 *Ibid.*
10 For more information, see: "M&A Activity Slowed in 2020, But is Poised to Accelerate in 2021" Health Capital Topics, Vol. 14, No. 2 (February 2021), available at: https://www.healthcapital.com/hcc/newsletter/02_21/HTML/MA/convert_covid-19_effects_on_m_a.php (Accessed 3/30/21).
11 "The reckoning begins for biotech-focused Spacs" By Amy Brown and Edwin Elmhirst, Evaluate Vantage, February 18, 2021, https://www.evaluate.com/vantage/articles/data-insights/ipo/reckoning-begins-biotech-focused-spacs (Accessed 3/30/21).
12 *Ibid.*
13 "Why 2021 could be the year of healthcare SPAC deals and the unicorns ripe to go public" By Heather Landi, Fierce Healthcare, March 10, 2021, https://www.fiercehealthcare.com/tech/why-2021-could-be-year-healthcare-spac-deals-and-unicorns-ripe-to-go-public (Accessed 3/30/21).
14 "Jeb Bush, Marilyn Tavenner getting in on healthcare SPAC frenzy" By Tara Bannow, Modern Healthcare, March 26, 2021, https://www.modernhealthcare.com/finance/jeb-bush-marilyn-tavenner-getting-healthcare-spac-frenzy (Accessed 3/30/21).
15 *Ibid.*
16 *Ibid.*
17 "Can Spacs shake off their bad reputation?" By Ortenca Aliaj, Sujeet Indap, and Miles Kruppa, Financial Times, August 12, 2020, https://www.ft.com/content/6eb655a2-21f5-4313-b287-964a63dd88b3 (Accessed 3/30/21).

18 *Ibid.*
19 *Ibid.*
20 *Ibid.*
21 *Ibid.*
22 *Ibid.*
23 *Ibid.*
24 *Ibid.*
25 "Why SPACs Are the New IPO" By Byrne Hobart, Marker, July 28, 2020, https://marker.medium.com/why-spacs-are-the-new-ipo-dcefe54b4bdd (Accessed 3/30/21).
26 Aliaj, Indap, and Kruppa, August 12, 2020.
27 "More healthcare startups go public through SPACs — but will they succeed?" By Elise Reuter, MedCity News, February 25, 2021, https://medcitynews.com/2021/02/more-healthcare-startups-go-public-through-spacs-but-will-they-succeed/ (Accessed 3/30/21).
28 *Ibid.*
29 *Ibid.*
30 Huddleston Jr., CNBC, February 23, 2021.
31 "The SPAC Boom: A Look at Health IT SPACs and their Sponsors" Healthcare Growth Partners, March 12, 2021, http://hgp.com/research-and-news/2021/03/12/healthcare-spacs/ (Accessed 3/30/21).
32 *Ibid.*
33 *Ibid.*
34 Bannow, March 26, 2021.
35 "The Spectacular Rise Of SPACs: The Backwards IPO That's Taking Over Wall Street" By Camila Domonoske, National Public Radio, December 29, 2020, https://www.npr.org/2020/12/29/949257672/the-spectacular-rise-of-spacs-the-backwards-ipo-thats-taking-over-wall-street (Accessed 3/30/21).

NASEM Recommends Assigning PCP to Every American

[Excerpted from the article published in May 2021.]

On May 4, 2021, the National Academies for Sciences, Engineering and Medicine (NASEM) released a major report expressing a dire need to improve primary care in the U.S.[1] Since January 2020, an extensive committee within NASEM has worked to develop an implementation plan that will reopen the discussion of improving primary care as a means to improving overall health and achieving health equity.[2]

Serious conversations related to health reform in primary care started over 25 years ago with the 1996 Institute of Medicine (IOM) report entitled, "*Primary Care: America's Health in a New Era*."[3] However, the 1996 IOM report's recommendations were thwarted by the collapse of the Clinton healthcare reform efforts a couple of years prior, and the resulting reticence to take on further reform efforts.[4] MCOs are a form of health insurance in which a referral from a primary care physician (PCP) is needed for all non-emergent services and members are usually required to stay in the MCO's network of providers. They were established in the 1970s to help control rising healthcare costs. However, by the time the IOM report was completed, MCOs were failing and the political window of opportunity to improve primary care had closed.[5] Then, nearly 25 years after the IOM report was published, NASEM began to establish its committee to revisit some of the IOM's recommendations and create an implementation plan to improve primary care in the U.S. Shortly following the committee's creation, the COVID-19 pandemic struck the U.S. and made gaps in access to healthcare and poor health outcomes glaringly obvious.[6] The NASEM committee strove to develop an action plan to improve the delivery of primary care in the U.S. with the following five objectives:

(1) "*Pay for primary care teams to care for people, not doctors to deliver services*;"
(2) "*Ensure that high-quality primary care is available to every individual and family in every community;"*
(3) "*Train primary care teams where people live and work*;"
(4) "*Design information technology that serves the patient, family, and interprofessional care team*;" and
(5) "*Ensure that high-quality primary care is implemented in the United States*."[7]

The second objective quickly became the most notable, with Action Item 2.1a causing the most controversy in the short time since the report's released.[8] This action item calls on the Centers for Medicare & Medicaid Services (CMS) to be the first payor to ask every beneficiary they cover to annually declare a source of primary care, and assign a provider to any non-responding enrollees.[9] NASEM then recommends that CMS push its state partners, as well as commercial insurers and employers, to do the same.[10] The report does not guarantee federal action, but NASEM reports have spurred health policy initiatives in the past, such as improving quality of care by reducing medical

errors.[11] Additionally, the recent NASEM report was supported by well-known organizations such as the American College of Physicians, Blue Shield of CA, the Commonwealth Fund, and approximately 15 others.[12] These endorsements add further credibility to NASEM's recommendations and may help achieve support from CMS and private payors.

Action Item 2.1a has garnered significant attention for several reasons. On one hand, assigning every beneficiary a PCP could be means to improving the health of Americans, as the U.S. has the worst health outcomes of wealthier nations.[13] NASEM researchers found that better access to primary care is a public health measure that will increase timely diagnoses, enhance management of chronic diseases, and lead to overall coordinated care.[14] Currently, the U.S. spends 5% on primary care versus other wealthy democracies, whose spending averages around 14%.[15] Increasing spending on primary care would emphasize a platform for continuous, person-centered care that would consider the needs and preferences of individuals, families, and communities.[16]

On the other hand, there are worrisome implications to such a mandate. First, a central requirement to this action item to make healthier people and healthier communities is to increase the supply of primary care. However, the U.S. is already experiencing critical primary care shortages and projections estimate that by 2033, PCP shortages could reach between 21,400 and 55,200.[17] Physicians would rather enter more lucrative specialties where they are less likely to experience burnout.[18] Such a shortage has significant consequences for those who live in rural areas and may not have access to primary care outside of the emergency department. Indeed, a 2019 Journal of the American Medical Association study confirmed that rural residents already consume over one-fifth of all emergency department visits.[19] Second, should the government adopt NASEM's recommendations, it would not be the first attempt to link patients to a PCP. Up until the 1990s, popular MCOs such as Kaiser Permanente used PCPs as "gatekeepers" that would refer patients to specialists as a way to keep premiums low. Originally hailed as a means for reducing health costs, these models instead caused physicians and hospitals to underprovide services for fear of surpassing their spending thresholds and by the late 1990s, driven by strong patient discontent, these companies were experiencing hundreds of millions of dollars in annual losses.[20] These organizations ultimately struggled to strike the right balance between gatekeeping to keep costs low, and giving patients the autonomy to seek care when needed.[21]

Any initiatives stemming from NASEM's recommendation to require patients to have PCPs could also receive backlash from patients themselves. First, patients may be concerned with what an annual enrollment period to choose their PCP would look like, and if all dependents on their health plan would have to use one specific PCP. Additionally, patients may be concerned that assigning a PCP may turn into gatekeeping. However, the NASEM committee addressed concerns with solutions that include a new generation of medical systems. They proposed that with new advanced primary care systems, emphasis on primary care should not limit access to overall care.[22] Their focus is to improve

continuity of care, which will in turn provide better preventative care, higher patient satisfaction, and better management of chronic conditions, while lowering costs.[23]

Since the initial IOM report, primary care has drastically changed in the U.S. and has driven care to become fragmented and expensive.[24] The goal of NASEM's report is to make primary care a common good to increase overall health and make chronic conditions easier to manage.[25]As the U.S. looks to solutions to improve the broken foundation of primary care and promote high quality care, assigning a PCP may be a solution to increase access for patients while simultaneously keeping costs down.[26]

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1 "A primary-care physician for every American, science panel urges" By Noam N. Levey, Modern Healthcare, May 4, 2021, https://www.modernhealthcare.com/physicians/primary-care-physician-every-american-science-panel-urges?utm_source=modern-healthcare-covid-19-coverage&utm_medium=email&utm_campaign=20210504&utm_content=article6-headline (Accessed 5/11/21).
2 "Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care" National Academies of Sciences, Engineering, and Medicine, May 4, 2021, Washington, DC: The National Academies Press, https://www.nap.edu/catalog/25983/implementing-high-quality-primary-care-rebuilding-the-foundation-of-health (Accessed 5/11/21), p. 4.
3 *Ibid*.
4 *Ibid*.
5 *Ibid*.
6 Levey, May 4, 2021.
7 National Academies of Sciences, Engineering, and Medicine, May 4, 2021, p. 5-6.
8 Levey, May 4, 2021.
9 National Academies of Sciences, Engineering, and Medicine, May 4, 2021, p. 10.
10 *Ibid*, p. 11.
11 Levey, May 4, 2021.
12 National Academy of Sciences, Engineering, and Medicine, May 2021.
13 "U.S. Health Care from a Global Perspective" By David Squires and Chloe Anderson, The Commonwealth Foundation, October 8, 2015, https://www.commonwealthfund.org/publications/issue-briefs/2015/oct/us-health-care-global-perspective (Accessed 5/19/21).
14 Levey, May 4, 2021.
15 *Ibid.*
16 National Academies of Sciences, Engineering, and Medicine, May 4, 2021, p. 21.
17 "The Complexities of Physician Supply and Demand: Projections from 2018 to 2033" Association of American Medical Colleges, June 2020, https://www.aamc.org/system/files/2020-06/stratcomm-aamc-physician-workforce-projections-june-2020.pdf (Accessed 5/13/21)
18 *Ibid.*
19 "Trends in Emergency Department Use by Rural and Urban Populations in the United States" JAMA Network, April 12, 2019, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730472 (Accessed 5/14/21).
20 "Kaiser Reports Huge Loss, Many HMOs Losing Money" By Robert Michel, The Dark Report, Vol. V, No. 3 (March 2, 1998), https://www.darkintelligencegroup.com/the-dark-report/laboratory-management/kaiser-reports-huge-loss-many-hmos-losing-money/ (Accessed 5/13/21).
21 *Ibid.*
22 Levey, May 4, 2021.
23 *Ibid.*
24 National Academies of Sciences, Engineering, and Medicine, May 4, 2021, p. 85.
25 *Ibid*, p. 4.
26 *Ibid.*

MedPAC Examines Private Equity Involvement in Medicare

[Excerpted from the article published in July 2021.]

In 2020, at the request of the U.S. House Committee on Ways and Means (the Committee), the Medicare Payment Advisory Commission (MedPAC) began investigating the role that private equity (PE) plays in healthcare provided to Medicare beneficiaries. In its June 2021 "Report to the Congress on Medicare and the Health Care Delivery System," MedPAC included for the first time a chapter on PE's effect on Medicare, wherein it discussed the findings and observations from its investigation and answered a number of questions posed by the Committee. This Health Capital Topics article will analyze MedPAC's answers to those questions, review its investigation of PE's role in healthcare, and summarize reactions from stakeholders.

Over the past decade, the number of deals involving PE has increased, from 107 physician medical group deals in 2011 (totaling $464 million) to 188 in 2020 (totaling $3.5 billion).[1] In total, PE firms were involved in 1,329 physician medical group deals over the past 10 years, signaling a growing interest in this healthcare sector.[2]

Due to PE's growing interest and involvement in healthcare, the U.S. House Committee on Ways and Means (the Committee) requested in March 2020 that MedPAC investigate PE's effect on Medicare, focusing on the following four questions:

1) *"What are the current gaps in Medicare data that create issues tracking private equity investments in Medicare? Are there levers that facilitate or allow for the collection of PE-related information in the current Change of Ownership (CHOW) process administered by the Centers for Medicare & Medicaid Services (CMS)?*
2) *What are private equity funds' business models when investing in health care? How do these strategies vary by health care setting?*
3) *How has private equity investment in health care affected Medicare costs and the beneficiary and provider experience?*
4) *To what extent are private equity firms investing in companies that participate in Medicare Advantage, and is it possible to evaluate the effects of such investments on Medicare costs?*"[3]

In answer to the Committee's first question regarding current gaps in Medicare data that create tracking issues with PE investments, MedPAC did find gaps in tracking PE's effect on Medicare. If an entity wants to participate in a PE-related CHOW, it must adhere to CMS's approval process, wherein the CHOW is reported to the Provider Enrollment, Chain, and Ownership System (PECOS).[4] However, this system is based on self-reporting providers, and CMS has no centralized data source for verifying PE ownership or financial details of PE transactions.[5] CMS only collects data on provider ownership to support the Medicare enrollment process, payment, fraud, and law enforcement.[6] When a CHOW occurs, PECOS does not require provider organizations to submit a

hierarchy of parent organizations.[7] Since PECOS does not closely track ownership data, providers may structure themselves within multi-level corporations that makes ownership difficult to trace, limiting their legal liability.[8] However, improving transparency of ownership could help beneficiaries when choosing a provider as well as researchers investigating the effects of PE in healthcare.

In MedPAC's answer to the Committee's first question, the Commission reported that increased transparency has become a growing concern, especially in nursing homes, which rely heavily on Medicare funding. Over the past few decades, nursing homes have been restructuring from one entity to several single-purpose entities (SPEs).[9] MedPAC found that unpacking the hierarchy of control in these relationships is often difficult for those involved in the approval process, and applicants may not provide complete information unless specifically asked.[10] For example, stakeholders are concerned that some high-profile nursing home bankruptcies have occurred over the past few years, but there may not be an entity to blame because the hierarchy is ambiguous.[11] Consequently, stakeholders are pushing for policies that improve and expand the required information reported to PECOS. MedPAC concluded their answer to the Committee's first question by indicating that evolving legal structures will continue to prevent CMS from making most data public; however, access to more complete ownership data could improve CMS's ability to address quality, access, and spending benchmarks, and whether to extend billing privileges.[12]

The Committee's second question requested that MedPAC investigate the types of business models PE funds use when investing in different healthcare settings. MedPAC remarked again that due to limited data sources for PE ownership, the actual numbers of providers with PE investment may be higher than estimated.[13] MedPAC examined the business models of hospitals, nursing homes, and physician practices and found that PE firms currently have at least some ownership in 4% of hospitals, 11% of nursing homes, and 2% of provider practices.[14] Once a PE firm acquires a hospital, practice, or nursing home, its main goal is to make the entity more profitable, either by reducing costs (such as lowering labor costs), increasing revenues (such as through providing the most profitable mix of services), or some combination of the two.[15] The pressure for PE investors to quickly make a return within a five to seven year timeframe has raised concerns regarding quality, safety, and referral issues.[16] Other PE business models, and related strategies, are specific to the particular healthcare sub-sector. For instance, hospitals and nursing homes may sell their real estate to PE firms and become tenants of that PE firm.[17] For PE firms, buying real estate from hospitals or nursing homes provides them with opportunities to reduce their corporate taxes if they meet requirements for real estate investment trusts (REITs).[18] Additionally, REITs are beneficial to PE firms because the nursing homes pay a portion of their income to the REITs, thus shifting nursing home profits to the REITs and further reducing corporate taxes.[19] In hospitals, PE firms may advise the hospital to sell some of their real estate holdings and allocate any profits among the hospital and its PE

investors.[20] Another strategy PE firms use to make a profit is through the acquisition and subsequent consolidation of physician practices and hospitals within a region.[21] Because many of these acquisitions and consolidations are relatively smaller in value ($60-70 million), they tend to fly under the radar of antitrust enforcement agencies and "quietly increase market power and reduce competition."[22] Ultimately, PE acquisitions are predicted to stay small for hospitals, remain constant in nursing homes, and grow among physician practices.[23]

The Committee's third question to MedPAC asked how PE investment affected Medicare costs and beneficiary and provider experiences. While interviewing physicians for the report, MedPAC established that quality of care metrics and practice patterns did not change as a result of PE investment. Further, the metrics and patterns have improved because the physicians do not have to focus as much attention on running a business and can focus more on the clinical side of a practice.[24] A February 2021 study from the National Bureau of Economic Research (NBER) found similar results when investigating PE-owned nursing homes. The NBER study reported that PE-owned facilities had positive impacts not only on the quality of clinical services, but also benefited the healthcare organization overall.[25] Further, NBER found that PE investment in nursing homes may lead to better quality through "better management, stronger incentives, and greater access to credit."[26] As regards hospitals, MedPAC found that PE-owned hospitals were more inclined to report lower costs and patient satisfaction than other hospitals (such as non-profit or federal, state, or local hospitals), but this did not directly impact Medicare costs.[27] Lastly, there is minimal evidence of PE's impact on Medicare costs in physician practices. However, PE firms may increase Medicare costs by putting pressure on physicians to perform more services and procedures to increase revenue.[28]

The Committee's fourth and final question regarded the extent to which PE firms are investing in companies and startups that participate in Medicare Advantage (MA), as well as the effects of the investments on Medicare costs. Again, MedPAC's results on Medicare costs may be inconclusive due to a lack of data.[29] However, the commission did find that PE funds own six companies of the 309 payors that offer MA plans who mainly target beneficiaries in nursing homes.[30] Through their research, MedPAC found that MA plans would not have an effect on Medicare spending unless they influenced plan bids, quality bonuses, or risk scores.

While the regulatory, demographic, and payment conditions that have made health care an attractive investment other regulations such as those related to the corporate practice of medicine (CPOM) may drive PE firms away from healthcare investments.[31] CPOM laws vary by state, but were enacted primarily out of concern that PE ownership obligations to shareholders may not align with a physician's duty to patients or medical judgments.[32] After a PE firm buys or invests in a provider practice, they must not influence or appear to influence a physician's behavior.[33] If a PE firm is suspected of influencing a physician's decision making, this could trigger enforcement of CPOM laws or raise

concerns about inducement of services under the Anti-Kickback Statute or the False Claims Act.[34] However, some physicians still seek PE ownership so they can focus on their clinical practice and be less involved (and burdened) with day-to-day management and operations.

As of the date of this article's publication, a number of stakeholders have spoken out about MedPAC's investigation. First, the American Investment Council touted PE's important role in improving patient care, providing capital, and creating innovation that will reduce Medicare costs, even though no recommendations were outlined in the report.[35] Further, the American Investment Council said that providing capital to healthcare organizations has been vital to lowering healthcare costs, delivering necessary treatments, and driving research.[36] Second, the American College of Emergency Physicians (ACEP) highlighted the need to close gaps in Medicare data for PE-owned provider practices, nursing homes, and hospitals, and that data was often incomplete.[37] ACEP found that PE firms' common strategy is to first acquire a "platform practice," then subsequently acquire multiple smaller physician practices in a region and then "roll up" the practices into the platform practice to maximize the combined entity's market power and create a continuum of care.[38] This strategy, however, does not always lead to cost savings.[39]

While MedPAC's June 2021 report found that PE investors have had increased interest and involvement in healthcare, mainly through hospitals, nursing homes, physician practices, and MA companies, their percent of ownership remains relatively small among the entire healthcare industry.[40] The major concerns surrounding the recent increases of PE in healthcare are the consolidation of providers and increased market power to raise payment rates, which may have insignificant effects on Medicare because those prices are set by CMS (i.e., not negotiated).[41] MedPAC's final comment in its report concluded that the commission will continue to monitor investment activity to see if certain sectors will highlight the need for regulation in payment or quality measures in future years.[42]

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1 "The Health Care M&A Report, 4th Quarter, 2011" Norwalk, CT: Irving Levin Associates, Inc., 2012, p. xxxvii; "The Health Care M&A Report, 4th Quarter, 2020" Norwalk, CT: Irving Levin Associates, Inc., 2021, p. 35.

2 As derived and calculated from reported Physician Medical Group transactional data from The Healthcare M&A Report by Irving Levin Associates, Inc. Quarterly Reports from 2011 to 2020.

3 "Report to the Congress: Medicare and the Health Care Delivery System" Medicare Payment Advisory Commission, June 2021, http://www.medpac.gov/docs/default-source/reports/jun21_medpac_report_to_congress_sec.pdf?sfvrsn=0 (Accessed 6/28/21), p. 75.

4 *Ibid*, p. 81.

5 *Ibid*.

6 *Ibid*.

7 *Ibid*, p. 72.

8 *Ibid*, p. 72, 81-82.

9 *Ibid*, p. 81.

10 *Ibid*.
11 *Ibid*, p. 84.
12 *Ibid*, p. 85.
13 *Ibid*, p. 72.
14 2% of provider practices only include acquisitions from 2013-2016. Does not include previous transactions, or take into account how PE acquisitions of provider practices have grown since 2016; *Ibid*, p. 72.
15 *Ibid*, p. 72-73, 89.
16 *Ibid*, p. 98, 100.
17 *Ibid*, p. 91.
18 *Ibid*, p. 108.
19 *Ibid*.
20 *Ibid*, p. 79.
21 *Ibid*, p. 93.
22 *Ibid*, p. 94.
23 *Ibid*, p. 94-96.
24 *Ibid*, p. 96.
25 "Does Private Equity Investment in healthcare Benefit Patients? Evidence from Nursing Homes" By Atul Gupta et al., Nation Bureau of Economic Research, February 2021, https://www.nber.org/system/files/working_papers/w28474/w28474.pdf (Accessed 6/28/21), p. 1.
26 *Ibid*, p. 10.
27 Medicare Payment Advisory Commission, June 2021, p. 100.
28 *Ibid*, P. 101.
29 *Ibid*, p. 73.
30 *Ibid*.
31 *Ibid*, p. 91.
32 *Ibid*.
33 *Ibid*.
34 *Ibid*.
35 "Private Equity Investments Support American Health Care & CVOID-19 Response" American Investment Council, February 18, 2021, https://www.investmentcouncil.org/icymi-new-medpac-report-highlights-value-of-private-equity-investments-in-health-care/ (Accessed 6/29/21).
36 "ICYMI: New MedPAC Report Highlights Value of Private Equity Investments in Health Care" American Investment Council, June 15, 2021, https://www.investmentcouncil.org/private-equity-investments-support-american-health-care-covid-19-response/ (Accessed 6/29/21).
37 "MedPAC Issues Another Annual Report to Congress: Includes Insights on Private Equity, Alternative Payment Models, and Rural Health" American College of Emergency Physicians, June 24, 2021, https://www.acep.org/federal-advocacy/federal-advocacy-overview/regs--eggs/regs--eggs-articles/regs--eggs---june-24-2021/ (Accessed 6/29/21).
38 *Ibid*.
39 *Ibid*.
40 Medicare Payment Advisory Commission, June 2021, p. 106.
41 *Ibid*.
42 *Ibid*.

Study Finds COVID-19 Accelerated Physician Practice Acquisitions

[Excerpted from the article published in August 2021.]

A recent study from Physicians Advocacy Institute (PAI), prepared by Avalere Health, associated the growing number of both physician practice acquisitions and employed physicians between 2019 and 2021 with the COVID-19 pandemic. To study COVID-19's impact on physician employment trends, the June 2021 study evaluated the IQVIA OneKey database that contains physician practice and health system ownership information.[1] To assess these trends at a national and regional level, Avalere researchers studied the two-year period from January 1, 2019 to January 1, 2021.[2] This allowed researchers to examine consolidation trends before the onset of the pandemic and how those trends changed during the subsequent nine months. Specifically, researchers observed acquisitions of hospitals, health systems, and other corporate entities such as private insurers, and physicians leaving independent medical practices for employment at hospitals, health systems, or other corporate entities.[3] From this data, Avalere found a rapid increase in physician employment in the months that followed the onset of the COVID-19 pandemic and concluded that nearly seven in ten physicians were employed by hospitals or corporate entities by the beginning of 2021.[4] This Health Capital Topics article will analyze the findings from Avalere's study and discuss the impact of physician employment trends.

National Trends

The Avalere study found that independent physician practices were particularly affected by hospital and health system acquisitions and physicians seeking employment in hospitals.[5] Throughout the two-year study period, 18,600 additional physicians sought employment at a hospital, with over half of those physicians shifting toward hospital employment following the onset of the public health emergency.[6] The latter half of 2020 saw a 3.1% increase in the growth rate of hospital-employed physicians and by the end of 2020, 49.3% of physicians were hospital-employed.[7] Additionally, hospitals acquired 3,200 physician practices over the two-year period, resulting in an 8% increase in the number of hospital-owned practices.[8] While acquisition trends prior to the pandemic were fairly consistent with steady increases, the onset of COVID-19 served as a catalyst, resulting in a 3.7% increase in the rate of hospital-owned physician practices during the last six months of 2020.[9]

Independent physician practices were also hit by corporate entity acquisitions and physicians seeking employment in corporate entities. During the two-year study period, 29,800 additional physicians sought employment at corporate entities, with nearly 11,300 of those physicians shifting to corporate employment after the onset of the pandemic.[10] The latter half of 2020 saw a 3.9% increase in the growth rate of corporate-employed physicians and by the end of 2020, 20% of physicians were employed by corporate entities.[11] Additionally, corporate entities acquired 17,700 physician practices over the

two-year period, resulting in a 32% increase in corporate-owned practices.[12] While acquisition trends at the beginning of the study increased steadily, the onset of COVID-19 resulted in a 14.6% increase in the rate of corporate-owned physician practices during the last six months of 2020.[13]

Regional Trends

The Avalere study also examined these trends by the following regions: Midwest, Northeast, South, and West. While researchers found differences across regions, all four regions generally followed the national trend of increased physician employment and hospital ownership of physician practices. The Midwest had the highest percentage of hospital-employed physicians at over 60% in January 2021.[14] In the Northeast and West, nearly half of all physicians were employed by hospitals, while hospitals in the South employed slightly over 40% of physicians.[15] The Midwest also led the regions with 37.5% of practices owned by hospitals, with the Northeast following at slightly over 25% the South and West having approximately 20% of physician practices owned by hospitals.[16] However, the South saw the largest percentages of corporate-employed physicians as of 2021, at approximately 23%.[17] The Northeast and West followed national trends, with 20% of their physicians employed by corporate entities; meanwhile, nearly 16% of Midwest physicians were employed by a corporate entity.[18] The South was also the leader with nearly 25% of physician practices being corporate-owned.[19] The West and Midwest closely followed national trends with approximately 21% of physician practices that were corporate-owned, while the Northeast had only 19% of corporate-owned physician practices.[20]

Impact

Not long after the Avalere study was released, President Joe Biden released an executive order on July 9, 2021, "Promoting Competition in the American Economy."[21] The executive order was part of an effort to boost competition and lower prices, but specifically aimed to more strongly scrutinize the transparency of mergers and acquisitions (M&A).[22] A White House press release attributed the fact that a quarter of the healthcare market is controlled by just ten healthcare systems to unchecked M&A activity, and also aligned rising healthcare costs with the increased number of transactions.[23] Such concerns expressed by the White House and industry stakeholders have not yet slowed down healthcare M&A, with investors in the second quarter of 2021 spending nearly 10 times more than they did in the second quarter of 2020.[24] Additionally, M&A transactions saw a shift in focus to primary care, after specialty care transactions (such as orthopedics and dermatology) had been in demand for many years.[25] In past years, investors looked to "roll-up" smaller specialty practices into an existing larger practice or "platform practice" to increase the combined entity's market power and create a continuum of care.[26] However, with the aging Baby Boomer population requiring increased amounts of healthcare and the continued expansion of Medicare Advantage, there has been an investment shift toward primary care.[27]

Conclusion

While the trend of physician consolidation has been occurring for approximately a decade, the Avalere study finds that the COVID-19 pandemic has accelerated this trend.[28] Additionally, regulatory burdens require physicians to focus less time on practicing medicine while spending more time on administrative tasks.[29] Between ever-changing regulations and additional burdens due to the COVID-19 pandemic, physicians may continue to seek employment at hospitals, health systems, or other corporate entities, where the employer will handle such burdens, freeing the physician up to focus on caring for patients. Another trend that may be moving physicians away from smaller practices is the U.S. health system's shift toward value-based care. Hospitals, health systems and corporate entities generally seek to create large networks of providers so that care can be streamlined at lower cost through economies of scale, resulting in better access to, and higher quality of, care for patients.[30] These trends are part of a greater shift toward physician consolidation, for which the COVID-19 pandemic served as a catalyst, resulting in a dwindling number of independent physician practices.[31]

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1 "COVID-19's Impact on Acquisitions of Physician Practices and Physician Employment 2019-2020" Physicians Advocacy Institute and Avalere Health, June 2021, available at: http://www.physiciansadvocacyinstitute.org/PAI-Research/Physician-Employment-and-Practice-Acquisitions-Trends-2019-20 (Accessed 8/2/21), p. 34.
2 *Ibid*, p. 4.
3 *Ibid*.
4 *Ibid*, p. 11.
5 *Ibid*, p. 6.
6 *Ibid*, p. 9.
7 *Ibid*, p. 9, 12.
8 *Ibid*, p. 15, 18.
9 *Ibid*, p. 18.
10 *Ibid*, p. 7.
11 *Ibid*, p. 13.
12 *Ibid*, p. 16.
13 *Ibid*, p. 19.
14 *Ibid*, p. 25.
15 *Ibid*, p. 28.
16 *Ibid*.
17 *Ibid*, p. 26, 29.
18 *Ibid*, p. 26.
19 *Ibid*.
20 *Ibid*.
21 "FACT SHEET: Executive Order on Promoting Competition in the American Economy" The White House, July 9, 2021, https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/ (Accessed 8/2/21).
22 *Ibid*.
23 *Ibid*.
24 "Physician practice acquisitions see 'staggering' spending uptick in Q2" By Tara Bannow, Modern Healthcare, July 19, 2021, https://www.modernhealthcare.com/mergers-acquisitions/physician-practice-acquisitions-see-staggering-spending-uptick-q2 (Accessed 8/3/21).

25 *Ibid*.
26 *Ibid*.
27 *Ibid*.
28 "Coronavirus Pandemic Driving Increase in Healthcare Consolidation" By Christopher Cheney, Healthleaders Media, July 2, 2021, https://www.healthleadersmedia.com/clinical-care/coronavirus-pandemic-driving-increase-healthcare-consolidation (Accessed 8/3/21).
29 *Ibid*.
30 "4 Strategies to Advance Value-Based Care During and After a Crisis" By Kelsey Waddill, Health Payer Intelligence, September 11, 2020, https://healthpayerintelligence.com/features/4-strategies-to-advance-value-based-care-during-and-after-a-crisis (Accessed 8/4/21).
31 "Saving private practice? Navigating the legal and ethical minefield of physician-private equity deals" By Khadijah M. Silver, MedCity News, May 28, 2021, https://medcitynews.com/2021/05/saving-private-practice-navigating-the-legal-and-ethical-minefield-of-physician-private-equity-deals/ (Accessed 8/3/21).

2021 Projected Physician Shortages Down from 2020 Report

[Excerpted from the article published in August 2021.]

In June 2021, the Association for American Medical Colleges (AAMC) released its seventh annual report on physician workforce projections. AAMC's "Complexities of Physician Supply and Demand: Projections from 2019-2034" predicts that demand for physicians will increase over the next 15 years.[1] Their report collected much of the data in 2019, before the COVID-19 pandemic highlighted many health disparities in the industry.[2] To address these rapid demand increases, congressional legislation is increasing medical school and residency spots for the first time in over 20 years.[3] The 2021 report took into account the increase of graduate medical education (GME) slots on supply projections, which resulted in a decrease in the shortage of physicians as compared to the June 2020 report.[4] This Health Capital Topics article will examine AAMC's physician workforce projections and the impact of new legislation on physician supply.

Summary of Physician Shortage Projections

After releasing their annual workforce report, AAMC announced that, by 2034, the total physician shortage could reach between 37,800 and 124,000 physicians due to demand outpacing supply over the next 15 years.[5] However, these 2021 projected shortages have decreased from AAMC's June 2020 report, wherein the total physician shortage was projected to fall between 55,100 and 139,000.[6] In AAMC's 2021 report, they explained that the ameliorated shortage is due to both a decrease in physician demand from immediate COVID-19 effects,[7] and an expected growth in supply due to the first increase in GME slots in over two decades.[8] In AAMC's 2021 report, projected primary care physicians will be in the greatest demand, with a shortage of 17,800 to 48,000 physicians, and other non-primary care specialties can expect a shortage of 21,000 to 77,100 physicians, by 2034.[9] Shortages among non-primary care physicians are comprised of:

(1) Surgical specialty shortages between 15,800 and 30,200 physicians;
(2) Medical specialty shortages between 3,800 and 13,400 physicians; and,
(3) Other specialty shortages between 10,300 and 35,600 physicians.[10]

Further, the COVID-19 pandemic has brought attention to issues such as access to healthcare and the health disparities in the U.S. population. AAMC estimates that if uninsured and underinsured populations have the same access to healthcare as those with adequate insurance and low access barriers, the aforementioned total physician shortage could increase 13% to 22%, or 102,400 to 180,400 physicians, respectively.[11] With President Biden's healthcare policy plans and other legislation aimed to increase access to care, physician shortages could skyrocket even further. Notwithstanding the systematic gaps COVID-19 revealed in the U.S. healthcare system, the AAMC report pointed out that direct effects from the COVID-19 pandemic are likely to be minimal and short-term.[12]

Demand Effects

Population growth and shifting demographics – specifically the aging of the U.S. population – will play a large role in the physician shortage through at least 2034.[13] First, AAMC projects the COVID-19 pandemic will likely affect the geographic distribution of the population, ultimately altering the distribution of the healthcare workforce (data suggests that the pandemic accelerated the migration from urban to suburban or rural areas).[14] Changes in insurance status and payor mix distributions originating from COVID-19-related job losses also may affect demand for healthcare, as well as providers' revenues from delivering this care.[15] Second, AAMC reported that the overall U.S. population will grow 10.6% over the next 15 years.[16] This growth – nearly 35 million Americans – will increase the demand for physicians, consequently limiting access to physicians (especially primary care).[17] Third, a factor that is directly influencing the physician shortage is the aging of the U.S. population. The entire Baby Boomer generation is expected to reach age 65 or older in the next 10 years, leading AAMC to project high demand growth among seniors, an age group that requires more costly care. With the 65-and-older population expected to grow 42.4%, and the 75-and-older population expected to grow 74%, over the next 15 years, AAMC predicts increased demand for geriatric care and internal medicine specialties.[18] Conversely, pediatric specialties are expected to be in low demand, as the under 18 population is only expected to increase 5.6% over the next 15 years.[19] Fourth, the growth in the older population raises similar concerns regarding the retiring physician workforce. Retirement patterns over the next 15 years could greatly influence the supply of physicians, as 40% of currently practicing physicians will be reaching the traditional retirement age.[20] Increased shortages from physicians reaching retirement age is exacerbated by an insufficient number of resident physicians entering the field to replace those entering retirement, as well as early- and mid-career physicians accelerating retirement due to burnout following the COVID-19 pandemic.[21]

Supply Effects

AAMC projected a lower future physician supply in its 2020 report than in previous reports.[22] However, modeled projections from the 2021 report indicate that physician supply is likely to increase over the next 15 years.[23] The COVID-19 pandemic has motivated an increase in medical school applications, tagged the "Fauci effect."[24] Additionally, the Consolidated Appropriations Act of 2021 (CAA) attempts to increase physician supply by funding an increase of 1,000 GME slots over five years.[25] Starting in 2023, the CAA will add 200 Medicare-supported positions per year until 2027, which will be the first change in the number of positions in a quarter century.[26] Previously, the number of medical residency slots had been capped in an attempt to reduce Medicare spending under the Balanced Budget Act of 1997 (BBA'97).[27] However, with immense support from Congress and industry leaders, this GME slot increase could motivate additional legislation to provide even more GME positions.[28] Increasing the number of residency positions at teaching hospitals may drive

supply in the right direction and ensure that physician shortages are not exacerbated.[29]

While AAMC outlines primary care shortages and non-primary care shortages, providers in the geriatric workforce specifically face extreme shortages of physicians and decreased entry into the field due to the burden of debt.[30] This raises supply concerns because certain specialties have significantly higher demand from the aging population, such as psychiatrists for dementia and Alzheimer's patients, pulmonary specialists, orthopedic specialties, thoracic specialties, cardiologists, and many others.[31]

Conclusion

After the universal support for the CAA's increase in GME positions, a new legislative solution has emerged to address the physician shortage. The Resident Physician Shortage Reduction Act, which was introduced in both houses of Congress in March 2021, will expand upon the previous legislation and could add approximately 14,000 new GME positions over the next seven years.[32] The Act plans to incentivize medical school graduates to pursue their residency training at hospitals in rural areas or areas where there is a health professional shortage.[33] The legislation is backed by numerous healthcare organizations such as AAMC, the American Hospital Association (AHA), and the American Medical Association (AMA). President of AMA, Dr. Susan Bailey, said that they are glad to support the new legislation, as the previous cap on Medicare-supported GME positions narrowed the pipeline of future physicians, thus limiting access to care.[34] Further, AHA Vice President Thomas Nickels sent a letter of gratitude to Senators Menendez, Schumer, and Boozman, recognizing their work to slow the physician shortage.[35] The consensus in the healthcare industry is that legislation should be passed to undo the effects that the cap, created by BBA '97, placed on residency programs, i.e. creating physician shortages. However, healthcare leaders are mutually concerned that the Resident Physician Shortage Reduction Act will die in Congress, as it did in 2013 and 2019.[36]

Physician shortfalls have been a known issue that have increased over the last several years. However, events over the past two years, such as the COVID-19 pandemic and the 2020 Presidential Election, which may bring rise to new legislation, may send shortfalls into a decline for the first time in decades. While AAMC projections are still unsure of the full impact of COVID-19 on the healthcare workforce, demographic trends such as the aging of the population are undeniably contributing to the potential 124,000 physician shortage predicted within the next 15 years.

1 "The Complexities of Physician Supply and Demand: Projections from 2019-2034" Prepared by IHS Markit Ltd. for the Association of American Medical Colleges, June 4, 2021, https://www.aamc.org/data-reports/workforce/data/complexities-physician-supply-and-demand-projections-2019-2034 (Accessed 6/28/21), p. viii.
2 *Ibid*.
3 *Ibid*, p. vii; "The Complexities of Physician Supply and Demand: Projections from 2018-2033" Prepared by IHS Markit Ltd. for the Association of American Medical Colleges, May 28, 2020, https://www.aamc.org/system/files/2020-06/stratcomm-aamc-physician-workforce-projections-june-2020.pdf (Accessed 6/28/21), p. viii.
4 IHS Markit Ltd., May 28, 2020, p. viii.
5 IHS Markit Ltd., June 4, 2021, p. viii.
6 IHS Markit Ltd., May 28, 2020, p. vii
7 For more information on COVID-19's effect on delayed care, view the Health Capital Topics article "Healthcare Costs Projected to Grow in 2022" Vol. 14, Issue 6 (June 2021), https://www.healthcapital.com/hcc/newsletter/06_21/HTML/COST/convert_healthcare-costs-increase-2022_6.25.21.php (Accessed 7/2/21).
8 IHS Markit Ltd., June 4, 2021, p. viii.
9 *Ibid*.
10 *Ibid*.
11 *Ibid*, p. ix.
12 *Ibid*, p. 13.
13 *Ibid*, p. viii.
14 *Ibid*, p. 21-22.
15 *Ibid*, p. 22.
16 *Ibid*, p. 29.
17 *Ibid*, p. viii.
18 *Ibid*.
19 *Ibid*, p. 21.
20 *Ibid*, p. viii.
21 *Ibid*.
22 IHS Markit Ltd., May 28, 2020, p. vi.
23 *Ibid*.
24 The "Fauci effect" is the nickname for the 18% increase in medical school applications in 2021. AAMC senior director of student programs, Geoffrey Young, predicts the increase could be due to students having more time to prepare for the MCAT, or motivation from physicians on the frontlines of the COVID-19 pandemic. HS Markit Ltd., June 4, 2021, p. 20: "Applications to medical school up big. Is it the 'Fauci effect'?" By Brendan Murphy, AMA, December 18, 2020, https://www.ama-assn.org/residents-students/preparing-medical-school/applications-medical-school-big-it-fauci-effect (Accessed 7/2/21)
25 IHS Markit Ltd., June 4, 2021, p. vii.
26 "Finally some relief for the looming physician shortage" By Kenneth E. Raske, Modern Healthcare, January 28, 2021, https://www.modernhealthcare.com/opinion-editorial/finally-some-relief-looming-physician-shortage (Accessed 7/2/21); H.R. 133 – Consolidated Appropriations Act of 2021, December 27, 2020, https://www.congress.gov/bill/116th-congress/house-bill/133/text (Accessed 7/6/21), p. 1793.
27 Modern Healthcare, January 28, 2021.
28 *Ibid*.
29 *Ibid*
30 IHS Markit Ltd., June 4, 2021, p. 21.
31 "Graying of America: How the elder boom could impact health care" By Vicki Martinka Petersen, The DO, February 16, 2017, https://thedo.osteopathic.org/2017/02/graying-of-america-how-the-elder-boom-could-impact-health-care/ (Accessed 6/29/21); "A massive physician shortage is coming – and it could hit cardiology especially hard" By Michael Walter, Cardiovascular Business, June 15, 2021, https://www.cardiovascularbusiness.com/topics/economics-policy/massive-physician-shortage-cardiologists-

specialists?utm_source=newsletter&utm_medium=cvb_healthcareecon (Accessed 6/29/21).

32 S.834 - Resident Physician Shortage Reduction Act of 2021, March 18, 2021 https://rodneydavis.house.gov/uploadedfiles/resident_physician_shortage_act.pdf (Accessed 6/30/21), p. 3-6.

33 *Ibid*.

34 "Press Release: Davis, Sewell, Katko, Suozzi Introduce Bipartisan Legislation to Tackle Doctor Shortages during COVID-19 Pandemic" By Rodney Davis, March 29, 2021, https://rodneydavis.house.gov/news/documentsingle.aspx?DocumentID=404039 (Accessed 6/29/21).

35 "GME Support Letter" By Thomas Nickels on behalf of the American Hospital Association, March 23, 2021, https://www.aha.org/system/files/media/file/2021/03/aha-expresses-support-for-resident-physician-shortage-reduction-act-of-2021-s834-3-23-21.pdf (Accessed 6/30/21).

36 "The Match and The Resident Physician Shortage Reduction Act of 2021" by Natalie Newman, Authentic Medicine, March 22, 2021, https://authenticmedicine.com/2021/03/the-match-and-the-resident-physician-shortage-reduction-act-of-2021/ (Accessed 7/1/21).

V. TECHNOLOGY TOPICS

Amazon's New Moves in Healthcare

[Excerpted from the article published in March 2021.]

Amazon, the largest e-commerce company in the world,[1] has made large, strategic moves over the past several years to make a place for themselves in healthcare. This article will review Amazon's most recent advancements in the industry, including those related to Amazon's voice-controlled personal assistant, Alexa, and Amazon's employee healthcare system, Amazon Care, and how this non-healthcare company is changing the industry.

Amazon Alexa

In 2019, Amazon launched an initiative using its personal assistant and Amazon Echo smart speaker technology, called Amazon Alexa (Alexa), to assist in home healthcare, health-related questions, health monitoring, and medication and other reminders.[2] According to new projections, the smart speaker market is expected to be worth over $23 billion by 2025.[3] Alexa and Amazon are leading this market with 61% of market share.[4] Early in 2019, Amazon released new technology abilities (termed "*skills*" by Amazon) for Alexa that are compliant with the *Health Insurance Portability and Accountability Act* (HIPAA).[5] These skills, made in collaboration with healthcare partners, include checking the status of prescription deliveries; managing health improvement goals; post-operation updates and symptom checking; scheduling urgent care appointments; providing personalized health information based blood sugar tracking and trends; and, reviewing prescriptions, setting reminders to take medications, and requesting prescription refills.[6] These skills were developed through partners such as Express Scripts, Cigna Health, Boston Children's Hospital, and Livongo (which recently merged with Teladoc Health).[7]

During the COVID-19 pandemic, Alexa has been trained in new skills, such as explaining an individual's risk level for the virus; analyzing their symptoms; disseminating up-to-date information from the *Centers for Disease Control and Prevention* (CDC) and *World Health Organization* (WHO); and, helping consumers find test centers.[8] Alexa devices were also used in overwhelmed hospitals to allow nurses to check in on patients remotely through video, saving clinical staff valuable time and reducing the risk of infection between provider and patient.[9]

Amazon has opened up the development of these skills to healthcare organizations, in order to allow providers to develop new healthcare skills for the device, and has a dedicated Health & Wellness team in their Alexa development branch.[10] The team's main goal is to connect patients with their care, and future innovations between Amazon and corporate partners hold the potential to enable patients to take control of their health, stick to prescribed regimens, watch videos and information on basic care and even physical therapy routines, more efficiently connect patients and providers, and reduce avoidable healthcare costs – such as those related to patient nonadherence with medication schedules.[11]

Amazon Care

Amazon also began offering their pilot employee benefit program, Amazon Care, in 2019.[12] The service is a combination of virtual and in-person care, offering home health services, telehealth appointments, and prescription delivery.[13] Employees are encouraged to use the Amazon-created telehealth smartphone application for non-urgent issues like colds and minor injuries; preventative health consults and vaccines; sexual health services; and, general health questions.[14] The program expanded quickly, from servicing only employees and their dependents in the Seattle area to operating throughout the entire state of Washington by September 2020.[15] Amazon Care contracts with a medical practice called Care Medical to provide these services.[16] Most recently, on March 17, 2021, Amazon announced that its telemedicine program will be made available to employers nationwide.[17] Services will be immediately available to Washington State employers, with all Amazon workers and any interested private employers able to join by the summer of 2021.[18]

The director of Amazon Care, Kristen Helton, attributed this recent expansion partially to the COVID-19 pandemic, which emphasized the need for in-home care and remote services, such as those provided by this program.[19] Helton also stated that Amazon's telemedicine services have garnered high satisfaction scores from its employees in Washington, where the service was launched in 2019.[20] Amazon Care's expansion of in-person services nationwide also appears to be eminent. In fact, Amazon Care's contractor, Care Medical, filed paperwork to begin operating in five new states in February 2021 alone, totaling 17 states where Amazon Care is preparing to provide in-person services outside of Washington State.[21]

Of note, the joint venture called Haven, formed between Amazon, Berkshire Hathaway, and JPMorgan Chase, disbanded in January 2021, three years after its formation.[22] The goal of Haven was to tackle high and increasing costs for employee healthcare.[23] While this joint venture did not live up to some expectations, it may have informed its three partners on how to better create healthcare systems for their respective employees.[24] Insights from this venture will likely be important for Amazon in its expansion plans for Amazon Care.

Further, Amazon Care appears to have picked up Haven's mantle in collaborating with others to bring sweeping legislative, regulatory, and reimbursement changes to the U.S. healthcare system. On March 3, 2021, a new coalition called "*Moving Health Home*" was announced.[25] The program includes eight founding organizations: Amazon Care, Landmark Health, Signify Health, DispatchHealth, Elara Caring, Intermountain Healthcare, Home Instead Senior Care, and Ascension.[26] Moving Health Home has five main policy priorities:

(1) Expand Medicare coverage of "*higher-acuity home-based services*," such as emergency services;

(2) Retain site of care flexibility for hospitals in order to allow them to treat patients in residential settings;

(3) Reform or eliminate the Medicare budget neutrality requirement[27] and include codes for home-based *evaluation and monitoring* (E/M) to provide seniors better access to treatment;

(4) Create a bundled payment model for extended home care as a quality-improving and cost-effective solution for long-term care facilities; and,

(5) Amend the *National Association of Insurance Commissioners* (NAIC) model law on commercial network adequacy to designate the home as a site of care, so that home-based care can more easily meet commercial and Medicare Advantage network requirements.[28]

Moving Health Home has created these priorities based on new evidence related to quality, cost savings, and patient satisfaction.[29] The COVID-19 pandemic accelerated the move to at-home care by temporarily removing many of the regulatory and financial restrictions that hampered growth in, and transitions to, this area.[30] Moving Health Home, as well as other organizations, are now advocating for many of these temporary allowances to become permanent, including those discussed above as well as telemedicine reimbursement.[31]

Conclusion

Similar to how Amazon developed its now widely-used *Amazon Web Services* (AWS) platform, the company developed Amazon Care to address its own needs for employee coverage at lower costs.[32] Now, as Amazon prepares to launch its healthcare system nationwide to employees and to other private businesses, its experience in contracting with businesses through AWS should serve it well.[33] One key to launching into the telemedicine space, experts say, will be these effective contracting skills, as well as differentiation and recognition.[34] Amazon's healthcare services provided through Alexa and its pharmacy services will likely help the organization differentiate itself.[35] Further, Amazon already enjoys widespread brand-name recognition that will aid its expansion into this new sector.[36] Should the Moving Health Home initiative create greater financial incentives for the kind of healthcare that Amazon Care provides, these services will be in even greater demand and position Amazon for long-term industry success. Whether this coalition will, in fact, have any major effects remains to be seen, but what is clear is that Amazon Care is making strategic moves to expand their own offerings and be an agent of change in the wider U.S. healthcare system.

1 "Largest e-commerce companies by market cap" CompaniesMarketCap.com, https://companiesmarketcap.com/e-commerce/largest-e-commerce-companies-by-market-cap/ (Accessed 3/9/21); "5 Largest Ecommerce Companies in the World" By Soma Dutta, Insider Monkey, November 16, 2020, https://www.insidermonkey.com/blog/5-largest-ecommerce-companies-in-the-world-ready-for-ian-890169/?singlepage=1 (Accessed 3/9/21).
2 "Introducing New Alexa Healthcare Skills" Rachel Jiang, amazon alexa, April 4, 2019, https://developer.amazon.com/blogs/alexa/post/ff33dbc7-6cf5-4db8-b203-99144a251a21/introducing-new-alexa-healthcare-skills (Accessed 3/9/21).
3 "Alexa, Can You Transform Healthcare?" By James D. Cimino, Richard G. Stefanacci, and Matthew Pakizegee, Managed Healthcare Executive, February 26, 2020, https://www.managedhealthcareexecutive.com/view/alexa-can-you-transform-healthcare-0 (Accessed 3/9/21).
4 *Ibid.*
5 "New ways to manage your medications at home using Alexa" By Rachel Jiang, The Amazon blog dayone, November 26, 2019, https://blog.aboutamazon.com/devices/new-ways-to-manage-your-medications-at-home-using-alexa (Accessed 3/9/21).
6 Jiang, April 4, 2019; "New ways to manage your medications at home using Alexa" By Rachel Jiang, The Amazon blog dayone, November 26, 2019, https://blog.aboutamazon.com/devices/new-ways-to-manage-your-medications-at-home-using-alexa (Accessed 3/9/21).
7 For more information on the Livongo-Teladoc merger, see the February 2021 topics article entitled: "M&A Activity Slowed in 2020, But is Poised to Accelerate in 2021" Vol. 14, Issue 2 (February 2021), https://www.healthcapital.com/hcc/newsletter/02_21/HTML/MA/convert_covid-19_effects_on_m_a.php (Accessed 3/9/21); "'Alexa, Can You Improve Healthcare?' – Rachel Jiang, Head of Alexa Health & Wellness" Episode 98, Raise the Line Podcast, Osmosis, December 30, 2020, https://www.osmosis.org/raisethelinepodcast/giving-voice-to-health-concerns-rachael-jiang-head-of-alexa-health-wellness (Accessed 3/9/21).
8 Jiang, December 30, 2020.
9 *Ibid.*
10 *Ibid.*
11 Nonadherence rates ranging from 25% to 50% attribute between $100 and $300 billion of avoidable health care costs. "Adherence and health care costs" By Aurel O. Luga and Maura J McGuire, Risk Management Healthcare Policy, Vol. 7, February 20, 2014, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/pdf/rmhp-7-035.pdf (Accessed 3/9/21), p. 35-37; Jiang, December 30, 2020.
12 "Amazon Care" Amazon, https://amazon.care/about (Accessed 3/9/21).
13 *Ibid.*
14 *Ibid.*
15 "Amazon Expands In-Home Care Program" By Robert Holly, Home Health Care News, September 23, 2020, https://homehealthcarenews.com/2020/09/amazon-expands-in-home-care-program/ (Accessed 3/9/21).
16 "Amazon Care's health provider has quietly filed paperwork to operate in 17 more states" By Erin Brodwin, STAT News, March 3, 2021, https://www.statnews.com/2021/03/03/amazon-care-medical-telemedicine-platform/ (Accessed 3/9/21).
17 "Amazon jumps into healthcare with telemedicine initiative" Modern healthcare, March 17, 2021, https://www.modernhealthcare.com/information-technology/amazon-jumps-healthcare-telemedicine-initiative (Accessed 3/23/21).
18 *Ibid.*
19 Brodwin, March 3, 2021.
20 Modern healthcare, March 17, 2021.
21 Brodwin, March 3, 2021.
22 "Haven, the Amazon-Berkshire-JPMorgan venture to disrupt health care, is disbanding after 3 years" By Hugh Son, CNBC, January 4, 2021, https://www.cnbc.com/2021/01/04/haven-

the-amazon-berkshire-jpmorgan-venture-to-disrupt-healthcare-is-disbanding-after-3-years.html (Accessed 3/9/21).

23 *Ibid.*

24 *Ibid.*

25 "Amazon Joins Home-Based Care Providers to Advocate for Better Health Care Policy" By Andrew Donlan, Home Health Care News, March 3, 2021, https://homehealthcarenews.com/2021/03/amazon-joins-home-based-care-providers-to-advocate-for-better-health-care-policy/ (Accessed 3/9/21).

26 *Ibid.*

27 Budget neutrality is the law that any changes made to relative value units (RVUs) must not add up to an increase or decrease in expenditures for physicians' services overall by more than $20 million. Thereby, increases for RVUs for a given service must be offset by decreases for other services, and vice versa.
"Medicare Physician Payment Formula Primer" American Academy of Orthopaedic Surgeons, https://www5.aaos.org/CustomTemplates/Content.aspx?id=22519&ssopc=1 (Accessed 3/23/21).

28 "Policy Priorities" Moving Health Home, https://movinghealthhome.org/policy-priorities/ (Accessed 3/9/21).

29 *Ibid*; "Intermountain, Ascension push for permanent CMS home care reimbursement changes" By Lisa Gillespie, Modern Healthcare, March 3, 2021, https://www.modernhealthcare.com/home-health/intermountain-ascension-push-permanent-cms-home-care-reimbursement-changes (Accessed 3/9/21).

30 *Ibid.*

31 For more information on telemedicine reimbursement before, during, and after the COVID-19 pandemic, see the October 2020 Health Capital Topics article entitled, "Valuation of Telemedicine: Reimbursement" Vol. 13, Issue 10 (October 2020), https://www.healthcapital.com/hcc/newsletter/10_20/HTML/TELE/convert_telemedicine_reimbursement_10.26.20.php (Accessed 3/9/21); "Intermountain, Ascension push for permanent CMS home care reimbursement changes" By Lisa Gillespie, Modern Healthcare, March 3, 2021, https://www.modernhealthcare.com/home-health/intermountain-ascension-push-permanent-cms-home-care-reimbursement-changes (Accessed 3/9/21).

32 "AMAZON CARE EXPANSION POSITIONS COMPANY TO BECOME SIGNIFICANT HEALTHCARE PLAYER" By Mandy Roth, HealthLeaders, March 17, 2021, https://www.healthleadersmedia.com/telehealth/amazon-care-expansion-positions-company-become-significant-healthcare-player (Accessed 3/23/21).

33 *Ibid.*

34 *Ibid.*

35 *Ibid.*

36 *Ibid.*

Walmart's "Super Center" Healthcare

[Excerpted from the article published in June 2021.]

Walmart, the world's largest retailer,[1] opened the first Walmart Health in 2019 with the main goal of helping to meet the healthcare needs of the communities they serve.[2] After opening six locations in almost two years, Walmart is looking to operate a total of 22 standalone clinics by the end of 2021.[3] This *Health Capital Topics* article will review Walmart Health's approach to delivering primary care, the communities into which it is expanding, partnerships it is developing in the healthcare sector, and the competitive landscape in which it operates.

Delivery of Care

Walmart believes that it can successfully deliver affordable healthcare because of the size and sheer number of stores it is already operating. Currently, 90% of Americans are estimated to live within 10 miles of a Walmart location.[4] The retail behemoth is creating "super centers" to aggregate key healthcare services under one roof and provide these services at affordable, transparent prices regardless of insurance status.[5] Walmart is currently rolling out these super centers in smaller communities, where their location already fulfills the everyday needs of residents, from grocery shopping to car repairs.[6] Now, Walmart visitors in certain Georgia and Arkansas locations can get their teeth cleaned for $25, talk with a counselor for $1 per minute, and/or get a medical checkup for $30 (for employees, this price drops even lower, to $4).[7] Additionally, Walmart Health's super centers offer primary and urgent care; x-rays and diagnostics; counseling; and, dental, optical, and hearing services, with flexible hours that serve both walk-ins and appointments throughout the day and evening, as well as on weekends.[8]

Walmart customers have responded favorably to the affordability and convenience of Walmart Health.[9] Walmart Health locations have seen a continual increase not only in first-time patient visits, but also in returning patients. Walmart is starting to see a shift in patient visits, from one-time appointments to routine visits for primary care and chronic care management services.[10] After approximately one year of operations, returning patients have made up over 50% of Walmart Health's booked visits.[11] With their current $36 billion health and wellness business, opening more full-service health centers to serve its 150 million weekly customers could propel a profitable market.[12] In response to the COVID-19 pandemic, Walmart had to quickly pivot from offering services strictly in their brick-and-mortar locations to offering telehealth services. Before the pandemic, telehealth visit prices had dropped from $40 to $4 for employees, but at the height of COVID-19, telehealth visits were free to those on Walmart's health insurance plan.[13]

Partnerships

Walmart has been able to provide its telehealth services through its numerous partnerships with telehealth companies. First, Walmart is expected to close on its acquisition of MeMD (announced May 2021) in the next few months.[14] By acquiring the 24/7 telehealth service, Walmart Health can begin providing virtual care services for urgent, primary, and behavioral healthcare to complement the in-person services at its super centers.[15] Subsequent to its acquisition announcement, Walmart expressed further interest in telehealth by filing the paperwork to expand virtual care in 16 additional states.[16] Walmart is currently registered through its primary care group, MC Medical, to operate in: Alaska, Delaware, Hawaii, Kentucky, Mississippi, Missouri, New Hampshire, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, and Washington.[17] Walmart also established a partnership with Doctor on Demand, which provides a platform for virtual visits to Walmart employees and will cost patients $4 per visit.[18] Finally, Walmart is partnering with Ro, a telehealth app for pharmacy services that produces health products, such as vitamins and supplements, and provides digital distribution services for over 4,000 Walmart stores around the country.[19]

Communities Walmart Serves

As stated above, Walmart currently has six standalone clinics – five scattered throughout Georgia and one in Springdale, Arkansas.[20] In 2021, the company is looking to expand by opening seven more locations in Georgia, two in Chicago, and seven in the northern Florida market; they have also begun talks regarding the establishment of additional clinics in Tampa and Orlando.[21] In recognition of these clinics' success, their board of directors approved a plan to open 4,000 clinics by 2029.[22]

Walmart's ambitious openings are fueled by the needs of their customers. President of Walmart Health and Wellness, Sean Solvenski, claimed that Walmart already has the volume and locations to support that expansion.[23] They are not tapping into healthcare to increase foot traffic or sales; rather, this is a serious solution to Walmart customers' healthcare access and affordability issues, especially in rural towns.[24] In less populated areas, Walmart may be the only access point for primary care because these towns have trouble obtaining resources for hospitals and finding physicians to work there.[25] Further, rural Americans tend to be less healthy, with higher blood pressure, higher rates of cigarette smoking and obesity, and less physical activity.[26] Combined with higher rates of poverty, rural residents have major gaps in their healthcare that need to be addressed.[27] Walmart is applying their strategic skills honed in the retail space to address those gaps in healthcare through their super centers.[28]

Competitors

Walmart's most recent opening in Dallas, GA occurred around the same time as CVS Health and Walgreens Boots Alliance pushed into the outpatient healthcare service space.[29] While CVS and Walgreens may not be direct competitors to Walmart, all are part of a larger trend of corporate big box

retailers offering health plans to a larger scope of individuals than just their employees. CVS's major concept to promote access within its stores is called HealthHUB, which aims to provide a scope of services in primary care and management of chronic conditions.[30] By the end of 2021, their goal is to expand to 1,500 HealthHUB clinics in major cities such as Houston, Atlanta, Philadelphia, and Tampa, as well as in southern New Jersey.[31] Walgreens, on the other hand, is looking to expand into primary care across the country through their partnerships with Humana operating senior clinics as well as with UnitedHealth's MedExpress urgent care centers, which will connect to a Walgreens store.[32]

Walmart's biggest direct competitor in the healthcare market is Amazon. Besides using Amazon Alexa devices to help with administrative tasks, such as checking patients in to overwhelmed hospitals during the COVID-19 pandemic,[33] Amazon has also opened up delivery of care to its employees (and non-employees) through Amazon Care. The service is a combination of virtual and in-person care, offering home health services, telehealth appointments, and prescription delivery.[34] Employees are encouraged to use the Amazon-created telehealth smartphone application for non-urgent issues such as: colds and minor injuries; preventative health consults and vaccines; sexual health services; and, general health questions.[35] However, Walmart has the upper hand with established physical (and convenient) locations across the nation. Meanwhile, Amazon has the advantage in digital health, virtual care, and an overall more sophisticated delivery strategy.

Conclusion

Retail giants such as Walmart and Amazon are establishing their stronghold in healthcare by stepping into the realm of delivering their own care and applying their own models of operation. With the

ir interest in healthcare ramping up, the next decade could see massive shifts in delivery and how patients pay for care (and cause healthcare to become significantly more consumer driven).[36] Walmart is using both its brick-and-mortar locations and telehealth technology to increase access to higher quality, more affordable, and more price transparent primary, preventative, and urgent care services.

1 "Who Are The 10 Biggest Retailers In the World?" By Cally Russell, Forbes, January 9, 2020, https://www.forbes.com/sites/callyrussell/2020/01/09/who-are-the-10-biggest-retailers-in-the-world/?sh=227721473802, (Accessed 5/20/21).

2 "One Year in, Walmart Health is delivering Affordable Healthcare – And Expanding" By Lori Flees, SVP and COO, Walmart U.S. Health & Wellness, September 17, 2020, https://corporate.walmart.com/newsroom/2020/09/17/one-year-in-walmart-health-is-delivering-affordable-healthcare-and-expanding (Accessed 5/18/21).

3 *Ibid*.

4 "9 numbers that show how big Walmart's role in healthcare is" By Jackie Drees, Becker's Hospital Review, May 12, 2021 https://www.beckershospitalreview.com/consumerism/9-numbers-that-show-how-big-walmart-s-role-in-healthcare-is.html (Accessed 5/18/21).

5 "Walmart's First Healthcare Services 'Super Center' Opens" By Bruce Japsen, Forbes, September 13, 2019, https://www.forbes.com/sites/brucejapsen/2019/09/13/walmarts-first-healthcare-services-super-center-opens/?sh=4ed7041579d2 (Accessed 5/20/21).
6 "Checkup for $30, Teeth Cleaning for $25: Walmart Gets Into Health Care" By Matthew Boyle, Bloomberg, February 25, 2020, https://www.bloomberg.com/news/articles/2020-02-25/walmart-takes-on-cvs-amazon-with-low-price-health-care-clinics (Accessed 5/20/21).
7 *Ibid*; "Walmart to bring telehealth nationwide with acquisition of MeMD: 8 details" By Jackie Drees and Hannah Mitchell, Becker's Hospital Review, May 6, 2021 https://www.beckershospitalreview.com/telehealth/walmart-health-to-acquire-telehealth-provider-6-details.html?origin=BHRE&utm_source=BHRE&utm_medium=email&utm_content=newsletter&oly_enc_id=9207F7402078E2D (Accessed 5/20/21).
8 Flees, September 17, 2020.
9 *Ibid*.
10 *Ibid*.
11 *Ibid*.
12 Boyle, February 25, 2020.
13 Drees and Mitchell, May 6, 2021.
14 *Ibid*.
15 *Ibid*.
16 "Walmart Health files plans to expand virtual care into 16 more states" By Alia Paavola, Becker's Hospital Review, June 7, 2021 https://www.beckershospitalreview.com/strategy/walmart-health-files-plans-to-expand-virtual-care-into-16-more-states.html?origin=BHRE&utm_source=BHRE&utm_medium=email&utm_content=newsletter&oly_enc_id=9207F7402078E2, (Accessed 6/7/21).
17 *Ibid*.
18 Drees and Mitchell, May 6, 2021.
19 *Ibid*.
20 Flees, September 17, 2020.
21 *Ibid*.
22 Drees, May 12, 2021.
23 Japsen, September 13, 2019.
24 *Ibid*.
25 "If You Build It: Rural hospitals are closing, but those who remain are reshaping and innovating" By Elizabeth Dougherty, Harvard Magazine, June, 19, 2017, https://hms.harvard.edu/magazine/rural-health/if-you-build (Accessed 5/20/21).
26 "About Rural Health" Centers for Disease Control and Preventions, August, 2, 2017, https://www.cdc.gov/ruralhealth/about.html#:~:text=Rural%20residents%20report%20less%20leisure,lead%20to%20poor%20health%20outcomes. (Accessed 5/21/21).
27 *Ibid*.
28 Dougherty, June, 19, 2017.
29 Japsen, September 13, 2019.
30 "CVS HealthHUB" https://www.cvs.com/content/health-hub (Accessed 5/20/21).
31 "CVS Health announces significant expansion of HealthHUB to deliver a differentiated consumer health experience" CVS.com, June 4, 2019, https://cvshealth.com/news-and-insights/articles/cvs-health-announces-significant-expansion-of-healthhub-to-deliver-a (Accessed 5/20/21).
32 Japsen, September 13, 2019.
33 "'Alexa, Can You Improve Healthcare?' – Rachel Jiang, Head of Alexa Health & Wellness" Episode 98, Raise the Line Podcast, Osmosis, December 30, 2020, https://www.osmosis.org/raisethelinepodcast/giving-voice-to-health-concerns-rachael-jiang-head-of-alexa-health-wellness (Accessed 3/9/21); "Amazon's New Moves in Healthcare, Health Capital Topics, March 2021, Volume 14, Issue 3.
34 "Amazon Care" Amazon, https://amazon.care/about (Accessed 5/20/21).
35 *Ibid*.
36 "Amazon vs. Walmart in healthcare: Who's winning and what it means for ASC's" By Laura Dyrda, Becker's ASC Review, May 12, 2021, https://www.beckersasc.com/leadership/amazon-vs-walmart-in-healthcare-who-s-winning-and-what-it-means-for-ascs.html?origin=ASCE&utm_source=ASCE&utm_medium=email&utm_content=newsletter&oly_enc_id=9207F7402078E2D (Accessed 5/20/21).

VI. About
Health Capital Consultants

FIRM PROFILE

HCC HEALTH CAPITAL CONSULTANTS

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

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

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

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  - 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.

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

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LEADERSHIP

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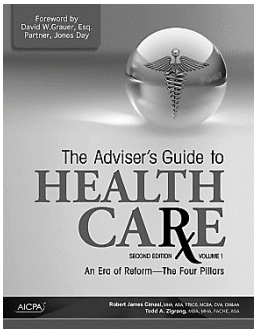

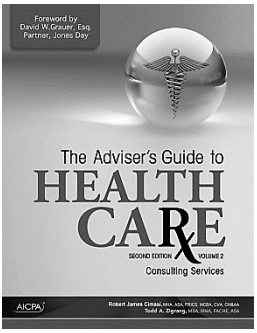

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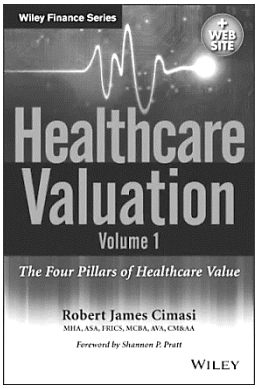

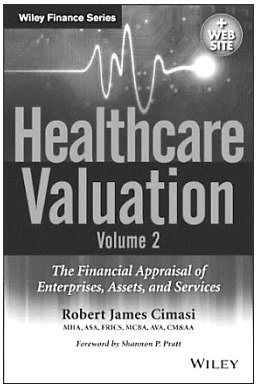

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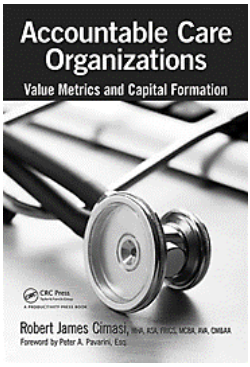

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