JOURNAL OF HEALTH CARE FINANCE

Spring 2021

When Telehealth went Viral: How the COVID-19 Pandemic Influenced the Rapid Move to Virtual Medical Treatment, and What Non-Rural Providers Not Treating COVID-19 Patients Should Do About It

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When Telehealth went Viral: How the COVID-19 Pandemic Influenced the Rapid Move to Virtual Medical Treatment, and What Non-Rural Providers Not Treating COVID-19 Patients Should Do About It

I. Introduction:

"COVID-19 has changed the way we view medicine and we're not going to go back," Martin Schreiber, MD, chief medical officer for DaVita Kidney Care's home treatments, said during his virtual presentation at the Annual Dialysis Conference. "We just have to get better at providing telemedicine. Everyone that is part of the health care team needs to get better at it."[1] The rapid spread of the virus has forced health systems to pivot and adapt to its effects. Experts estimate that we have made 10 years of progress in the required migration to telemedicine over the first three months of the Coronavirus Disease of 2019 (COVID-19) pandemic, which was caused by an outbreak of the strain of novel beta coronavirus that began to spread in 2019[2]. In order to understand the impact of the pandemic on independent, non-rural physician practices not treating COVID-19 patients, we need to understand how each component of the response to the pandemic has directly affected these practices, including: Stay-at-home orders and the abrupt decline in patient visits due to voluntary compliance with movement restrictions *and* the forced cancellation of elective medical procedures. Also important is the distinct lack of federal funds directed to these practices – especially those who do not bill Medicare. It is essential to consider the regulatory response, which includes the prosecution of providers who do not adhere to licensing restrictions when practicing via telemedicine, and the temporary suspension of the enforcement of the Privacy and Security rules. Similarly, it is vital that practices pay attention to the increased federal funding of enforcement activities designed to pick up irregularities in billing practices regarding the provision of telemedicine services when implementing or increasing their telehealth offerings. Virtual medical care has been a life raft for these independent practices as they try to rebuild their business, but it is **essential** that they pay attention to the risks presented by the regulatory landscape in order to avoid an enforcement *coup de grace*.

II. Stay-at-home Orders Were Effective at Slowing the Spread but Created a Fiscal Cliff for Independent Physician Practices Not Treating COVID-19 Patients

a. Almost a 60 Percent Reduction in COVID Fatalities after Four Weeks.

Stay-at-home orders reduced the community spread of COVID-19 by limiting the person-to person interactions that enabled the SARS-CoV-2 virus to spread so rapidly.[3] To identify the broader impact of these stay-at-home-orders, the Centers for Disease Control and Prevention (CDC) and the Georgia Tech Research Institute used publicly accessible, anonymized location

[1] Webb, M. COVID-19 Incites 'Explosive Growth' in telehealth, but Questions Remain. Healio News. Accessed on 6 April 2021 at: https://www.healio.com/news/nephrology/20210309/covid19-incites-explosive-growth-in-telehealth-but-questions-remain#:~:text=To%20illustrate%20the%20profound%20impact,rose%20to%20more%20than%2060%25.

[2] Id.

[3] CDC, How COVID-19 Spreads. Accessed on 4 December 2020 at: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html

data from mobile devices to analyze changes in population movement relative to stay-at-home orders issued during March 1 - May 31, 2020, by all 50 states, the District of Columbia, and five U.S. territories.[4] Based on the study of this data, they found that in 97.6% of counties with mandatory stay-at-home orders, a decreased median population movement was observed after the orders were published.[5] The magnitude of such orders' effectiveness is uncertain – in the United States they were not coordinated nationally, which creates the opportunity to evaluate different state policies. In preliminary research, it appears that when compared to counties that did not implement stay-at-home orders, the orders are associated with a 30.2 percent (11.0 to 45.2) percent (31.1 to 61.7) reduction in cases after one week, a 40.0 percent (23.4 to 53.0) reduction after two weeks, and that this correlates with a 59.8 percent (18.3 to 80.2) reduction in weekly fatalities after three weeks.[6] These results suggest that stay-at-home orders reduced confirmed cases by 390,000 and, consequently, fatalities by 41,000 within the first three weeks in localities where they were implemented.[7]

b. Practices Trying to Make Perfect

There is no doubt that as the COVID-19 death toll increases, so does the public's concern for individual wellbeing. People immediately avoided contact in public situations, and many avoided medical offices for fear that they may contract the virus from sick people seeking care. Hospitals across the United States even suspended elective procedures in response to 36 state mandates related to an uptick in the hospitalization of COIVD-19 patients.[8] Independent physician practices not treating COVID-19 patients suspended business under mandatory closure orders: Yet as their revenue decreases, overhead remains the same, threatening the financial viability of the U.S. health system's private practice infrastructure as providers scrambled to reopen, and, for some, to keep their doors open. This struggle was not only due to financial constraints, but also in consideration of the likelihood of COVID-19 exposures and required protocol.[9] Despite coordinating operations with government guidance, practices have had to furlough up to 75 percent of staff. According to the California Medical Association, where about half of the medical care is delivered by small practice physicians, a member survey revealed that 50 percent of doctors have had to lay off employees and 11 percent closed down temporarily.[10] It is estimated that as much as 8 percent of all physician practices nationally (almost 16,000)

[4] CDC, Timing of State and Territorial COVID-19 Stay-at-Home Orders and Changes in Population Movement — United States, March 1–May 31, 2020. Accessed 4 December 2020 at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6935a2.htm

[5] Id.

[6] Fowler, J. et al. "The Effect of Stay-at-Home Orders on COVID-19 Cases and Fatalities in the United States." Accessed on 10 March 2021 at: https://www.medrxiv.org/content/10.1101/2020.04.13.20063628v3

[7] Id.

[8] Paavola, A. 116+ Hospitals Postponing Elective Surgeries Broken Down by State. Accessed on 10 March 2021 at: https://www.beckershospitalreview.com/patient-flow/110-hospitals-postponing-elective-surgeries-by-state.html

[9] Robeznieks, A. "Physician Survey Details Depth of Pandemic's Financial Impact." Accessed 10 March 2021 at: https://www.ama-assn.org/practice-management/sustainability/physician-survey-details-depth-pandemic-s-financial-impact

[10] Dembosky, A. "Doctors Offices Are Small Businesses Too. And They're Struggling to Stay Afloat During the Pandemic." Accessed 10 March 2021 at: https://www.kqed.org/news/11812402/doctors-offices-are-small-businesses-too-and-theyre-struggling-to-stay-afloat-during-the-pandemic

have closed under the stress of the pandemic.[11] Even as practices re-opened, reduced capacity and other restrictions on operations coupled with COVID-19 exposures created new challenges.

Despite many states' easing of stay-at-home orders and associated restrictions, physicians report that business is still well below pre-pandemic levels and that it is expected to stay that way, at least as long as social distancing is recommended.[12] For physician practices who do not treat COVID-19 patients, the move to telehealth has in some ways stemmed the tide, with one provider estimating that as many as 40% of patient visits *could* be handled via telemedicine, but commenting that many practices are reluctant to commit the necessary resources because it is unclear whether they'll continue to be reimbursed for telemedicine visits after the pandemic ends.[13] Even if reimbursement continues, it is unclear whether they will be paid at the current rate. The government's commitment to practices who do not treat COVID-19 patients is in question as physician practices have joined the American Hospital Association in asking the federal government to pass a payroll tax cut to support practice viability for the duration of the national Public Health Emergency (PHE) in a March 18, 2021 letter.[14] Despite the declaration that the United States has fallen into a recession on March 19, 2021,[15] the letter did not result in any action by the government.

III. Independent Physician Practices Not Treating COVID-19 Patients Excluded from Initial Federal Aid

a. Water, Water Everywhere, but Not a Drop to Drink

Very little of the $2 trillion in The Coronavirus Aid, Relief, and Economic Security Act (CARES) relief funds is currently earmarked for independent physician practices who are not treating COVID-19 patients:[16] [17]

The Provider Relief Fund (PRF) provides phased general distribution payments from a $175 billion fund to physician practices in proportion to their share of Medicare fee-for-service reimbursements from 2018 and part of 2019:[18]

i. Phase 1 saw distribution of payments from an initial $30 billion to 320,000 providers from April 10 – April 17, 2020.[19] Another $20 billion was made

[11] Ungar, L. "Thousands of Doctor's Offices Buckle Under Financial Stress of COVID." Accessed 10 March 2021 at: https://khn.org/news/thousands-of-primary-care-practices-close-financial-stress-of-covid/

[12] Rubin, R. "COVID-19's Crushing Effects on Medical Practices, Some of Which Might Not Survive." Accessed on 10 March 2021 at: https://jamanetwork.com/journals/jama/fullarticle/2767633

[13] Id.

[14] LaPointe, J. "Providers Ask Congress for Financial Assistance to Combat COVID-19." Accessed 10 March 2021 at: https://revcycleintelligence.com/news/providers-ask-congress-for-financial-assistance-to-combat-covid-19

[15] CNBC: Bank of America says the recession is already here – jobs will be lost, wealth will be destroyed. Accessed on April 15 at: https://www.cnbc.com/2020/03/19/bank-of-america-says-the-recession-is-already-here-jobs-will-be-lost-wealth-will-be-destroyed.html

[16] Seefield, M. "Seize the data: How physician practices survived COVID-19 by leveraging financial forecasting." MGMA. Accessed on 13 May 2020 at: https://www.mgma.com/resources/financial-management/seize-the-data-how-physician-practices-survive-co

[17] Mulvany, C. "Key hospital provisions and some questions requiring resolution from the CARES Act." HFMA. Accessed on 13 May 2020 at: https://www.hfma.org/topics/payment-reimbursement-and-managed-care/article/key-hospital-provisions-and-some-questions-requiring-resolution-.html

[18] American Academy of Orthopaedic Surgeons, "Public Health and Social Services Emergency Fund – provider Relief Fund. Accessed on 15 March 2021 at: https://www.aaos.org/about/covid-19-information-for-our-members/practice-management-and-telehealth-resources/provider-relief-fund/

available with the same qualifications between April 24 – June 9, 2020: $9.1 billion went to 15,000 providers based on revenues from the Center for Medicare and Medicaid Services (CMS) cost report data, and an additional $10.9 billion went to providers based on revenue submissions to the provider portal.[20]

ii. By October 22, 2020, Phase 2 made $18 billion available to providers participating in Medicaid and Children's Health Insurance Program (CHIP) who had not received Phase 1 distributions, Medicaid managed care plans, dentists, and Medicare Part A providers who had a change in ownership in 2019 or 2020.[21] This made a broader category of providers eligible for PRF payments, but still excluded providers who did not bill Medicaid/Medicare/CHIP and those who work in group settings without an ownership interest.

iii. In Phase 3, providers who have already received PRF payments were invited to apply for additional funding that considers financial losses and changes in operating expenses caused by the pandemic and ensures that they have received the full 2 percent of revenue from patient care either as part of the previous phases or as a Phase 3 payment. [22]

iv. A separate, targeted distribution - not part of the phase plan, occurred on June 9, 2020 when the Department of Health and Human Services (HHS) announced that $15 billion would be available to Medicaid providers who billed state Medicaid and CHIP providers who had not received any general distribution from the PRF. This distribution was equal to 2 percent of a provider's gross revenue from Medicaid and CHIP patient care.

v. There were additional, more targeted distributions of PRF payments to hospitals, assisted living facilities, facilities that experienced a disproportionate intensity of COVID admissions, and providers on the frontlines of the pandemic.[23] These did not impact physician practices not treating COVID-19 patients and so they are not discussed here.

Notably, providers *who did not* bill their state Medicaid or CHIP programs or Medicaid Managed care plans for health-care related services between January 1, 2018 and March 31, 2020 *did not qualify* for general distributions from the PRF.[24] Additionally, providers who have ceased providing patient care are not eligible for any distributions despite losses and outstanding debt.[25]

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[19] HHS Press Office, "CARES ACT Provider Relief Fund: General Information." Accessed on 15 March 2021 at: https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/general-information/index.html#phase2

[20] Id.

[21] Id.

[22] HHS Press Office, "CARES ACT Provider Relief Fund: General Information." Accessed on 15 March 2021 at: https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/general-information/index.html#phase2

[23] HHS Press Office, "CARES ACT Provider Relief Fund: General Information." Accessed on 15 March 2021 at: https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/general-information/index.html#phase2

[24] HHS Press Office, "HHS to Begin Immediate Delivery of Initial $30 Billion of CARES Act Provider Relief Funding." Accessed on 15 March 2021 at: https://www.hhs.gov/about/news/2020/04/10/hhs-to-begin-immediate-delivery-of-initial-30-billion-of-cares-act-provider-relief-funding.html

[25] HHS Press Office, "General Distribution Frequently Asked Questions." Accessed on 15 March 2021 at: https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/faqs/general-distribution/index.html#phase3

In examining the potential payment that a practice may receive from any of these phases, consider the following summary of eligibility:
We consider the case of two practices, Theoretical Practice 1,(T1) with a $50,000 fee-for-service 2019 Medicare reimbursement and 2019 annual gross receipts of $120,000, and Theoretical Practice 2,(T2) having $2,000,000 in 2019 Medicare reimbursement and $3,000,200 in 2019 annual gross receipts, and 95 percent of this revenue is earned from patient care. These practices have incurred an estimated loss of $80,000 and $600,000, respectively, in the first half of 2020 that is attributable to the pandemic. While they would not be eligible for payments from **both** Phase 1 and 2, they may have qualified for 1 **or** 2, **and** 3 (with the targeted distribution discussed above being supplemented or replaced by Phase 3). The possible payments are summarized in Figure 1, overleaf:

Figure 1: Eligibility for Provider Relief Fund Payments[26] and` Payment Methodology[27]

Phase 1 General Distribution		
Distribution and Eligibility	Formulas to Determine Allocation	
Initial $30 billion	Payment allocation per Provider:	
Automatic based on provider's share of Medicare fee-for-service reimbursements in 2019	(Provider's 2019 Medicare fee-for-service payments/$453 billion) x $30 billion	
Theoretical Practice 1 ($50,000 FFS)	$ 3,099	
Theoretical Practice 2 ($2,000,000 FFS)	$ 123,966	
Phase 1, Additional $20 billion	Payment allocation per Provider:	
Based on CMS cost reports	((Most recent tax year annual gross receipts x $50 billion) / $2.5 trillion) - Initial General Distribution Payment to Provider	
	With Phase 1 initial payment	**Without**
Theoretical Practice 1 ($50,000 FFS)	$ (699)	$ 2,400
Theoretical Practice 2 ($2,000,000 FFS)	$ (63,962)	$ 60,004
Phase 2 General Distribution		
Distribution and Eligibility	Formulas to Determine Allocation	
$18 billion	Payment allocation per Provider:	
Providers who participate in state Medicaid/CHIP programs, Medicaid managed care plans, or provide dental care, as well as certain Medicare providers, including those who missed Phase 1 general distribution payment equal to 2% of their total patient case revenue or had a change in ownership	2%(Revenues x percent of revenues from patient care)* *Most recent tax filings (2017, 2018, or 2019	
Theoretical Practice 1 ($50,000 FFS)	$ 2,280	
Theoretical Practice 2 ($2,000,000 FFS)	$ 57,004	
Phase 3		
Distribution and Eligibility	Formulas to Determine Allocation	
Providers who have already received PRF payments may apply for consideration, must have billed state Medicaid/CHIP programs or Medicaid managed care plans between January 1, 2018 and March 31, 2020, or be a Medicare Part A provider that experienced a change in ownership who billed Medicare fee-for-service between January 1, 2019 and March 31, 2020.	Providers will be paid the greater of up to 88 percent of their reported losses (both lost revenue and health care-related expenses attributable to coronavirus incurred during the first half of 2020), or 2 percent of annual revenue from patient care.	
Theoretical Practice 1 ($50,000 FFS)	$ 70,400	
Theoretical Practice 2 ($2,000,000 FFS)	$ 528,000	

[26] [26] HHS Press Office, "HHS to Begin Immediate Delivery of Initial $30 Billion of CARES Act Provider Relief Funding."

[27] HHS Press Office, "CARES ACT Provider Relief Fund: General Information." Accessed on 15 March 2021 at: https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/general-information/index.html#phase2

Simply put, T1 would either receive a Phase 1 payment of $3,099 or $2,400 depending on whether the payment was based on data in the CMS cost report or self-submitted through the provider portal. T2 would receive either $123,966 or $60,004 under the same conditions. Had neither practice qualified for payments in Phase 1, they may have qualified under Phase 2, in which case the payment would have been either $2,280 for T1 or $57,004 for T2. Since both practices had qualified losses in the first half of 2020, they could have applied for an additional payment under Phase 3. The largest payment T1 would have been eligible for is approximately $67,301. The largest payment T2 would have been eligible for is approximately $404,034. These payments are subject to pro-rata reduction, which depends on the number of claims received.

These payments are not large enough to mitigate the impact of the pandemic on independent physician practices not treating COVID-19 patients: The calculation considers only losses from the first six months of the pandemic and completely excludes independent practices who do not bill Medicare/CHIP. Although the Phase 2 and 3 distributions increase benefit payments for practices with a smaller Medicare patient population, they still do not benefit practices who do not bill Medicare/CHIP, and their calculation does not include an offset for the second six months of 2020. In a letter to the Senate leadership on February 25, 2021, when the House was expected to consider the $1.9 trillion relief package, a collection of healthcare providers stated that the $178 billion PRF has not been enough to help their practices, and asked for more funding for the PRF, "To date, the bulk of this funding has either been distributed or allocated for payments to account for losses incurred into the first quarter of this year – However, we anticipate financial challenges will persist."[28] The fiscal cliff persists: In a recent survey, the American Medical Association reported that physicians averaged a 32% drop in revenue since February 2020. One in five doctors saw revenue drop by 50% or more, one-third saw declines of between 25% and 49%. Only 19% of physicians reported no drop in revenue. [29]

On March 11, 2021, President Joe Biden signed H.R. 1319, the American Rescue Plan Act of 2021 (ARP), into law. It did not include any additional funding for the PRF or loan forgiveness for accelerated payments under Medicare.[30] It did, however, include $8.5 billion to reimburse *rural* healthcare providers for expenses and lost revenues attributable to COVID-19.[31] It also includes $5 million in funding for the HHS OIG for PRF oversight activities.[32] In February 2021, the U.S. Department of Justice (DOJ) announced its first PRF-related criminal indictment,

[28] American Hospital Association, "AHA, Other Health Organizations Urge Senate to Include Provider Relief Funding in Reconciliation Package." Accessed on 20 March 2021 at: https://www.aha.org/system/files/media/file/2021/02/aha-health-orgs-urge-senate-include-provider-relief-funding-in-reconciliation-package-2-24-21.pdf

[29] The American Medical Association, "COVID-19 Financial Impact on Physician Practices." Accessed on 20 March 2021 at: https://www.ama-assn.org/practice-management/sustainability/covid-19-financial-impact-physician-practices

[30] Morgan Lewis, "The American Rescue Plan Act and Healthcare Providers – a First Look." Accessed on 20 March 2021 at: https://www.morganlewis.com/pubs/2021/03/the-american-rescue-plan-act-and-healthcare-providers-a-first-look-first100

[31] LaPointe, J. "Providers Blast Medicare Spending Cuts in COVID Relief Package." Accessed on 20 March 2021 at: https://revcycleintelligence.com/news/providers-blast-medicare-spending-cuts-in-covid-relief-package

[32] Dine, E. McGuireWoods LLP. "American Rescue Plan Funds OIG's Provider Relief Fund Oversight." JD Supra. Accessed on 2- March 2021 at: https://www.jdsupra.com/legalnews/american-rescue-plan-funds-oig-s-7976856/

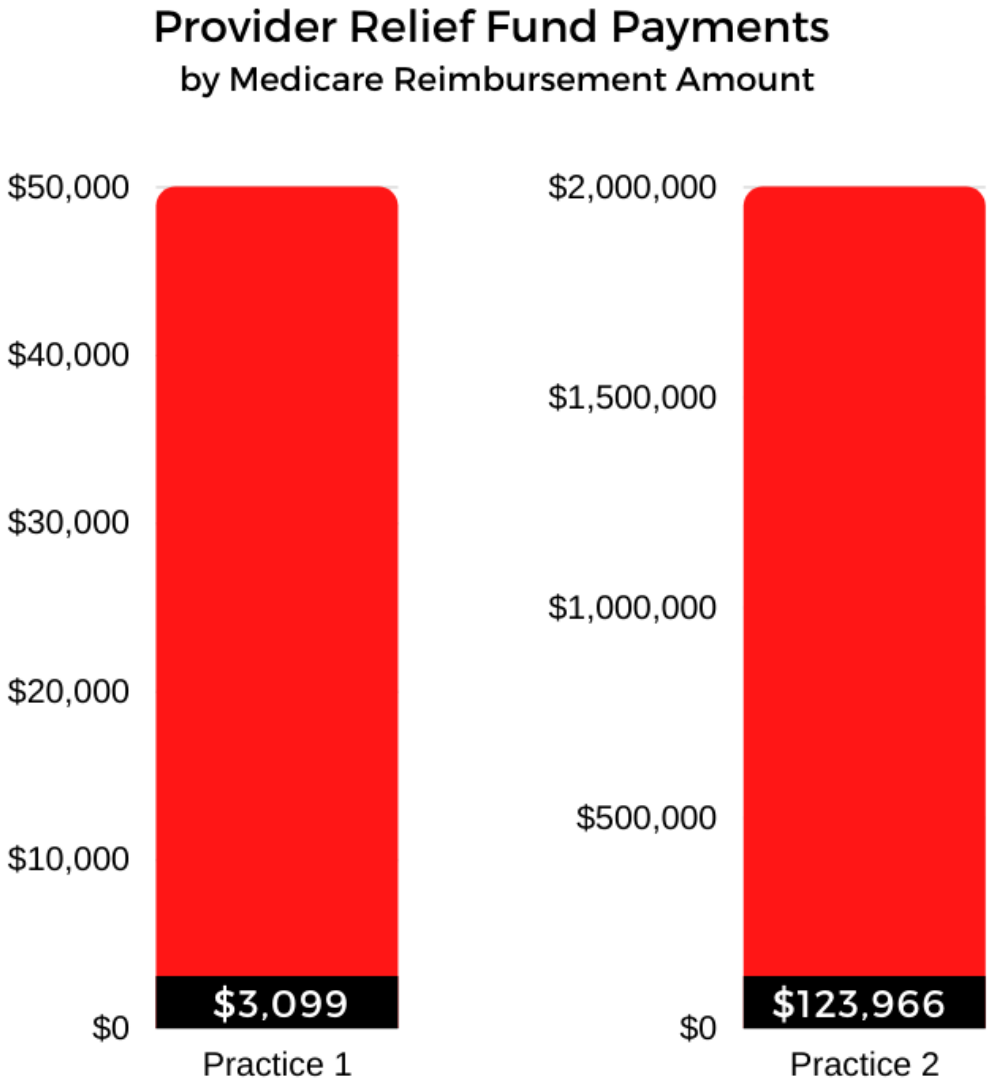
for a home health service that closed and was never operational during the pandemic. The DOJ maintains that the provider kept the funds and used them for personal gain.[33] The ARP also includes a significant amount of funding for vaccine manufacture and distribution, for the enhanced use of the Defense Production Act for the production of Personal Protective Equipment and COVID-19 tests, and for related genomic sequencing and surveillance.[34] The largest allocation of public health focused funding was $47.8 billion, directed to HHS for testing, contact tracing, surveillance, and other COVID-19 mitigation activities.

Even for those providers who do bill Medicare, more than two-thirds report that 2019 Medicare payments will not cover the cost of delivering care to beneficiaries.[35] For these practices, the initial PRF payments would help to balance this deficit – but not enough to meaningfully supplement lost income from the pandemic. The ARP recognizes the enormity of the deficit experienced by rural providers and makes provisions to reimburse them for their COVID-19-related losses but is silent when it comes to non-rural providers, and also towards those who do not bill Medicare.

Recall that under the CARES Act, T1, receiving a $50,000 fee-for-service Medicare reimbursement is entitled to a once-off $3,099 grant payment.[36] T2's $2,000,000 in Medicare reimbursement generates just $123,966.[37] This means Phase 1 of the Provider Relief Fund offers a single rebate of about 16 percent, as seen in Figure 2, below. This is less than a third of the average decline in revenue for these practices (55%).[38]

[33] Fry, T. et al. The FCA Insider, "First Provider Relief Fund Indictment." Accessed on 20 March 2021 at: https://www.thefcainsider.com/2021/02/first-provider-relief-fund-indictment/
[34] H.R. 1319, American Rescue Plan Act of of 2021. Subtitle D – Public Health. Accessed on 20 March 2021 at: https://www.congress.gov/bill/117th-congress/house-bill/1319/text#H5CEDB6383B4E47EE8F72C8ACBB05AF8F
[35] Voytal, D, and Gelburd, M. "Medicare reimbursement falls short of care delivery costs." Accessed on 26 May 2020 at: https://www.mgma.com/data/data-stories/2019-medicare-reimbursement-rates
[36] *See* Figure 1
[37] Id.
[38] Pecci, A. "97% of physician practices take COVID-19 financial hit." MGMA. Accessed on 13 May 2020 at: https://www.healthleadersmedia.com/finance/97-physician-practices-take-covid-19-financial-hit

Figure 2: Provider Relief Fund Payments by Medicare Reimbursement Amount.



An important consideration when receiving these funds is the recipient's certification that the payment be used to prevent, prepare for, and respond to coronavirus, or to reimburse expenses or lost revenues attributable to coronavirus[39]. The CARES Act also established the Paycheck Protection Program (which allows businesses to apply for a loan of 250% of payroll costs for

[39] Department of Health and Human Services Acceptance of Terms and Conditions, Relief Fund Payment from Initial $30 Billion General Distribution Terms and Conditions." Accessed on 26 May 2020 at: https://www.hhs.gov/sites/default/files/terms-and-conditions-provider-relief-30-b.pdf

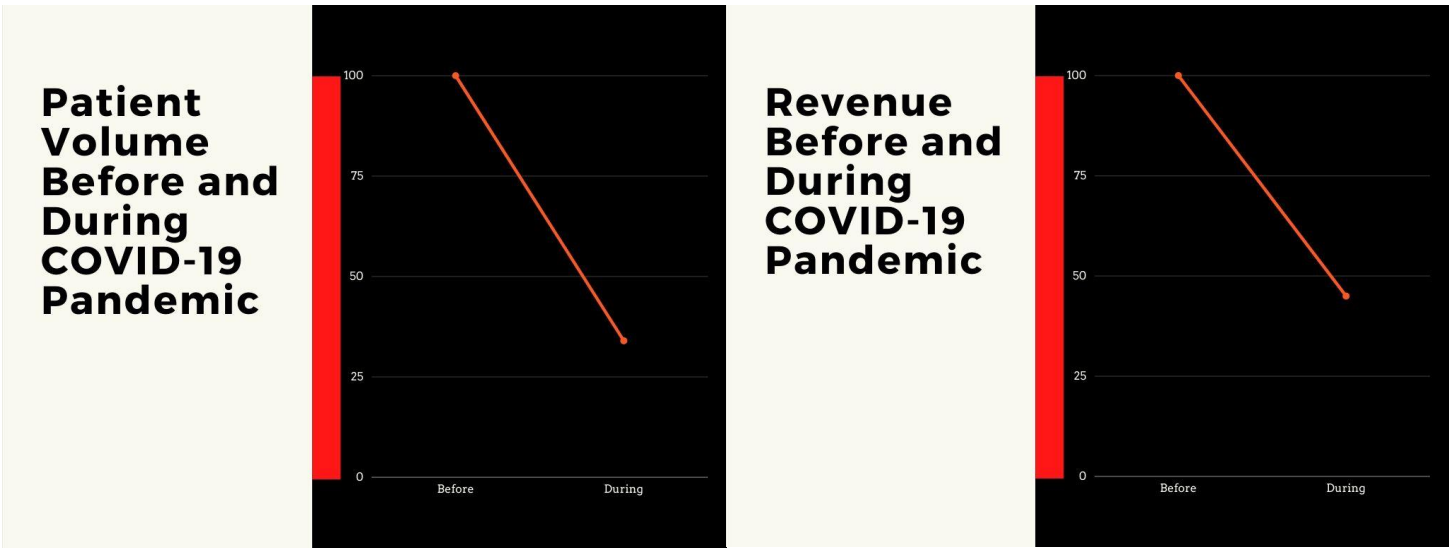
eight weeks),[40] and the Main Street Lending Program (which provides low-interest loans with more flexible repayment options).[41] These programs both require that applications for funding be made *after* the offsets from the Provider Relief Fund and that the applications do not contain duplicate expenses:

> "Payments from the Provider Relief Fund may not be used for expenses or losses that have been reimbursed from other sources, or that other sources are obligated to reimburse. Even if qualified expenses are eligible for reimbursement from another mechanism, an entity may still apply for funding from the Provider Relief Fund while simultaneously applying for funding from other sources. However, should the entity subsequently receive reimbursement for expenses from any other source after receiving funding for the same expenses from the Provider Relief Fund, the entity will be required to repay the funding it received from the Provider Relief Fund."

The staggered phases of the PRF make this process cumbersome, and miscalculating eligibility is punishable under the federal False Claims Act.

Due to the significant and lasting effects of the Coronavirus on independent physician practices, additional funding is necessary to prevent degradation of medical services. The narrow application of the PRF and the fact that the reimbursement makes up less than a third of the average loss for physicians not treating COVID-19 patients means that the amounts proposed so far simply are not enough to ensure that these practices remain able to provide affordable, quality care that is accessible and available.

Figure 3: Patient Volume and Revenue Before and During the COVID-19 Pandemic



[40] Paycheck Protection Program Report. Accessed on 21 March 2021 at: https://help.justworks.com/hc/en-us/articles/360041493232-Paycheck-Protection-Program-Report

[41] Federal Reserve, Main Street Lending Program. Accessed on 21 March 2021 at: https://www.federalreserve.gov/monetarypolicy/mainstreetlending.htm

Despite experiencing an average 66% decrease in patient volume and a 55% decrease in revenue[42], independent practices who do not bill Medicare will not receive *any* of the CARES Act Federal Aid designed to mitigate the impact of the pandemic on the Healthcare Industry. These funds are reserved for practices treating COVID-19 patients. This comes at a pivotal time in history for medical care, as ratings agencies Moody and Fitch have both changed their ratings for the Healthcare sectors from Stable to Negative, citing lower cash flow in 2020 compared to 2019 and revenue declines associated with widespread cancellation of elective medical treatment.[43] Even once contained, "[The] ripple and lingering effects to the economy will also drive lower cash flow. These include a reduction in the value of investment portfolios held by medical institutions and potential rising unemployment… [resulting] in the loss of health benefits.[44]"

For physician practices who are able to continue to operate in a limited capacity serving patients via telehealth, the reimbursement process during a pandemic is predictably imperfect, and there are emerging unintended consequences from the rapid modification of legislation. Private insurers' telemedicine coverage varied from payer-to-payer pre-COVID 19. In response to the pandemic, several health plans announced that they will make telehealth more widely available for a certain period of time.[45] "One problem is that insurers waived copays and other telehealth cost sharing for in-network doctors only. Another is that Blue Cross Blue Shield, Aetna, Cigna, UnitedHealthcare, and other carriers promoting telehealth have little power to change telemedicine benefits for self-insured employers whose claims they process."[46] Often, these employers eliminate telemedicine cost-sharing to save money.

IV. The Move to Telehealth

Notwithstanding the significant historical barriers and resistance to its adoption,[47] telehealth has always been a conceptually viable means to achieve the goals of the Healthcare Triple Aim: efficiency, better health outcomes, and better care.[48] Significant obstacles to the widespread implementation of telehealth include limited access to the internet (specifically in rural areas), limited access to cellphones, a lack of interoperability,[49] reluctance to adopt technology necessary to comply with the Health Insurance Portability and Accountability Act's (HIPAA) Privacy, Security, and Breach Notification Rules,[50] complex licensing requirements for medical

[42] Pecci, A. "97% of physician practices take COVID-19 financial hit." MGMA. Accessed on 13 May 2020 at: https://www.healthleadersmedia.com/finance/97-physician-practices-take-covid-19-financial-hit
[43] O'Brien, J. "Ratings agencies change healthcare outlook to negative due to coronavirus." MGMA. Accessed on 13 May 2020 at: https://www.healthleadersmedia.com/finance/ratings-agencies-change-healthcare-outlook-negative-due-coronavirus
[44] Id.
[45] Center for Connected Health Policy: COVID-18 Telehealth Coverage Policies. Accessed 26 May 2020 at: https://www.cchpca.org/resources/covid-19-telehealth-coverage-policies
[46] Hancock, J. "Telehealth will be free, no copays, they said. But angry patients are getting billed." Accessed on 26 May 2020 at: https://khn.org/news/telehealth-will-be-free-no-copays-they-said-but-angry-patients-are-getting-billed/
[47] Kruse, D., Karem, P., Shifflett, K., Vegi, L., ravi, K., and Brooks, M., "Evaluating Barriers to Adopting Telemedicine Worldwide: A Systemic Review." Journal of Telemedicine and Telecare 2018, Vol. 24(1) 4-12 P.7.
[48] Berwick, D. "The Triple Aim: Care, Health, and Cost." Health Affairs, 27, no.3 (2008) 761, 759-769.
[49] Bajowala, S. "Telemedicine Pays: Billing and Coding Update." Curr Allergy Asthma Rep. 2020; 20(10): 60
[50] Kruse, D., Karem, P., Shifflett, K., Vegi, L., ravi, K., and Brooks, M., "Evaluating Barriers to Adopting Telemedicine Worldwide: A Systemic Review." Journal of Telemedicine and Telecare 2018, Vol. 24(1) 4-12 P.8.

professionals,[51] and lack of reimbursement increasing the consequent utilization failure by providers and patients.[52] The COVID-19 pandemic eliminated many of these barriers while separately increasing the utilization rate as patients complied with mandatory stay-at-home orders.[53]

An example of how significant the regulatory shift towards telehealth has been is evident in the examination of the current state of three considerable barriers to telehealth's success: Pre-pandemic restrictions on reimbursement for Medicare services rendered over telehealth included that the visit be initiated over a real-time video medium (telephone was not acceptable), that the doctor and patient had an already established relationship, and that the call be initiated from a medical facility (not the patient's home, and in a medically underserved area). Even when all of these restrictions were met, the reimbursement rates were less than in-person visits. These restrictions made telehealth a cumbersome pursuit for patients and providers.[54]

> As a result of pressure from politicians, patients who required care, and physicians who needed to provide it, major changes in the CMS Fee-For-Service telehealth reimbursement schedule occurred.[55] Private insurance companies announced waivers of cost-share and copays for COVID-19 related treatment[56] and some waived all telehealth copays for treatment during the pandemic.[57] Particularly notable were the easing of the restrictions discussed above: For the first time, audio-only communication was covered,[58] providers were allowed to establish new patient relationships via telehealth,[59] and telehealth could be provided at sites other than established medical sites[60] (without regard to restrictions related to whether the area was medically underserved). These rapid and dramatic shifts are likely to create and reinforce a behavioral change in healthcare delivery, better oriented to serve a diverse patient base in many areas of medicine. It is unlikely that the entirety of this shift towards a relaxed regulatory approach to telehealth will survive the COVID-19 pandemic, and advocates need a broad understanding of the second and third order effects of regulations to effectively campaign for which rules should be amended.

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[51] Edmunds et. Al, "An Emergent Research and Policy Framework for Telehealth." The Journal for Electronic Health Data and Methods. Published online 2017 Mar 29. Accessed on 10 March 2021 at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5389433/

[52] Id.

[53] Mehrotra, A., "Telemedicine: What Should the Post-Pandemic Regulatory and Payment Landscape Look Like?". Accessed on 10 February 2021 at: https://www.commonwealthfund.org/publications/issue-briefs/2020/aug/telemedicine-post-pandemic-regulation

[54] Id.

[55] Id.

[56] Health Insurance Providers Respond to Coronavirus (COVID-19). Accessed 4 December 2020 at: https://www.ahip.org/health-insurance-providers-respond-to-coronavirus-covid-19/

[57] 5 Payers waiving telehealth visit costs during coronavirus pandemic. Accessed 4 December 2020 at: https://www.beckershospitalreview.com/telehealth/5-payers-waiving-telehealth-visit-costs-during-coronavirus-pandemic.html

[58] Telehealth Coverage Policies in the Time of COVID-19. Accessed on 4 December 2020 at: https://www.cchpca.org/resources/covid-19-telehealth-coverage-policies

[59] 50-state survey: Establishment of a Patient-Physician Relationship via Telemedicine. Accessed on 4 December 2020 at: https://www.ama-assn.org/system/files/2018-10/ama-chart-telemedicine-patient-physician-relationship.pdf

[60] Telehealth Coverage Policies in the Time of COVID-19. Accessed on 4 December 2020 at: https://www.cchpca.org/resources/covid-19-telehealth-coverage-policies

a. A Brief History of Telehealth: Definition and Applicability in the Time of COVID-19.

Telehealth, telemedicine, and related terms generally refer to the exchange of medical information from one site to another through electronic communication to improve a patient's health.[61] HHS defines telehealth as, "the use of electronic information and telecommunications technologies to support and promote long-distance clinical healthcare, patient and professional health-related education, and public health and health administration."[62] Technologies include videoconferencing, the internet, asynchronous imaging, streaming media, landline, and wireless communications. Using these technologies, telehealth may be provided through audio, text messaging, or video communication, among other means.[63]

Suddenly commonplace in the wake of the COVID-19 pandemic, telehealth is ideally suited to addressing fundamental challenges posed by the coronavirus[64]: Physicians can safely triage and treat patients without unnecessary exposure to the virus, and can help manage chronic illnesses or non-virus related complaints without putting otherwise healthy patients at risk of the virus.[65] As virtual care becomes the new normal, a COVID-19 patient's treatment would start at home, where she may feel the first symptoms of COVID-19 and using a screening app she returns a high risk score. The same day, a GP could order a test and use a telemedicine platform to monitor her. Typically, since symptoms remain mild to moderate until the tenth day, when she may begin to experience a marked shortness of breath, an ambulance could be prioritized to pick her up from her home. She is then isolated at the hospital with a wearable biosensor that tracks her vital signs. When she returns home, a biosensor may continue to assist doctors in monitoring her there.[66]

b. Regulatory History: Government Health Insurance Reimbursement Requirements

Medicare telehealth reimbursements are historically tightly controlled.[67] To be covered, Medicare regulated *where* the interaction originated, *who* offered the service (providers had to be licensed in the patient's state and have a valid license in the state of Medicare enrollment and patients had to be established – no new patients could be seen remotely for an initial visit), *how* it was conducted (initially only real-time, live video visits were covered - and even then, only for rural beneficiaries), and *set the rate of reimbursement*.[68] According to researchers, "Telehealth

[61] CMS. "Medicare Telemedicine Health Care Provider Fact Sheet," CMS. Accessed on 10 November 2020 at: https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet
[62] Office for Civil Rights, FAQs on Telehealth and HIPAA during the COVID-19 Nationwide Public Health Emergency, accessed on 10 February 2021 at: https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf
[63] Id.
[64] Mehrotra, A., "Telemedicine: What Should the Post-Pandemic Regulatory and Payment Landscape Look Like?". Accessed on 10 February 2021 at: https://www.commonwealthfund.org/publications/issue-briefs/2020/aug/telemedicine-post-pandemic-regulation
[65] College of Healthcare Information Management Executives, "Letter to CMS Administrator Seema Varna". Accessed on 10 February at: https://chimecentral.org/wp-content/uploads/2020/05/CHIME-Letter-to-CMS-on-COVID-19-Interim-Final-Rules.pdf
[66] Philips. Healthcare Has Made 10 Years of Progress in Just a Few Months. Here's How. Accessed on 6 April 2021 at: https://www.philips.com/a-w/about/news/archive/blogs/innovation-matters/2020/20200618-healthcare-has-made-10-years-of-progress-in-just-a-few-months-heres-how.html
[67] CMS. "2019 Physician Fee Schedule List of Telehealth Codes," CMS. Accessed on 10 November 2020 at: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html.
[68] Id.

reimbursements for office visits for evaluation and management of established patients with low complexity were 30% lower than the corresponding non-telehealth service, and reimbursements by clinical diagnosis code also tended to be lower for telehealth than non-telehealth claims."[69] CMS also regulated providers' cost sharing practices: Ordinarily, if physicians or practitioners routinely reduce or waive costs owed by Federal health care program beneficiaries, including cost sharing amounts such as coinsurance and deductibles, they would potentially implicate the Federal anti-kickback statute, the civil monetary penalty and exclusion laws related to kickbacks, and the civil monetary penalty law prohibition on inducements to beneficiaries.[70] This means that despite the lower reimbursement rates, patients were responsible for the same co-pays for covered telehealth services that they would have been if they went to see a provider in person. The cost savings were not passed on to patients.

Traditionally, the only acceptable originating site for a telehealth interaction was a medical establishment (including physician offices, hospitals, rural health clinics, Federally qualified health centers, hospitals, hospital-based renal dialysis centers, skilled nursing facilities, and community mental health centers).[71] This meant that even patients in rural areas had to travel to one of these locations to initiate the consultation or pay out of pocket for the service. Pre-pandemic this was possibly the greatest promise of telehealth: To provide medical services to people who would not otherwise be able to access care because of their remote geographic location.[72]

In consideration of the promise that telehealth has for providing care to patients in geographically dispersed areas, the Federation of State Medical Boards (FSMB) represents 70 State Medical and Osteopathic Boards. Member State Medical Boards protect the public by regulating the practice of medicine in their jurisdictions through licensure and discipline. Central to this is the establishment of education, training, and examination competencies for state licensure. They also regulate the use of telemedicine in the practice of medicine. The FSMB's model guidelines allow for the establishment of the physician-patient relationship in a telemedicine setting if the in-person standard of care is met. While 50 State Medical Boards specifically state that a physician providing telemedicine must be licensed in the state where the patient is located, the Interstate Medical Licensure Compact (IMLC), launched in 2017, has processed 1,867 and renewed 497 licenses through the compact, to date. 24 states, Guam and the District of Columbia have enacted legislation to join the Compact. These states are Alabama, Arizona, Colorado, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, Pennsylvania, South Dakota, Tennessee, Utah, Vermont, Washington, West Virginia, Wisconsin, and Wyoming. Michigan is currently considering signing on to the Compact. The requirements for Compact licensure include: Holding a full, unrestricted medical license in a state that is a member of the Compact, called the State of Principal License (SPL). In addition, the physician must either live in the SPL, conduct

[69] Wilson FA, Rampa S, Trout KE, Stimpson JP. Reimbursements for telehealth services are likely to be lower than non-telehealth services in the United States. J Telemed Telecare. 2017 May;23(4):497-500. P 2.
[70] HHS OIG Policy Statement on Practitioners That Reduce, Waive Amounts Owed by Beneficiaries for Telehealth Services During the COVID-19 Outbreak, accessed on 10 February 2021 at: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/factsheet-telehealth-2020.pdf
[71] 42 USC. § 1395(m) (2003).
[72] Bagchi AD. Expansion of Telehealth Across the Rural–Urban Continuum. State and Local Government Review. 2019;51(4):250-258.

at least 25% of their practice of medicine in the SPL, be employed by an entity in the SPL, or be domiciled for Federal Income Tax purposes in the SPL. In addition to the SPL requirement, the physician must have graduated from an accredited medical school, or a school listed in the International Medical Education Directory, must have passed graduate medical education, must have passed each component of the United States Medical Licensing Examination or Comprehensive Osteopathic Medical Licensing Examination of the United States, in no more than three attempts per component, and must hold a current specialty or time unlimited certification by an American Board of Medical Specialties or American Osteopathic Association Bureau of Osteopathic Specialists board. In addition, the physician must not have any history of disciplinary actions toward their medical license, not have any criminal history, not have any history of controlled substance actions towards their medical license, and not currently be under investigation.

Some improvements to the rigidity of Medicare reimbursement for telehealth had been made over the past four years: Following the creation of the Centers for Medicare and Medicaid Services' (CMS) Fostering Innovation Strategic Initiative (2017), and passage of the Medicare Telehealth Parity Act of 2017, the Bipartisan Budget Act of 2018 and the CMS 2019 Physician Fee Schedule, CMS had expanded some medical services' telehealth eligibility. These include complex patient management, care for patients experiencing a stroke, and chronic in-home care for patients with End Stage Renal Disease.[73] The Federal Communications Commission (FCC) unveiled the Connected Care Pilot Program (CCPP), a $100 million project, in 2018 to improve access to telehealth for low-income Americans and veterans.[74] The groundwork for the CCPP has provided a framework for the more recent COVID-19 Telehealth program, which supports care providers who are launching or expanding telehealth programs in response to the pandemic.[75] Following the 2019 changes to the CMS Physician Fee Schedule, "store-and-forward" type asynchronous interactions and brief virtual check-ins were covered.[76] This included transmitting remote monitoring of patient data from a patient's home to a provider's office.[77] Another provision of the Bipartisan Budget Act of 2018 was a waiver of the geographic limitation on Medicare's coverage of telehealth services.[78] [79] In 2020, President Trump signed an executive order to expand telehealth and to support health care in rural communities. This order made permanent Medicare telehealth payments for certain healthcare providers and services – ensuring expansion of telehealth after the pandemic.[80] A more permanent extension will need to be enacted by Congress to provide the budget necessary to sustain the expansion. The proposed 2021 Physician Fee Schedule rule, issued in advance copy on August 3, 2020,

[73] Verma, S. "Early Impact Of CMS Expansion Of Medicare Telehealth During COVID-19, " Health Affairs Blog, July 15, 2020.
[74] Wickland, E. FCC Pushes Telehealth Connectivity With Connected Care Pilot Program. MHealth Indelligence. Accessed on 10 March 2021 at: https://mhealthintelligence.com/news/fcc-pushes-telehealth-connectivity-for-connected-care-pilot-program
[75] Id.
[76] CMS. "Medicare Telemedicine Health Care Provider Fact Sheet," CMS. Accessed on 10 November 2020 at: https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet
[77] CMS. "2019 Physician Fee Schedule," CMS
[78] Id.
[79] Bipartisan Budget Act of 2018, HR 1892, 115th Cong., §§ 50323–50325 (2018).
[80] HHS, "Trump Administration Announces New Actions to Improve Access to Healthcare across America." Accessed on 10 February 2021 at: https://www.hhs.gov/about/news/2020/08/03/trump-administration-announces-new-actions-to-improve-access-to-healthcare-across-america.html

indicates that CMS intends to expand the use of telehealth technologies for Medicare beneficiaries.[81] The changes include extended audio-only assessment services, new frequency limitations for telehealth in nursing facilities, permanent allowance for therapists to bill for telehealth services within their scope of practice, the temporary allowance of physicians to directly supervise remotely, and including new telehealth services for 2021. The PFS which is now in effect, allows physicians to fulfill direct supervision requirements remotely, provided there is immediate access to audio-video engagement with the physician if needed.[82] The current definition of direct supervision requires that the physician be present in the office, immediately available to perform assistance and direction throughout the performance of a procedure. If finalized, this change would be effective through December 31, 2021 or at the end of the PHE, whichever is later.[83] The change is time-limited because CMS has concerns about the safety of widespread direct supervision through virtual presence, and that overutilization may occur.[84] Under the new definition, CMS states that services provided incident to the professional services of a distant site physician could be billed when they meet direct supervision requirements through the virtual presence of the billing physician.[85] Also encouraging for the future of telehealth is the permanent change that permits therapists, including licensed clinical social workers, clinical psychologists, speech language pathologists, occupational therapists, and other non-physician providers to bill Medicare directly for services within the scope of the provider's benefit category. This billing was previously allowed under the PHE waivers, but this new modification makes the allowance permanent, effective January 1, 2021.

Although CMS has not yet indicated precisely what the future of telehealth coverage will be, we may look to recent trends in the coverage of Remote Patient Monitoring (RPM) for an indication of how remote services will be viewed after the pandemic. One of the biggest advancements in modern telemedicine, RPM allows a patient to wear a device that sends information to a connected device, like a phone or tablet, and can be sent to the patient's physician, allowing instant access to this data.[86] CMS created new codes for RPM services in 2019 and 2020 and has recently changed its guidelines for services provided for purposes of incident to billing.[87] CMS initially expanded RPM coverage to new patients during the COVID-19 public health emergency. After the pandemic, however, CMS will revert to RPM coverage only for established patients. This has been clarified in the 2021 Proposed Rule, limiting RPM service coverage to physicians who possess the information needed to understand the current medical

[81] Lacktman, N. Telehealth: CMS Proposes New Medicare Changes for 2021. Accessed on 10 March 2021 at: https://www.foley.com/en/insights/publications/2020/08/telehealth-cms-proposes-new-medicare-changes-2021
[82] Id.
[83] Id.
[84] Ferrante, T. et al. Top Five New Telehealth Policies in Medicare 2021 in Physician Fee Schedule. Accessed on 10 March 2021 at: https://www.jdsupra.com/legalnews/top-five-new-telehealth-policies-in-16765/#:~:text=Direct%20Supervision%20via%20Telehealth,%2C%20interactive%20audio%2Dvideo%20technology.&text=The%20new%20definition%20opens%20opportunities%20for%20telehealth%20and%20incident%2Dto%20billing.
[85] Id.
[86] Jin MX, Kim SY, Miller LJ, Behari G, Correa R. Telemedicine: Current Impact on the Future. Cureus. 2020;12(8):e9891. Accessed on 10 March 2021 at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7502422/

[87] Wicklund, E. CMS Proposes Significant Changes to Remote Patient Monitoring Coverage. MHealth Intelligence. Accessed 10 March 2021 at: https://mhealthintelligence.com/news/cms-proposes-significant-changes-to-remote-patient-monitoring-coverage

status and needs of the patient prior to ordering RPM services for them.[88] The Proposed Rule is subject to comment, and it is unclear whether CMS will clarify in the final rule that a provider-patient relationship can be established, and a patient can be enrolled into an RPM program virtually using telehealth.[89]

A new study by researchers from Harvard Medical School and the American Board of Family Medicine evaluated the total cost of the pandemic for primary care practices in 2020 by incorporating national data on primary care use, staffing, expenses, and reimbursements, including telemedicine visits: The total cost to neutralize the revenue losses caused by COVID-19 among primary care practices (after PRF payments) is estimated to be $15.1 billion.[90] This is a reminder that it is important to remain focused on upcoming changes in the law and to be mindful as telehealth reimbursement provisions sunset as the PHE subsides.

c. Regulatory History: HIPAA

Providing medical services remotely prompts additional concern for provider compliance with HIPAA's Privacy, Security, and Breach Notification Rules.[91] Since one of the main internal barriers to the adoption of telehealth in physician practices is a reluctance to adopt the technology required to run the service,[92] it is unsurprising that those new to the practice of telemedicine are especially vulnerable to unanticipated risks to patients' sensitive data.[93] HHS's Office of Civil Rights (OCR) enforces HIPAA compliance, imposing penalties for violations by health care providers. Typically, this includes receiving complaints related to improper disclosure of sensitive patient information and random audits of providers to ensure compliance with HIPAA rules. For a provider in a telehealth setting before the COVID-19 pandemic, attention would need to be paid to the vendor providing the technology that facilitates the patient interaction. Commercially available video calling clients, like Skype, Microsoft Teams, Zoom, Google G Suite, and Whatsapp, become Business Associates because the use of the service necessarily involves the use and disclosure of protected health information. The HIPAA Security Rule requires that all business associates sign an agreement with providers, as covered entities, including the elements specified at 45 CFR 164.504(e).[94] These include that the

[88] Lacktman, N, et. Al. Top Ten Medicare Remote Patient Monitoring FAQs for 2021. Accessed on 10 March 2021 at: https://www.foley.com/en/insights/publications/2020/08/ten-medicare-remote-patient-monitoring-faqs-2021

[89] Wicklund, E. CMS Proposes Significant Changes to Remote Patient Monitoring Coverage. MHealth Intelligence. Accessed 10 March 2021 at: https://mhealthintelligence.com/news/cms-proposes-significant-changes-to-remote-patient-monitoring-coverage

[90] Basu, S et al, "Primary Care Practice Finances in the United States Amid The COVID-19 Pandemic." Accessed on 21 March 2021 at: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00794?utm_campaign=covidfasttrack&utm_medium=press&utm_content=basu2&utm_source=mediaadvisory

[91] Hall JL, McGraw D. For telehealth to succeed, privacy and security risks must be identified and addressed. Health Aff (Millwood). 2014;33(2):216-221. P.218.

[92] Kruse, D., Karem, P., Shifflett, K., Vegi, L., ravi, K., and Brooks, M., "Evaluating Barriers to Adopting Telemedicine Worldwide: A Systemic Review." Journal of Telemedicine and Telecare 2018, Vol. 24(1) 4-12 P.7.

[93] Hall JL, McGraw D. For telehealth to succeed, privacy and security risks must be identified and addressed. Health Aff (Millwood). 2014;33(2):216-221. P.218.

[94] 45 CFR 164.504(e)

business associate will not use or further disclose the protected health information besides as allowed by the contract or law and requires the business associate to use appropriate safeguards to prevent a use or disclosure of the protected health information other than as provided for by the contract.[95] Where there are security breaches, the covered entity must take reasonable steps to cure the breach including termination of the contract if the remedy is not successful.[96] A reasonable safeguard of client communication data in the telehealth setting may be encrypting the data and using a secure transmission protocol, so that even if the data is intercepted it is not usable.[97]

d. COVID-19: Immediate Federal Regulatory Response

The pandemic has forced physician practices to close while striving to simultaneously flatten the curve of COVID-19 infections. Effective January 1, 2020, Medicare beneficiaries in rural and urban areas were able to access telehealth services from their homes. The novel coronavirus pandemic expanded that right of access and now advocates seek to make this provision permanent. On March 13, 2020, President Donald Trump proclaimed a national Public Health Emergency (PHE) under the Stafford Act and the National Emergencies Act (NEA). The same day, Alex Azar (the Secretary of HHS) waived the provisions of numerous healthcare laws and regulations, including certain requirements of the Medicare, Medicaid, and State Children's Health Insurance Programs (and of the HIPPA Privacy Rule) throughout the duration of the COVID-19 PHE.[98] The Stafford Act and The NEA empower CMS to issue waivers to Medicare program requirements to support patients and providers during the pandemic.[99] Originally scheduled to expire on October 23, 2020, the PHE was initially extended for 90 days and extended through January 20, 2021. On January 8th, 2021, HHS announced that the PHE has been renewed for another 90 days, now set to expire on April 20, 2021.

Even though the HIPAA portion of the HHS Section 1135 blanket waiver permitted waiving these requirements to the fullest extent permitted, this had limited impact because the HIPAA waivers are so narrow. In practice, the waivers meant that for the 72-hour period after a hospital declared they were operating under a disaster protocol, they could temporarily disregard *some* HIPAA rules.[100] The limitation of the waiver to a three-day period meant that the waiver did not have a significant impact on hospitals and had no impact on providers other than hospitals.[101] Identifying this, OCR issued three notifications of enforcement discretion for the duration of the PHE: On March 17, 2020, OCR announced that it would exercise enforcement discretion for all provisions of the HIPAA Privacy, Security and Breach notification rules if a telehealth provider acted in good faith compliance with the guidance in providing telehealth service during the

[95] Id.
[96] 45 CFR 164.410(a)(1)
[97] 45 CFR 164.306(e)
[98] The White House, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. Accessed 11 November 2020 at: whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/
[99] Verma, S. "Early Impact Of CMS Expansion Of Medicare Telehealth During COVID-19, " Health Affairs Blog, July 15, 2020.
[100] Dworkowitz, A. "Key HIPAA Changes in Light of COVID-19". Accessed on 10 February 2021 at: https://www.manatt.com/insights/newsletters/covid-19-update/key-hipaa-changes-in-light-of-covid-19
[101] Id.

PHE.[102] Under these guidelines, providers who were new to telehealth were able to rapidly transition to virtual appointments using non-public facing digital platforms that did not meet all HIPAA requirements. There was no requirement that the service be provided for the diagnosis or treatment of COVID, just that it occur during the PHE.[103] On April 2, 2020, OCR issued another notification of enforcement discretion for business associates to make disclosures of protected health information (PHI) to public health agencies if the contract between the covered entity and the business associate allowed it.[104] This means that the OCR will not enforce penalties when business associates disclose PHI to public health agencies like the Center for Disease Control and CMS that may otherwise violate the HIPAA Privacy Rule. Disclosure must be made in good faith, and the business associate must notify the covered entity within 10 days of disclosure.[105] On April 9, 2021, OCR issued a third notice of enforcement discretion, this time for community-based testing sites, allowing for HIPAA noncompliance regarding the collection of specimens for COVID testing in public parking lots.[106] The response by OCR under the 1135 waiver and these notifications of enforcement discretion are summarized in Figure 4, below.

This temporary relaxation of regulatory enforcement has allowed providers the opportunity to offer telehealth services without the risk of major financial penalties related to the unique threat of exposure the technology presents.[107] Providers should be planning for HIPAA-compliant solutions in the post-pandemic future, including a risk-based assessment of vulnerabilities, consistent with the HIPAA Security rule. The cybersecurity risk increases when providers use unsecured networks and unencrypted technology, including mobile devices, to conduct activities related to telehealth. Another common vulnerability is a lack of physical security and privacy controls in work-from-home environments.[108]

Independent physician practices still reeling from the pandemic may lack the scale or capital to take on the increased compliance risk presented by telemedicine as the OCR's enforcement discretion ends. Telemedicine presents a viable opportunity for providers to build a new capability that could lead to success post-pandemic.[109] This will require investment as they

[102] HHS, "Notification of Enforcement Discretion for Telehealth Remote Communications during the COVID-19 Nationwide Public Health Emergency." Accessed on 10 February 2021 at: https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html
[103] Id.
[104] Federal Register, "Enforcement Discretion Under HIPAA To Allow Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities in Response to COVID-19." Accessed on 10 February 2021 at: https://www.federalregister.gov/documents/2020/04/07/2020-07268/enforcement-discretion-under-hipaa-to-allow-uses-and-disclosures-of-protected-health-information-by
[105] Id.
[106] HHS, "Enforcement Discretion Regarding COVID-19 Community-Based Testing Sites (CBTS) During the COVID-19 Nationwide Public Health Emergency." Accessed on 10 February 2021 at: https://www.hhs.gov/sites/default/files/notification-enforcement-discretion-community-based-testing-sites.pdf
[107] Fisher Phillips. "The Intersection of Technology and Patient Privacy in the COVID-19 Landscape (and Beyond)". Accesssed on 11 February 2021 at: https://www.fisherphillips.com/resources-newsletters-article-the-intersection-of-technology-and-patient-privacy
[108] Brito, M. "Security and Privacy Risks Associated with COVID-19 and Telehealth" Accessed on 11 February 2021 at: https://www.bkd.com/article/2020/04/security-privacy-risks-associated-covid-19-telehealth
[109] McKinsey & Company Healthcare Systems & Services. "Virtual health: A look at the next frontier of care delivery." Accessed on March 20, 2021 at: https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/virtual-health-a-look-at-the-next-frontier-of-care-delivery

transition from COVID-19 rapid communication delivery solutions to sustainable, secure, integrated virtual platforms. In planning this, it remains important to consider interoperability (including electronic health records, digital informed consent, and supporting infrastructure.[110]).

[110] Id.

Figure 4: Summary of OCR's actions under the 1135 waiver and notifications of enforcement discretion:[111]

Organization	Hospitals implementing disaster protocols	Telehealth Providers	Business Associates	COVID-19 Community-based testing sites
Rules Waived	• Obtaining patient's consent to speak with family/friends • Honoring requests to opt out of facility directory • Distributing notice of privacy practices • Allowing patient requests for privacy protections	HIPAA Privacy, Security, and Breach notification rules	Terms of business associate agreement related to public health and health oversight disclosures	HIPAA Privacy, Security and Breach notification rules
Time Period	Only 72 hours after a hospital implements a disaster protocol	Until OCR issues notice of chance in policy	During the COVID-19 public health emergency	During the COVID-19 public health emergency
Limits	Any HIPAA requirements except the four waived rules noted above must still be complied with	• Telehealth must be provided in good faith • Public-facing technologies cannot be used	• Disclosure must be made in good faith • A business associate must notify the covered entity within 10 days of use or disclosure	• Must act in good faith • Non-enforcement doesn't apply to other activities of the same provider
Optional Precautions (recommended but not required)	N/A	• Notify patients of privacy risks • Enter into Business Associate Agreements with technology vendors • Providers should not communicate in a public forum or from public settings	N/A	• Follow minimum necessary rules • Set up barriers to protect privacy • create adequate distancing to reduce risk of overhearing conversations
Waiver or non-enforcement	Waiver	Non-enforcement	Non-enforcement	Non-enforcement

e. Continued Regulatory Response: The Coronavirus Aid, Relief, and Economic Security Act.

On March 17, 2020, CMS announced the expansion of telehealth services on a temporary, emergency basis pursuant to Section 1135 and Coronavirus Preparedness and Response

[111] Dworkowitz, A. "Key HIPAA Changes in Light of COVID-19". Accessed on 10 February 2021 at: https://www.manatt.com/insights/newsletters/covid-19-update/key-hipaa-changes-in-light-of-covid-19

Supplemental Appropriations Act, 2020.[112] Effective March 30, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act created a general waiver provision that enabled the HHS to temporarily lift restrictions on Medicare's coverage of telehealth services.[113] On March 31, CMS issued an interim final rule with comment period (IFC) with 30 immediate rule changes and temporary waivers to the current regulatory framework.[114] The IFC aims to provide the flexibility needed to respond effectively to the serious public health threats posed by the spread of COVID-19.

For the duration of the PHE, the most significant barriers to telehealth adoption are temporarily lifted, including the historic restrictions on patient/provider location, the manner of the interaction, the strict licensing requirements, the requirement that the patient-provider relationship be already established, and the lower rate of reimbursement: Telehealth services will be reimbursed at the same rate as in-person visits with that provider, a move designed to avoid inadvertently creating incentives to place cost considerations above patient safety.[115] Additionally, while coinsurance and deductibles would generally apply for telehealth services, HHS is providing flexibility for providers to waive or reduce cost sharing for telehealth services paid by Federal programs.[116] This means that patients who may not be able to afford co-pays are still able to access care. Importantly, providers do not risk enforcement action if they waive any cost-sharing for telehealth visits during the PHE. OIG would not bring an enforcement action under either the Federal anti-kickback statute or the beneficiary inducements civil monetary penalty statute for reducing cost-sharing, provided all applicable CMS payment and coverage rules are met.[117]

f. State Regulatory Response

Despite some similarities in the language used, no two states are alike in how telehealth is treated.[118] One of the most significant state-controlled obstacles to widespread adoption of telehealth is state licensing requirements for providers. Typically, providers must hold licensures in the state they sit in but also must be licensed or allowed to practice in the state in which their

[112] Pub. L. 116-123, March 6, 2020

[113] American Medical Association. Senate bill would nix geographic, site restrictions on telehealth. Accessed 10 November 2020 at: https://www.ama-assn.org/practice-management/digital/senate-bill-would-nix-geographic-site-restrictions-telehealth

[114] McGuire Woods, "COVID-19: Consolidated Medicare Telehealth Expansion Update." Accessed 11 November 2020 at: https://www.mcguirewoods.com/client-resources/Alerts/2020/4/covid-19-consolidated-medicare-telehealth-expansion-update

[115] Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency." 42 CFR Part 400.

[116] Manatt, "Executive Summary: Tracking Telehealth Changes State-by-State in Response to COVID-19," accessed on 10 February 2021 at: https://www.manatt.com/insights/newsletters/covid-19-update/executive-summary-tracking-telehealth-changes-stat#collapseNewsletter

[117] HHS OIG Policy Statement on Practitioners That Reduce, Waive Amounts Owed by Beneficiaries for Telehealth Services During the COVID-19 Outbreak, accessed on 10 February 2021 at: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/factsheet-telehealth-2020.pdf

[118] CCHP. State Telehealth Laws and Reimbursement Policies Report. Accessed on 10 February at: https://www.cchpca.org/sites/default/files/2020-10/CCHP%2050%20STATE%20REPORT%20FALL%202020%20FINAL.pdf

patients are located.[119] Additionally, the practice of medicine becomes complicated when nurses can only take orders from physicians who are licensed in the state where the patient is located, not where the nurse is located.[120] In remembering this, it is important to consider that malpractice lawsuits will be brought in the state the patient is located.

In an early case addressing telemedicine, Hageseth v Superior Court of California, a California Court asserted jurisdiction over Dr. Hageseth, then a Colorado-licensed psychiatrist, and criminally charged him with practicing medicine without a license in California. Dr Hageseth prescribed medication over the Internet to a patient in California, who then committed suicide two months later.[121] The provider surrendered his Colorado medical license in 2005 after this patient death.[122] While Dr. Hageseth was aware that the patient was in California, he maintained that he never interacted directly with him. When asked by a Florida-based company to assess the patient's request for medication, Dr. Hageseth reviewed the patient's questionnaire and the medicine was shipped from a pharmacy in Mississippi to the patient in California. Dr. Hageseth argued that the California Court did not have jurisdiction, and, in the alternative, that the Court's assertion of jurisdiction would deter the future practice of telemedicine.[123] The Court did not agree.[124] In deciding the jurisdictional dispute, the court held:

> "a preponderance of the evidence shows petitioner prescribed medication for a resident of this state, aware of the virtual certainty his conduct would cause the prescribed medication to be sent to that person at his residence in California. This state is thus the place where the crime is "consummated." The fact that other parts of the crime were committed elsewhere is immaterial, as there is no constitutional or other reason "that prevents a state from punishing, as an offense against the penal laws of such state, a crime when only a portion of the acts constituting the crime are committed within the state." (People v. Botkin (1908) 9 Cal. App. 244, 251 [98 P. 861].). Accordingly, respondent court possesses the necessary jurisdiction."[125]

Despite the emergence of Federal legislation easing interstate licensing restrictions, the future practice of telemedicine depends on understanding the licensing requirements of multiple different states and ensuring these are met at the initiation of any provider-patient telehealth relationships. The development of the Interstate Medical Licensure Compact by the Federation of State Medical Boards has created an avenue for providers to apply for licensure in multiple states simultaneously. Even with this easing, the Hageseth problem would still apply because though Colorado is part of the IMLC, California is not.[126]

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[119] Health Resources and Services Administration (HRSA). What is telehealth? Accessed on 11 February 2021 at: http://www.hrsa.gov/healthit/toolbox/ RuralHealthITtoolbox/Telehealth/whatistelehealth.html

[120] Federation of State Medical Boards (FSMB). Model policy for the appropriate use of telemedicine technologies in the practice of medicine. Accessed on 11 February 2021 at: https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB_Telemedicine_Policy.pdf.

[121] Becker CD, Dandy K, Gaujean M, Fusaro M, Scurlock C. Legal Perspectives on Telemedicine Part 1: Legal and Regulatory Issues. The Permanente Journal. 2019;23:18-293.

[122] Palo Alto Online, "Doctor Convicted in Internet Prescriptions Case." 10 March 2009. Accessed 11 February 2021 at: https://www.paloaltoonline.com/news/2009/03/10/doctor-convicted-in-internet-prescriptions-case

[123] Hageseth v. Superior Court 150 Cal. App. 4th 1399, at 1422.

[124] Id., at 1423-24

[125] Hageseth v. Superior Court 150 Cal. App. 4th 1399, at 1418

[126] Interstate Medical Licensure Compact Website. Accessed 11 February 2021 at: https://www.imlcc.org/

V. The Future of Telehealth

a. Regulatory Future

On December 1st, 2020, CMS finalized changes to the Medicare telehealth covered services list:[127] First, CMS is adding permanent coverage for a range of services, including group psychotherapy, low-intensity home visits, and psychological and neuropsychological testing. Second, CMS has finalized temporary coverage for certain services through the end of the calendar year in which the COVID-19 PHE ends, including high-intensity home visits, emergency department visits, specialized therapy visits, and nursing facility discharge day management. Finally, CMS is indicating which services will not be covered permanently when the PHE ends. These include telephonic evaluation and management, initial nursing facility visits, radiation treatment management services, and new patient home visits.[128] After a period of comment, CMS finalized that providers must have an established patient relationship in order to initiate remote physiologic monitoring services (RPM).[129] Patients with acute conditions are permitted to participate in RPM provided the data from the device be automatically collected and transmitted, and that when discussing RPM results, the "interactive communication" involves a real-time synchronous two-way interaction by video or telephone.[130] In January 2021, CMS confirmed that the 20-minutes of intra-service work allowed under some codes includes a provider's time engaged in "interactive communication" includes the same allowance for telehealth services.[131] On December 3rd, 2020, HHS issued an amendment to the Public Readiness and Preparedness (PREP) Act. Now, any licensed healthcare provider who is permitted to order and administer a Covered Countermeasure in any one state may now order and administer that Covered Countermeasure in any other state via telehealth, even if the

[127] CMS List of Telehealth Services. Accessed on 10 February 2021 at: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes

[128] Manatt, "Executive Summary: Tracking Telehealth Changes State-by-State in Response to COVID-19," accessed on 10 February 2021 at: https://www.manatt.com/insights/newsletters/covid-19-update/executive-summary-tracking-telehealth-changes-stat#collapseNewsletter

[129] CMS List of Telehealth Services. Accessed on 10 February 2021 at: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes

[130] Manatt, "Executive Summary: Tracking Telehealth Changes State-by-State in Response to COVID-19," accessed on 10 February 2021 at: https://www.manatt.com/insights/newsletters/covid-19-update/executive-summary-tracking-telehealth-changes-stat#collapseNewsletter

[131] Federal Register, "Medicare Program; CY 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-In Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions From the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID-19; Correction." Accessed 10 February 2021 at: https://www.federalregister.gov/documents/2021/01/19/2021-00805/medicare-program-cy-2021-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part?inf_contact_key=221bbb66cd959d1ec1443f884bb2ea81

provider is not licensed in the other state (subject to compliance with rules established by the provider's licensing state.)[132]

b. Telehealth: Current Impact, Future Potential, and Enforcement Predictions

Despite these initial complications, between 40% and 55% of patient visits could be handled via telehealth,[133] making up to $250 billion of the current healthcare spend potentially virtualized.[134] The relaxation of reimbursement regulations coupled with the policy statements by the HHS OIG and OCR enable providers to use familiar technology and reduce patient copays without fear of consequence from potential violations of the HIPAA Privacy Rule or anti-kickback statutes when starting or transitioning to a telehealth business.

On February 20, 2021, Principal Inspector General Grimm issued a statement on Telehealth, acknowledging the promise that telehealth expansion has, including offering opportunities to increase access to services, decreasing burdens for both patients and providers, and enabling better care, including enhanced mental health care.[135] She emphasized that, "OIG is conducting significant oversight work assessing telehealth services during the public health emergency." The goal of these reviews is to ensure that, "telehealth delivers quality, convenient care for patients and is not compromised by fraud."[136] The OIG Work plan includes telemedicine projects aimed at audits of Home Health Services and of Medicare Part B services provided as telehealth during the PHE. There is also a planned focus on "program integrity risks" to the provision of Medicare telehealth services, and an examination of the expansion of telehealth in Medicaid during the PHE.[137] What these audits are likely to yield is unclear, although the HHS OIG released a report on Medicare telehealth billing in 2018 with a small sample size. That report found a 31% error rate for claims that did not meet Medicare standards and requirements for the payment of telehealth services.[138]

The DOJ recently announced the newest addition to the Health Care Fraud Unit: The National Rapid Response Strike Force. This Strike Force has led the response to detection and prevention of telehealth fraud during the pandemic, but the future scope of its work will be much broader.[139]

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[132] Federal Register, "Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration." Accessed on 10 February 2021 at: https://www.federalregister.gov/documents/2020/12/09/2020-26977/fourth-amendment-to-the-declaration-under-the-public-readiness-and-emergency-preparedness-act-for

[133] JAMA, "COVID-19's Crushing Effects on Medical Practices, Some of Which Might Not Survive…" Accessed 13 November 2020 at: https://jamanetwork.com/journals/jama/fullarticle/2767633

[134] Bestsennyy, O. "Telehealth_. A quarter-trillion-dollar post-COVID-19 reality?" McKinsey & Company Healthcare Systems & Services. Accessed on 20 March 2021 at: https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality

[135] Grimm, C. Principal Deputy Inspector General Grimm on Telehealth. HHS Office of the Inspector General. Accessed on 10 March 2021 at: https://oig.hhs.gov/coronavirus/letter-grimm-02262021.asp?utm_source=oig-home&utm_medium=oig-hero&utm_campaign=oig-grimm-letter-02262021

[136] Id.

[137] Goodman, R. et al. OGI has Seven (Yes Seven) Different National Telemedicine Audits. Foley & Lardner for JD Supra. Accessed on 10 March 2021 at: https://www.jdsupra.com/legalnews/oig-has-seven-yes-seven-different-4602993/

[138] Id.

[139] United States Department of Justice. Health Care Fraud Unit National Rapid Response Strike Force. Accessed on 29 March 2021 at: https://www.justice.gov/criminal-fraud/health-care-fraud-unit#:~:text=Specifically%2C%20the%20newly%20created%20National,a%20focus%20on%20investigations%20and

The Strike Force is expected to build on the Health Care Fraud Unit's work, but also to focus on the investigation and prosecution of fraud cases involving major health care providers that operate in multiple jurisdictions, including major regional health care providers operating in the Strike Force cities. This Strike Force played a major part in investigating the largest health care fraud and opioid enforcement action in the department's history.[140] On September 20, 2020, the DOJ publicly announced that this enforcement action involved 345 charged defendants across 51 federal districts, with 75% of the $6 billion in losses attributable to Telemedicine fraud cases.[141] The DOJ alleges that these defendants were paid by telemedicine executives to order unnecessary durable medical equipment (DME), genetic tests, and pain medications – often over the phone, with little interaction.[142] They further assert that DME companies, genetic testing labs, and pharmacies purchased these orders in exchange for illegal kickbacks and bribes.[143] In one of the charged cases, prosecutors in Florida, New Jersey, and Southern California investigated two San Diego men for conspiring to defraud Medicare through the submission of medically unnecessary DME claims.[144] They formed a conglomerate of fraudulently established DME companies and submitted more than $343 million in illegal DME claims to Medicare and to the Civilian Health and Medical Program of the Department of Veterans Affairs, resulting in over $180 million in overpayments. According to court documents, the defendants paid millions in kickbacks and bribes to acquire the DME claims, which had been generated using aggressive telemarketing strategies in concert with fraudulent telemedicine involving bribed doctors who rarely spoke to the beneficiaries.

"Telemedicine can foster efficient, high-quality care when practiced appropriately and lawfully. Unfortunately, bad actors attempt to abuse telemedicine services and leverage aggressive marketing techniques to mislead beneficiaries about their health care needs and bill the government for illegitimate services," HHS Deputy Inspector General Gary Cantrell said in a news release. "Unfortunately, audacious schemes such as these are prevalent and often harmful. Therefore, collaboration is critical in our fight against health care fraud." As a result of their alleged involvement in schemes to provide unnecessary medical treatment via telemedicine services, the CMS Center for Program Integrity (CPI), through a coordinated effort with the DOJ, revoked the Medicare billing numbers for 256 medical professionals involved in these schemes.[145]

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[140] United States Department of Justice. National Health Care Fraud and Opioid Takedown Results in Charges against 345 Defendants Responsible for More than $6 Billion in Alleged Fraud Losses. September 30, 2020. Accessed on 29 March 2021 at: https://www.justice.gov/opa/pr/national-health-care-fraud-and-opioid-takedown-results-charges-against-345-defendants

[141] Morgan Lewis Health Law Scan. Tele-Tuesday: DOJ National Healthcare Fraud Takedown Targets Telehealth – But Should DOJ's Focus be Elsewhere? October 20, 2020. Accessed on 29 March 2021 at: https://www.morganlewis.com/blogs/healthlawscan/2020/10/tele-tuesday-doj-national-healthcare-fraud-takedown-targets-telehealth-but-should-dojs-focus-be-elsewhere

[142] United States Department of Justice. National Health Care Fraud and Opioid Takedown Results in Charges against 345 Defendants Responsible for More than $6 Billion in Alleged Fraud Losses. September 30, 2020. Accessed on 29 March 2021 at: https://www.justice.gov/opa/pr/national-health-care-fraud-and-opioid-takedown-results-charges-against-345-defendants

[143] Id.

[144] Reuter, E. MedCity News. DOJ Cracks Down on Telehealth Kickbacks in $6 billion fraud investigation. October 5, 2020. Accessed on 29 March 20201 at: https://medcitynews.com/2020/10/doj-cracks-down-on-telehealth-kickbacks-in-6b-fraud-investigation/

[145] Morgan Lewis Health Law Scan. Tele-Tuesday: DOJ National Healthcare Fraud Takedown Targets Telehealth – But Should DOJ's Focus be Elsewhere? October 20, 2020. Accessed on 29 March 2021 at:

Consequently, providers who have billed federal healthcare programs for telehealth services since the beginning of the PHE should expect these claims to be subject to review,[146] as should providers who have made claims in excess of $10,000 from the PRF, which carry special reporting requirements. Noncompliance with any of the provisions required by Medicare (for telehealth reimbursement) and the HHS (for PRF payments) may cause recoupment of some or all of the payments received. PRF recipients who violate the terms of the grants are also subject to civil and criminal prosecution for fraud under the federal False Claims Act, which provides civil penalties of up to $23,331 per claim plus three times the amount of actual damage to the government.[147]

VI. Conclusion

2020 redefined the practice of medicine. Starting in February 2020, when it became clear that the Coronavirus pandemic was serious and now well into the first quarter of 2021, while vaccines are becoming more readily available but social distancing continues, the pandemic forced physicians to adapt to a virtual environment so patients can receive care while social distancing. It is clear that while every organizations vision of the future with telehealth will be different; what matters is defining how telehealth will enable the organization to reposition itself to meet the growing needs of diverse patient populations.[148] Also accelerated has been the consumerization of healthcare as patients realize they have more virtual and digital options for healthcare services.[149] From a policy perspective, it is important to remember non-rural provider groups who were not able to optimize care during the pandemic and to offer assistance as they attempt to rebuild. This will include the judicious use of enforcement activity as the pandemic abates.

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https://www.morganlewis.com/blogs/healthlawscan/2020/10/tele-tuesday-doj-national-healthcare-fraud-takedown-targets-telehealth-but-should-dojs-focus-be-elsewhere.

[146] Goodman, R. et al. OGI has Seven (Yes Seven) Different National Telemedicine Audits. Foley & Lardner for JD Supra. Accessed on 10 March 2021 at: https://www.jdsupra.com/legalnews/oig-has-seven-yes-seven-different-4602993/

[147] Alvarez and Marsal, "Recipient of Provider Relief Funds? How to Best Position Yourself for Future Oversight and Enforcement Activities." Accessed on 21 March 2021 at: https://www.alvarezandmarsal.com/insights/recipient-provider-relief-funds-how-best-position-yourself-future-oversight-and-enforcement

[148] McHale, D. et al, "Repositioning for the Future with Telehealth." Huron Consulting Group. Accessed on 20 March 2021 at: https://www.huronconsultinggroup.com/insights/repositioning-future-telehealth?utm_source=adwd&utm_medium=paidsearch&utm_campaign=2021-hc-dta&utm_content=futuretelehealth-7014O000001u23qQAA&creative=469874128983&keyword=%2Btelehealth&matchtype=b&network=g&device=c&gclid=Cj0KCQjwutaCBhDfARIsAJHWnHtSutYv2HCtjrl_cxMyZnWzeui_jN7oiGk6dN4YzpO8uGwfu5oYV4gaAhyfEALw_wcB

[149] Landi, H. "The COVID-19 Pandemic will have a Long-term Impact on Healthcare. Here are 4 changes to Expect." Accessed on 20 March 2021 at: https://www.fiercehealthcare.com/tech/4-ways-healthcare-will-change-from-impact-covid-19-experts-say