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Improving Pharmacy
Benefits Strategy

Waste in
Prescription Drugs

Prescription Digital
Therapeutics

BENEFITS Quarterly

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Special Section on

Prescription Drugs and PBM Trends



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Fourth Quarter 2022

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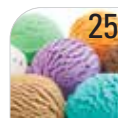
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executive summaries

Improving Pharmacy Benefits Strategy to Reduce Costs and Risk

by **Dawn G. Holcombe** | *DGH Consulting*
William Lacy | *Association for Corporate Health Risk Management*

Rising health care benefit costs, in part driven by the acceleration of cost increases for specialty medications and high-tech medical treatments, are challenging for both employers and their insured members. There will always be diverse perspectives on pharmacy management, and no one size fits all. It is important to consider several options, which can then be matched to the dynamics of a specific location. Although neither the current fully insured nor the stop-loss marketplace offers adequate protection from high-cost claims beyond one year for most employers, many implementable strategies have proved to be successful in significantly reversing the upward cost trend. This article focuses on recent successful strategies to mitigate and, in many cases, avoid rapid escalation in prescription drug spending to provide employers struggling with high pharmacy costs with tangible, implementable actions.

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The Three Most Misunderstood Words in Health Care: Fraud, Waste and Abuse

by **Susan A. Hayes, D.Crim.J.**
Pharmacy Investigators and Consultants

Many people may emphasize the “fraud” in the phrase *fraud, waste and abuse*, but waste is actually creating an enormous drain to the health care system. Chain pharmacy refill programs encourage and reward pharmacists to refill as many prescriptions as possible. But when patients do not want these refills, often no one in the pharmacy has the time to restock and reverse these prescriptions due to national technician staffing shortages. Without reversing abandoned prescriptions, multiple plan sponsors may end up paying for the same medication. Plan sponsors and employers need to make sure they have discussed the issue with their pharmacy benefit managers and ensure that they are not paying for abandoned prescriptions.

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Prescription Digital Therapeutics: A Treatment Tool for Substance Use Disorder and Other Diagnoses

by **Barbara Fahmy** | *ClearLight Writing and Editing Services, LLC*
William Lacy | *Association for Corporate Health Risk Management*

Pharmaceutical digital therapeutics (PDTs) are a newly created medical device class that can significantly reduce patient and employer costs relative to treatment as usual. Based on early evidence, PDTs, which are software-based products approved by the Food and Drug Administration (FDA), offer potentially greater efficacy and cost-effectiveness. However, with any innovation, market acceptance requires considerable education amongst stakeholders. This article describes the basics of PDTs for employers, employees/patients, physicians, pharmacy benefit managers (PBMs) and other stakeholders. Supported by an employer case study, the article discusses the challenges and opportunities in relation to market acceptance.

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Advanced Primary Care: Meeting Millennials’ Needs and Reducing Health Care Costs

by **Melina Kambitsi, Ph.D.** | *The Alliance*

Millennials make up nearly 25% of the U.S. population and will soon account for a large portion of future health care spending (\$3.4 trillion in total). However, their participation thus far in the current health care system has been lacking—specifically within the realm of primary care. This is highly important, because in a perfect world, primary care would be used by patients first and most frequently. However, primary care utilization is trending downward, and Millennials’ lack of participation—among other factors, such as consolidation and diversification of primary care—plays a large part in that downward slide. This article takes a deep dive into reasons that Millennials aren’t utilizing primary care. The article also explains the concept of advanced primary care (or direct primary care); its benefits (especially as they relate to Millennials); and how employers can use it to lower their costs, improve employees’ health and well-being, and increase employee engagement and satisfaction with their health plans.

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Pushing the Boundaries: Emerging Global Health Care Needs for a Work- From-Anywhere Culture

by **Noelle Weinrich** | *GeoBlue*

Employees are increasingly pushing the boundaries to define *working remotely* as working anywhere in the world. Many employers' remote work policies are narrowly defined as working from home and do not include benefits for employees who desire to be globally mobile and work from outside the United States without traveling officially for the company or on a global assignment. With employers struggling to attract and retain talent, they are left to figure out how to manage this growing trend and how to apply benefits that they can use to their advantage. Considering that 80% of U.S. workers would turn down a job that did not offer a flexible working arrangement, the need for location flexibility cannot be ignored. The ability to offer location flexibility worldwide only enhances the appeal to potential talent that employers are seeking to add to their ranks as well as highly valuable and productive employees that employers are hoping to retain.

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Identity Authentication Versus Criminal Counterinnovations: Pension Account Security

by **Sally Shen, Ph.D.** | *Global Risk Institute*
John A. Turner, Ph.D. | *Pension Policy Center*

The COVID-19 pandemic's social distancing norms and the growing popularity of online financial services have made it increasingly important to implement strong cybersecurity systems designed to protect identities, data and assets. Pension transactions often involve large amounts of participant money, which incentivizes criminals to overcome online protections and leads to what could be described as a "cybersecurity arms race." This article examines issues related to remote identity authentication for pension plans and participants. It addresses alternatives to traditional forms of identity authentication (e.g., ink signatures and in-person notarization), such as the use of remote electronic signatures.

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Improving Pharmacy Benefits Strategy to Reduce Costs and Risk

by **Dawn G. Holcombe** | *DGH Consulting*
and **William Lacy** | *Association for Corporate Health Risk Management*

Rising health care benefit costs, in part driven by the acceleration of cost increases for specialty medications and high-tech medical treatments, are challenging for both employers and their insured members. Health benefit availability and affordability are significant considerations for workers and their families. Employers struggle to protect plan members from higher copays and deductibles, while at

the same time trying to keep plan benefit costs within a reasonable budget.

Specialty medication costs have grown from \$335 billion in 2018 to a predicted \$475-\$505 billion by 2021.¹ They accounted for nearly 15% of total health care claim costs in 2019² and could lead to an average annual growth rate of almost 12% over the next three years.³

AT A GLANCE

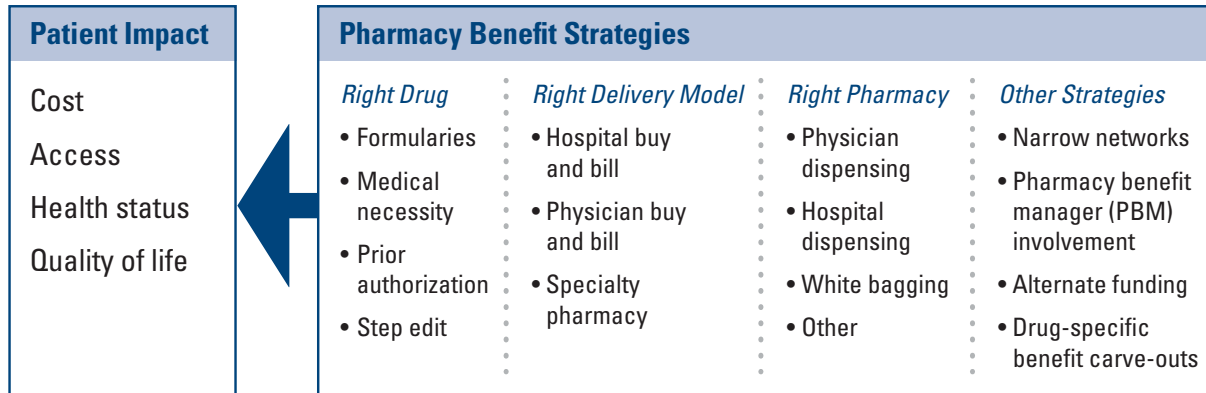
- Rising health care benefit costs, in part driven by the acceleration of cost increases for specialty medications and high-tech medical treatments, are challenging for both employers and their insured members.
- Although neither the current fully insured nor the stop-loss marketplace offers adequate protection from high-cost claims beyond one year for most employers, many implementable strategies have proved to be successful in significantly reversing the upward cost trend.
- Recent successful strategies can mitigate and, in many cases, avoid rapid escalation in pharmacy spending to provide employers struggling with high pharmacy costs with tangible, implementable actions.

Perspective Creates Challenges

There will always be diverse perspectives on pharmacy management, which may at times be in conflict. Employers, physicians, hospital systems, pharmacists, patients, drug manufacturers, and brokers and managers in specialty pharmacy and pharmacy benefits each look at the cost, benefit, value, challenges and opportunities from a different view. A reduction of cost to a broker or employer may lead to a lack of access to treatment for a patient or physician. Shifting expense from one entity to another will be perceived as an asset by one and a detriment by the other. There is no one-size-fits-all solution, and key variables will include the geographic location, disease, patient health status, players and dynamics of a particular market area. It is important to consider several options, which can then be matched to the dynamics of a specific location.

FIGURE

The Patient Impact of Pharmacy Benefit Strategies Ultimately Determines Success



Strategies Will Lead to Patient Impact

Each option will affect the patient in some manner. Most successful strategies follow a general hierarchy of key touch points. The figure offers a general framework for consideration of pharmacy management strategies. Each possible strategy should be balanced against the parallel concerns for impact on the patient. If a strategy leads to a downstream consequence of adverse cost, access, health status or quality of life for a patient, it will not be ultimately successful.

Framework for Consideration of Pharmacy Management Strategies

This article focuses on successful strategies implemented by self-funded employers throughout the U.S. to mitigate costly pharmacy claims. The goal is to provide employers struggling with high-cost pharmacy claims with implementable means to achieve dramatic cost reductions for both the plan and plan participants. The pharmacy benefit, typically the most used component of employer-sponsored health plans, holds several challenges:

- **Costs**—Annual price increases for existing brand and generic drugs
- **Expansion**—A rapidly expanding pipeline of high-cost specialty medications that now represent more

than 60% of spending in the pharmacy benefit channel, which grew 20.5% in claims utilization in 2020.⁴

- **Performance** (or failure) of the fiduciary responsibility of the traditional pharmacy benefit manager (PBM)—Many may prioritize profit agendas over clients’ budgets and often allow dispensing of less-than-optimal medications that increase PBM revenues and margin while driving up plan sponsor costs.
- **Impact**—Many employees and dependents face spending an increasing percentage of annual income on plan premiums, deductibles and copayments/coinsurance.

While the growing impact of pharmacy claims on self-insured employers is clear, actionable solutions are not always as clear. Many employers feel somewhat helpless against increasing pharmacy costs.

There are several effective strategies that self-insured employers can implement to dramatically reduce the risk of waste and overspending in the pharmacy benefit as well as potentially devastating high-cost claims.

Employers can begin by asking basic questions about their vendor partners in benefits management. At the highest level, questions include the following:

- Can you trust that your vendors are always looking out for the best interest of your organization and plan participants?

- Are there misaligned incentives with your vendors that can drive up costs?

At a more granular level, employers may not be optimally aligned with their vendors if the answer is “yes” to any of the following.

- Are conflicts of interest negatively impacting clinical decisions and utilization management?
- Are benefit design and formulary structure influenced by rebates or vendor credits?
- Are exclusive vendor contracts restricting access to the lowest net cost options for care?
- Are you not allowed to carve out clinical review, rebate or dispensing functions from your vendors?
- Are prohibitions against making changes to formulary, guidelines or covered/not-covered status driving up your cost?

- Are your vendors given unlimited discretion to authorize any drug or service no matter the cost?
- Are you being penalized for not carving in services?

If the answer to any of these basic questions is yes, then employers can take meaningful steps to ensure better alignment of PBM vendors and pharmacy benefit management to the best interest of the employer plan and plan participants.

The National Alliance of Healthcare Purchaser Coalitions summarizes some of the most popular, successful options available to deliver immediate savings and mitigate pharmacy benefit costs (see Table).

Employers can take steps to remove undesirable conflicts of interest and misaligned “PBM profit centers.” Such PBM profit centers arise when PBM profit is directly or indirectly aligned to total employer spending. One emerging contracting strategy for self-funded employers is the introduction of

TABLE

Strategies for Superior Pharmacy Benefit Cost Management

Contracting Strategies	Plan Design Strategies	Clinical Rigor	Cost-Effective Sourcing
<ul style="list-style-type: none"> • Deconflict pharmacy benefit manager (PBM) and medical carrier relationships (fiduciary compliant) • Reduced/fixed markups for provider buy/bill drugs • Outcomes-based drug pricing <ul style="list-style-type: none"> – Specialty generics filled in retail, not at specialty pharmacy – Payment amortization (pay over time) – Hospital at home/telehealth – Narrow networks – More timely and transparent reporting – Bill review/negotiation 	<ul style="list-style-type: none"> • All drug management under the pharmacy benefit • Dose-rounding protocols (for injectables) • More rigorous utilization management for high-cost drugs <ul style="list-style-type: none"> – Prior authorization/precertification functions – Preferred drug lists/formularies – Quantity limits – Step therapy – Specialty carve-out – Exclusions/coverage limitations • Aligned financial incentives with plan participants • Leverage secondary coverage when available (e.g., spouse employer, Medicaid or Medicare) 	<ul style="list-style-type: none"> • Separation of dispensing/rebates from clinical functions • Independent, expert clinical management • Cost-effective step therapy, when appropriate • Elimination of waste • Same level of clinical rigor applied to specialty drugs on medical side 	<ul style="list-style-type: none"> • Better align copay and patient assistance programs • Unrestricted, competitive dispensing options and sources • Site-of-care optimization for provider-administered drugs

Source: National Alliance of Healthcare Purchaser Coalitions, “Rethinking How We Mitigate High-Cost Claims,” June 2021.

fiduciary compliance into the benefit administration equation.

As defined by the Employee Retirement Income Security Act of 1974 (ERISA), there are three primary elements associated with the fiduciary role:

- No conflicts of interest
- A duty to look out only for the best interest of the plan and plan participants
- Full disclosure of all utilization and financial information (no hidden revenue or profit centers).

With the recent passage of the Consolidated Appropriations Act of 2021 and transparency in coverage regulations, there is now governmental support and regulatory drive to ensure that the fiduciary control remains with and is actively exercised by plan sponsors.

Plan Design Strategies— Medical Benefit, Pharmacy Benefit, Buy and Bill

Prescription drugs may be administered by hospitals or private physicians under the medical benefit (often termed as *buy and bill*) or through prescriptions and pharmacies under the pharmacy benefit. The costs of the drugs can vary depending upon the pricing at the site of service and the extent of medical intervention required for the treatments.

In general, outpatient care in a hospital setting creates higher drug costs than identical treatments in the private physician office setting. Medical intervention and oversight of administered drugs can vary by disease and specialty. Since drugs are not administered without an ongoing patient assessment, the buy-and-bill pro-

cess under the medical benefit can be the most effective care management strategy for costly treatments for patients with a rapidly changing health status. When patients are in a fragile health status or need to change treatments rapidly due to adverse events or lack of response, drugs ordered and shipped in advance become a waste and needless expense to an employer because once they are shipped from a pharmacy in response to a prescription for an individual patient, they cannot be returned or used for another patient. However, hospitals have acquired private physician practices in substantial numbers and, once treatment moves to a hospital-based system, the advantages of buy and bill may be offset by increased pricing on drugs and the addition of hospital facility costs.

Employers can reduce exposure to markups on some hospital-administered drugs by encouraging alternative care-delivery settings (such as private physician offices) or through moving some drug management under the pharmacy benefit and then shipping expensive medications to cost-effective sites of administration (such as shipping directly to the employee's home instead of to a hospital clinic). This strategy will not be effective in all situations: Many hospitals and physician offices refuse to accept drugs that come from outside sources due to liability, and many drugs and disease treatments are not suited for home administration.

Employers are also waving copays/coinsurance as well as deductibles to incentivize plan participants to adopt cost-effective sources of care and embrace quality-of-care opportunities.

The adoption of a center of excellence that contracts with large health systems could lead to inadvertent higher cost of drugs in the outpatient setting of those facilities than from appropriate alternative settings like private physician offices. Benefit design incentives should consider the full impact of such preferred networks on total cost of care.

Payments to hospital providers for drugs they administer and bill through carriers under the medical benefit are often hundreds of percent above the benchmark “list price,” known as the average wholesale price (AWP). If these medications were dispensed through a private physician's office or—if accepted by the hospital provider—shipped from a pharmacy or medical supply company at lower rates, some costs could easily be cut in half without changing the prescribed drug.

In some specialties, such as oncology, the coding structure for services deliberately left drug margins as the means for covering private office costs that were not covered by the conventional medical office professional fees. When the resource-based relative value scale (RBRVS), which is used to determine how much money medical providers should be paid, was created, the acute medical care private oncology community center did not exist. Years later, a review of the professional charges and drug reimbursements decided to leave oncology drug margins in place as the most effective way to cover the 75% of acute care community cancer center costs that were not covered by professional fees.⁵

PBM Clinical Rigor

There is also a strong movement to increase clinical rigor within overall benefit management and PBM oversight. Unfortunately, drug manufacturer incentives for PBM managers have led to a deterioration in clinical rigor and fiduciary responsibility in deference to profit margins. More than 70% of traditional PBM profits are derived from specialty medications. To address the decline in this clinical rigor, many employers are taking steps to separate dispensing profits and rebate incentives from clinical decision making. This is occurring in three primary ways: (1) utilization of independent clinical management firms to perform prior authorization and/or pre-certification review functions instead of the PBM or provider network administrator/carrier, (2) removal of the ability of PBMs to refer to pharmacy facilities owned by themselves or corporate affiliates, (3) the elimination or capping of buy-and-bill reimbursement under the medical plan for hospital-administered drugs to more appropriately align with buy-and-bill reimbursement in the private office setting.

PBM Fiduciary Responsibility and Dispensing

“Alternative sourcing” has also become a more commonplace buzzword to describe a range of drug sourcing and discount options outside of traditional PBM channels. When the PBM becomes the primary dispensing entity, or most of an employer’s pharmacy spending is paid to PBM or PBM affiliate-owned pharmacies, that introduces a significant conflict of interest that should be

a concern for any employer. The higher the employer spend and the higher the cost of dispensed medications, the more profits increase for the PBM and its affiliated companies. Strategies to avoid, or at least balance, the conflict include driving member utilization to the lowest cost dispensing physicians or pharmacies, which may not always be PBM-owned, particularly for mail-order and specialty pharmacies; encouraging members to participate in appropriate manufacturer copay assistance or zero-cost patient assistance programs; sourcing from an alternative (lower cost) site of care; and modifying buy-and-bill reimbursement for appropriate hospital-administered drugs.

To highlight the effectiveness of several of the strategies mentioned above, some employer examples follow.

Clinical Management Strategy Examples

\$601,855 Annual Savings

The employer decided to carve out the prior authorization review from its PBM to an independent third party. The PBM previously approved chronic use of a specialty medication for treatment of side effects attributable to another medication used for hereditary angioedema. Upon independent clinical review, a recommendation was made to use an inexpensive generic alternative for the add-on therapy and to lower the dose of the treatment drug. Both recommendations were consistent with nationally accepted guidelines. The treating physician agreed. The patient’s condition was well-controlled with no side effects. The plan saved more than \$600,000 per year.

\$991,118 Annual Savings

The employer decided to carve out the prior authorization from its PBM to an independent third party. A PBM approved HP Acthar® Gel for a 35-year-old male diagnosed with focal segmental glomerulosclerosis (FSGS). Previous steroid therapy had failed. Upon independent clinical review, based on the individual’s medical record, a combination of mycophenolate mofetil or cyclosporine with glucocorticoids was recommended. The prescriber agreed, the member’s therapeutic response was excellent and the plan saved over \$900,000 per year.

\$40 Million in Annual Savings for 30 School Districts Across the U.S.

Thirty school districts engaged in a program that operated in tandem with their PBM to advocate on behalf of members to increase utilization of lower cost therapy equivalents under the plan formulary and to provide in-depth clinical review and oversight of specialty medications. As of 2022, with time in the program ranging from one year to over seven years for individual districts, the program is saving the participants more than \$40 million annually in drug costs over and above the many cost-management programs also in place through their PBMs.

Plan Design Strategy Examples

\$233,000 Savings per Course of Chemotherapy Treatment

An employer moved hospital outpatient pharmaceutical coverage to the pharmacy benefit, thus excluding it under the medical benefit. Prior to

AUTHORS

the benefit change, the entity was paying \$248,000 per course of two chemotherapy agents to a prominent cancer center. After the benefit change, both agents were shipped from a pharmacy and billed through the pharmacy benefit at a combined cost of \$15,000 per treatment. This external provision of the drug (called *white bagging*) was allowed by the hospital but may not be in other situations.

\$2 Million Annual Savings

A union health and welfare trust fund was paying a local pharmacy \$3.5 million a year for hemophilia medications for three adolescent boys on the plan. Upon investigation from an independent consultant, it was determined that secondary coverage was available for all three boys. After making a benefit change related to the secondary coverage, the cost for the medications is being shared with the secondary payer, and the plan is saving over \$2 million annually.

Contracting Strategy Examples

Over 50% Reduction in Annual Pharmacy Benefit Spend

A service company with 4,300 employees contracted with a fiduciary pharmacy risk manager to manage its pharmacy benefit. The year prior to engaging with the firm, plan spending on prescription drugs had increased by more than 17%. After 12 months, the plan expenditures had dropped by more than 40% by leveraging more rigorous clinical oversight and accessing lower cost sourcing options that were not offered by the prior PBM un-



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der a traditional PBM model. After 24 months, plan spending is down a cumulative 58%. This equates to approximately \$2.8 million in annual savings and \$4.6 million in total savings to the plan over the year.

More Than \$12 Million Reduction in Annual Pharmacy Spending

A group with 10,000 covered lives accessed a clean and audited PBM con-

tract through a national coalition. The only source of revenue to the coalition was a per member per month transparent service fee. It received no payments from the PBM or drug manufacturers related to pricing, market share or rebates. By avoiding vague and misleading PBM contractual language and carving out prior authorization for specialty medications, the group was able to hold the PBM accountable for all

pricing and rebate guarantees in addition to reducing overall plan spend by over \$12 million annually.

Cost-Effective Sourcing Strategy Examples

\$1.1 Million Savings

A self-insured employer activated a variable copay assistance program through its PBM with more than 360 individual drugs included in the program. The plan saved more than \$1.1 million in the first 12 months of the program (an average of 20% savings for specialty drugs), which reflected approximately 8% of total drug spend for the year.

\$5.9 Million in Annual Savings


A large employer spending over \$14 million annually in the pharmacy benefit implemented a program providing access to pharmaceutical manufacturer patient assistance programs. After enrolling eligible members in the

programs, the plan was able to reduce total specialty prescription spend by approximately 80%, which at the time reflected over 40% of total plan spending. This strategy may not be available in all situations.

Additional Considerations and Next Steps

Human resources and C-suite management may question whether these strategies could add complexity or disrupt member access to care. Neither of those concerns appeared to be an issue for the employers that implemented the strategies described above when using experienced firms with proven track records. There was a low administrative burden on the plan sponsor other than approving member communications and fielding the occasional employee question.

There is no universal solution for every case. Exploring and implement-

ing options like these highlighted here should allow any employer to effectively reduce and mitigate its pharmacy benefit risk while also allowing it to better withstand high-cost claims when they arise. 

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The Three Most Misunderstood Words in Health Care: Fraud, Waste and Abuse

by **Susan A. Hayes, D.Crim.J.** | *Pharmacy Investigators and Consultants*

When reading the words “fraud, waste and abuse in health care,” many people likely think of shady physicians upcoding claims for services they never rendered followed by a massive bust by the Department of Justice or FBI. Like all professionals, physicians, nurses and pharmacists can be charged with committing fraud. In September 2021, 138 defendants—including 42 doctors, nurses and other licensed medical professionals—in 31 federal districts across the United States were arrested for their alleged participation in various health care fraud schemes that resulted in approximately \$1.4 billion in alleged losses (Department of Justice website, 2021). These kinds of schemes would make for a great television series, like *The Pharmacist* true crime series on Netflix.

But waste is an even bigger problem that does not make for great binge-worthy television shows. And it’s a problem that has been exacerbated by the pandemic.

What Is Waste?

To understand waste in prescription drugs, it’s important to first understand how a pharmacy claim is processed.

In 2001, the National Association of Chain Drug Stores and the National Community Pharmacists Association, together with the leading three pharmacy benefit managers (PBMs)—OptumRx, Express Scripts, Inc. and CVS/Care-

AT A GLANCE

- Employers that sponsor health plans need to be aggressive in directing pharmacy chains and independents to not allow medication autorefills and autofills, since unlike with Medicare and Medicaid, there are no laws prohibiting this practice for commercial plans.
- Plan sponsors can also require an aggressive pharmacy benefit manager (PBM) fraud, waste and abuse (FWA) program that includes requiring patient signatures for every prescription dispensed, with reporting to plan sponsors the results of this program.
- Employers should insist that PBMs put programs in place to prevent medication from being “recycled” within the pharmacy, as pharmacies outright not reversing claims is fraud, particularly if that medication is bought a second time.

mark—formed an alliance called SureScripts (SureScripts, 2022). This alliance allowed prescription drug orders to be sent electronically from a patient’s electronic medical record (EMR) to the pharmacy. Patients no longer had to take handwritten prescriptions to the pharmacy, wait for the prescription to be filled and then go home to take the medication.

According to the 2021 SureScripts *National Progress Report*, 35 states—including New York, California and Florida—representing 75% of all U.S. residents, now require all prescriptions to be prescribed electronically. The remaining 23 states and territories have pending or enacted legislation. In the next few years, all prescriptions will likely be processed electronically since 99% of all people in the U.S. are represented in the SureScripts database (SureScripts, 2021 *National Progress Report*, p. 2).

When a prescription is sent from a patient’s EMR to the pharmacy, the pharmacy immediately begins the adjudication process. This means that the claim is electronically sent to the patient’s PBM, which prices the claim and checks for eligibility for both the patient and the drug. Any other requirement, like a prior authorization, is checked by pharmacy personnel. Documentation is retained by the pharmacy—No actual documents are sent to the PBM.

Electronic claims processing has achieved the following:

- Reduced the median wait time for a prior authorization decision by more than two-thirds, from 18.7 to 5.7 hours
- Made it easier to understand whether prior authorization was required for 60% of users
- Improved timeliness of care for 71% of users.

PBMs and health plans representing 98% of insured patients are contracted by SureScripts for electronic prior authorization. Because less time is being spent on prior authorization, critics have questioned whether this has come at the cost of meaningful clinical counseling between patients and providers to ensure medical necessity. Prior authorizations may not be receiving thorough and proper clinical oversight or a complete medical necessity determination. This really is the first stop is understanding how waste occurs.

The next stop in understanding waste is the practice of autorefills and autofills. *Autorefills* are system-generated messages from the pharmacy to the prescriber asking for the pre-

scription to be refilled. In most states, the physician must see the patient annually to refill a prescription, but physicians—many of whom are overworked—will generally refill the prescription without seeing the patient, especially for chronic conditions. “This (autorefills) is a major flaw with pharmacy automation (and) is well-known to the industry. But there hasn’t been much movement to fix the problem,” states Michael Cohen, R.Ph., in a *Philadelphia Inquirer* article (Cohen, 2015). Unfortunately, rarely do patients or their doctors remember to communicate to the pharmacy a discontinuation of a prescription. And if the pharmacist doesn’t know about changes, the computer is not reset. “The auto-refill system just keeps rolling along, dispensing unneeded and possibly harmful medicines,” said Cohen.

Autofills are another problem. Autofills occur at regular intervals so that the patient’s medication will never run out. Take the example of a physician who writes a prescription in January for a year’s supply of a medication, refillable every 30 days. With autofills, when 75% of the prescription is consumed at day 22 for a 30-day fill, the pharmacy system generates the fill, a robocall is generated to the patient and the medication awaits the patient’s return to the pharmacy. Particularly during the pandemic, some local chains were mailing the autofills to patients and automatically charging the copay to the patient’s credit card on file and the balance of the cost to the plan sponsor. With autofills, at 22-day intervals, a prescription could be refilled 16 times with a whopping 497 days’ supply within a 365-day period. An article in *Consumer Reports* (Gill, 2020) even told patients exactly how to get their medication autofilled (and switched to even greater and more wasteful 90-day supplies).

This system can generate waste because the patient may no longer need or want the medication.

Both autorefills and autofills are prohibited by Medicare Part D and Medicaid regulations unless they are approved by the patient. Retailers and PBMs have been hit with judgments and investigations over the use of these refill programs (Mazina, 2018) for Medicare and Medicaid patients.

If this avalanche of medications is not picked up in the pharmacy, what happens to them? Called *abandoned* or *unclaimed prescriptions*, these medications are typically returned to stock by pharmacy technicians. The cost to restock

and reverse these claims is about \$25 per prescription in time and materials (Doucette and Al-Jumaili, 2016). The workload for pharmacy technicians increased during the pandemic, as they were asked to take on additional details, including giving vaccination shots. But staffing levels did not increase, and many stores lost workers and struggled to fill positions. This may mean that return-to-stock duties, including the reversal of prescriptions, were relegated to the back burner by pharmacy technicians who just attempted to get through a shift at the pharmacy (Kaplan, 2021). Reversing the claim (and not just returning the medication to stock) is important because that is the step that takes the charge off the invoice submitted to plan sponsors by PBMs.

Lastly, many executive orders by governors suspended rules imposed by managed care to obtain patient signatures on prescriptions (Council of State Governments, 2021) in states such as Michigan, California and New Jersey. Many of these rules remain in place, although some are scheduled to expire in late 2022. Therefore, there was really no record in the pharmacy to substantiate whether a patient actually picked up medications, and auditors' hands were tied in attempting to ascertain whether patients did consent to autorefills or autofills or whether they requested and picked up the medication refills.

What Is the Impact?

With more prescriptions to fill than ever, no check of autorefill or autofill prescriptions in commercial plans, no one able to return medication to stock,

and no auditors able to enforce patient signature mandates, wasteful prescription drugs were dispensed. It is possible that many medications were adjudicated and paid for by one plan sponsor, then put back on the shelf only to be paid again by another plan sponsor (referred to as *recycled medications*).

Further, automation of the prior authorization process has yielded increases in specialty drug dispensing. Drug Channels Institute estimates that in 2020, retail, mail, long-term care and specialty pharmacies dispensed about \$176 billion in specialty pharmaceutical prescriptions (Fein, 2021). That's an increase of 9.1% from the 2019 figure. The top three dispensers of specialty medication are PBMs (CVS, Express Scripts and Prime Therapeutics). In 2020, overall pharmaceutical expenditures in the U.S. increased by 4.9% compared with 2019, for a total of \$535.3 billion. Utilization (a 2.9% increase) and new drugs (a 1.8% increase) drove this increase, with price changes having minimal influence (a 0.3% increase).

These increases in pharmacy spending occurred at the same time the American Medical Association was reporting a dramatic decrease in medical visits (American Medical Association, 2022). The Medicare Physician Fee Schedule (MPFS) spending dropped sharply in March and April of 2020, falling as much as 57% below expected levels. Although it recovered from the April low, MPFS spending in the fourth quarter of 2020 was still 10% less than expected. For all of 2020, the estimated reduction in Medicare physician spending associated with the pandemic was \$13.9 bil-

lion (a 14% decrease compared with the expected reduction). An estimated 39% of Medicare fee-for-service enrollees received a telehealth service in 2020, up from less than 1% in 2019.

In other words, even though patients went to their physicians much less frequently, drug spending increased along with the frequency of dispensing medications.

Plans had to foot the bill for this. The Society for Human Resource Management (SHRM) states that health plan premium cost increases are estimated to be around 5% in 2022 and back to prepandemic levels (Miller, 2021). Some consulting firms have projected the annual cost trend will be as high as 8.4%, mostly driven by price increases and new specialty drugs.

What Can Be Done to Reduce Waste in Pharmacy Spending?

One way to identify when patients pick up drugs would be for health plans to text members that a prescription has been paid for on their behalf. Members could then easily notify their plan if a prescription has been adjudicated but not requested by the patient. These texts would be similar to the ones sent by banks when customers make a payment, have an unusually high dollar charge or change their password. If the patient indicated that they did not order the prescription or never picked it up, the PBM could then reverse the claim. Plan sponsors may encounter some resistance to this system since it would reduce the number of prescriptions dispensed and therefore reduce revenue to the PBM.

Fully insured plans are at risk for the cost of prescription drugs and should also be interested in wasteful spending. However, many of these plans simply pass on the additional costs in higher premiums. Many insured plans also never provide plan sponsors with claims history, so plan sponsors do not know to ask members whether they received the medications (i.e., through an explanation of benefits or through texting).

Other challenges to this approach include laws that govern texting confidential protected health information (PHI) to members and dependents such as the Health Insurance Portability and Accountability Act (HIPAA) and the Telephone Consumer Protection Act. Further, plans have also not been proactive in obtaining up-to-date cell phone numbers for members, let alone spouses and dependents. This makes texting problematic for health plans (with multiple and underage dependents) as opposed to banking, where the relationship is between a single account owner and the bank.

Like Medicare and Medicaid programs, employer-sponsored plans should only allow PBMs to autorefill or autofill medication at the patients' request *and* prohibit this practice by pharmacies through network contracting. Pharmacy network contracts between PBMs and network pharmacies should strictly prohibit autorefills and autofills unless patients have authorized these programs on a prescription-by-prescription basis. It may be difficult to obtain this safeguard since both pharmacies and PBMs profit from these practices.

Another option is to directly contract with a separate non-PBM entity for fraud, waste and abuse auditing. This would provide employers with visibility of pharmacy practices.

Wasted Away Again

Considering the expense of medications, plan sponsors cannot afford waste in the prescription drug plan. U.S. Surgeon General C. Everett Koop famously stated in 1985 that "Drugs don't work in patients that don't take them." Sadly, drugs don't work in patients who don't take them, even if their employers are paying for them. Plan sponsors should take aggressive stances with PBMs, directing pharmacy chains and independents to not allow autorefills and autofills since, unlike with Medicare and Medicaid, there are no laws prohibiting this practice for commercial plans.

AUTHOR




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She has consulted to employers, unions, government agencies and state plans for more than 40 years. She is a testifying expert in leading pharmacy cases such as *Rutledge v. PCMA*.

In addition to her consulting work, she is the director of the Health Care Ethics and Analytics Program and assistant professional practice professor at Roosevelt University. Hayes holds a bachelor's degree in criminal justice from Northeastern Illinois University, a master's degree in criminal justice from Boston University, Metropolitan College, and a doctorate degree in criminal justice from the University of Portsmouth, United Kingdom. She is a certified registered pharmacy technician in the State of Illinois and a licensed private detective in Illinois and Washington.

In 2012, Hayes earned her Accredited Health Care Fraud Investigator (AHFI®) designation from the National Health Care Anti-Fraud Association.

Plan sponsors can also require their PBMs to have an aggressive fraud, waste and abuse program that includes requiring patient signatures for every prescription dispensed and reporting to plan sponsors the results of these programs. It is fraudulent for pharmacies to not reverse claims for unclaimed prescriptions, particularly if the medication is "bought" a second time. A flimsy fraud, waste and abuse program that looks the other way on such activity amounts is a fraudulent scheme.

It is doubtful that the next Netflix drama will be titled *Wasted Away Again in the Pharmacy*. But plan sponsors should realize the occurrence of "recycled" medication at pharmacies (paid for by two or three plan sponsors) and insist that their PBM put programs in place, such as fraud, waste and abuse monitoring programs and text verification. Plan sponsors should not be the losers by paying for wasted medication. 

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Prescription Digital Therapeutics: A Treatment Tool for Substance Use Disorder and Other Diagnoses

by **Barbara Fahmy** | *ClearLight Writing and Editing Services, LLC*
and **William Lacy** | *Association for Corporate Health Risk Management*

The U.S. health care system continues to be plagued by the devastating effects of the opioid crisis, alcohol abuse and other substance use disorders (SUDs). The rise in prescription opioid overdose deaths began way back in 1999. When attempts to curtail prescription opioid abuse started to occur, patients turned to heroin, which caused a second wave of increased mortality beginning in 2010. The third spike in overdose death rates began in 2013 thanks to synthetic opioids. Not surprisingly, there is widespread consensus that the United States has largely failed at treating addiction. As COVID-19 lockdowns cut patients off from mental health services, support groups and other support systems, the challenges of keeping patients safe and alive have intensified.¹

Prescription digital therapeutics (PDTs) are a new class of software-based disease treatments that deliver evidence-based therapeutic interventions through a smartphone or tablet. Unlike nonprescription digital therapeutics (DTs) or wellness apps, PDTs are authorized by the Food and Drug Administration (FDA) to treat specific disease conditions.² At the time of this article writing, the FDA has thus far authorized nine PDTs (including for treatment of SUDs,

chronic insomnia and chronic low back pain), although the list is likely to continue to grow.³

This article describes how PDTs can make a positive impact on helping those who suffer from opioid addiction and

AT A GLANCE

- Pharmaceutical digital therapeutics (PDTs) are a newly created medical device class and software-based solution approved by the Food and Drug Administration (FDA) that may significantly reduce patient and employer costs relative to treatment as usual for substance use disorder (SUD) and other conditions.
- Nine PDTs are available currently, but numerous others are in development that offer evidence-based interventions for a wide range of conditions.
- Potential early adopters could be industries that require random drug testing, such as trucking, police/fire, construction and health care, since PDTs for SUD provide flexibility to meet with therapists and physicians in the privacy of patients' homes at a convenient time schedule.

other SUDs. It will offer a case study on how the Teamsters Health and Welfare Fund of Philadelphia and Vicinity has embraced and supported the use of software-based treatments for its beneficiaries.

There are several key differences between PDTs and conventional DTs, wellness applications and other forms of health information technology (IT). Specifics of how a patient enters and progresses through PDT interventions will also be discussed.

As with any new treatment, acceptance by employers, payers, health care providers, claims managers and other stakeholders requires communication and education. The authors will propose avenues for reaching these objectives.

How PDTs Work

Use of the PDT begins first with a physician writing a prescription. When the application appears on the patient's device, they enter identifying information and accept the terms, just like any other application. The software is encrypted and approved under the Health Insurance Portability and Accountability Act (HIPAA) for privacy. A typical treatment period for a patient with an SUD is about 12 weeks. During this period, the patient is asked to complete lessons, answer questions and enter into the application if any cravings or lapses occur. A built-in contingency system allows the patient to receive rewards when certain benchmarks are achieved, keeping the patient motivated and engaged.

Throughout the treatment period, the physician has digital access to all

information and can evaluate progress. Patient data can be collected in real time as opposed to waiting until the next medical appointment.

How Do PDTs Differ From DTs?

PDTs differ from DTs in several key areas that can have a major effect on patient outcomes.

- PDTs require a physician prescription. Thus, a credentialed and licensed health care professional determines whether this treatment might be beneficial to the patient.
- The physician also monitors patient progress.
- PDTs are subjected to the rigors of FDA regulations to become approved as safe and effective.
- PDTs must comply with FDA requirements of current good manufacturing practices (CGMP).⁴

Although some scientific research supports the concept of DTs, it is normally not as rigorous as the clinical trials and other regulatory requirements dictated by the FDA. Also very important to remember, the requirements to report continued safety, efficacy and adverse events do not end with initial FDA authorization. The sponsoring agency must continue to comply with regulations for the documentation of adverse events and subsequent research results.

More About PDTs and FDA Authorization

The FDA authorized the first mobile application for SUDs in 2017. A large part of the FDA approval process is the analysis of medical evidence and clinical trials. The results of a 399-

person study were quite positive, with an increase in adherence to abstinence from alcohol, cocaine, marijuana and stimulant SUDs. The results were deemed clinically significant, with a 40.3% increase in adherence to abstinence compared with only 17.6% for those who did not use the app.⁵

Also, it's important to note that with all pharmaceuticals and medical devices, including PDTs, the FDA authorizes use for specific disease conditions, indications and contraindications. This requirement should impart credibility and security to employers, benefits managers and health care providers in that the device or pharmaceutical has been adequately scrutinized and fits the unique needs of the specific patient.

On a more comprehensive scale, in 2018, the FDA launched an innovation challenge to combat the continuously worsening opioid crisis. The objective of this challenge is to create novel solutions, including digital health technologies, that detect, treat and prevent addiction.⁶

"Medical devices, including digital health devices like mobile medical apps, have the potential to play a unique and important role in tackling the opioid crisis. We must advance new ways to find tools to help address the human and financial toll of opioid addiction," FDA Commissioner Scott Gottlieb⁷ stated.

Blazing Trails

Similar to the distribution of pharmaceuticals and medical devices, PDTs have comparable entry channels. These include:

- Pharmacy benefit managers (PBMs)
- Prescribers (such as physicians and nurse practitioners)
- Pharmacies
- Employers/payers
- Employees/patients.

The Challenges

PDTs cost a fraction of drug-based treatments. This could cause revenue concerns for PBMs, treatment clinics and other medical providers. Because PDTs are relatively new to the arsenal of treatment options for SUDs, many professionals lack

familiarity with the potential advantages. Some may question logistical issues, such as the lack of high-speed internet, unpredictable Wi-Fi or other access issues; although use of smartphones and other mobile devices is widespread, such access is not guaranteed for everyone.⁸

CASE STUDY

A Plan Sponsor's Perspective

Tanika Smith and Maria Scheeler from the Teamsters Health and Welfare Fund of Philadelphia and Vicinity share their accounts of working with plan members to address an increasing need for accessible services.

“Over the last three years, 2019 to 2021, the Teamsters Health and Welfare Fund of Philadelphia and Vicinity has seen a significant increase in members seeking overall mental and behavioral health services. There has also been a growing concern about new or increased substance use due to COVID-19 pandemic-related stress as utilization in the employee assistance program has increased by 15% just for SUDs. Due to the rise in SUDs and an increasing need for accessible behavioral health services during the pandemic, the fund recognized that it needed another tool to support its members.

This need led to the seeking out of prescribed digital therapeutics (PDTs) and the 24/7 support they could provide to those members in need. If a prescribed phone application could increase a member's odds of success when in treatment for an SUD, then the fund needed to make this option available. After seeing the published clinical data that demonstrated the success of PDTs in conjunction with therapy, it only made sense that the fund add them to its pharmacy benefits plan.

The goal with PDTs is to provide members who have an SUD with another opportunity to be successful in their treatment. Not only are PDTs shown to be successful, but they are also cost-efficient in the overall course of care.”

Tanika Smith, Director of Communications,
Teamsters Health and Welfare Fund of Philadelphia and
Vicinity

“I see the use of PDTs as a viable option for those experiencing an SUD. I'm responsible for overseeing member services for about 17,000 covered lives. Teamster members include truckers and warehouse workers who are subject to random drug testing per rules of the Department of Transportation (DOT). The Teamsters fund provides numerous traditional benefits for SUDs, such as inpatient and outpatient rehabilitation and counseling. It is in the period of aftercare that patients have the highest risk for relapse.

We have identified several unique benefits of PDTs:

- *Patients feel more comfortable meeting virtually from their homes as compared with in person at a therapist's office where they may feel judged or embarrassed by not making progress (although this would never be the intent of the therapist). Entering information over a smartphone creates a feeling of privacy.*
- *Truckers have 24/7 schedules in multiple locations and are faced with an abundance of “alone” time. A PDT offers greater flexibility and can also help the patient through cravings and triggers while they are isolated.*
- *Often, cravings for drugs or alcohol occur in the evening hours when the therapist is typically not available. A phone app is always at the patient's fingertips.*
- *PDTs provide users with rewards, which keep them engaged and progressing.*

About 500 of our 17,000 members may be PDT candidates. Of those, about 70% of them are 19- to 26-year-olds, a demographic that normally has a very high usage of mobile phones.”

Maria Scheeler, Administrator Executive Director,
Teamsters Health and Welfare Fund of Philadelphia and Vicinity

Another issue that understandably causes confusion, as one analyst put it, is that “The world is awash in apps.” Health-related apps number in the tens of thousands. Although there could be some benefit to using them, they can also be innocuous or frivolous.¹⁰ A large portion of them are simply vehicles for advertisements.

Potential Solutions

There are a number of potential solutions that may encourage all stakeholders to take a closer look at the value of PDTs. One of these solutions is obviously to keep decision makers informed about not only patient safety and efficacy but also cost-effectiveness.

In a clinical study that compared health care resource utilization between patients with opioid use disorder who used one PDT vs. those who did not (n=444), a net savings of \$2,708 per patient was realized over a period of nine months. The savings was largely driven by a 46% decrease in hospital-related stays.^{11, 12}

In another study, researchers documented similar results. Substantial savings (\$2,385/patient) were realized for hospital-based services among patients who received treatment through a PDT.¹³

Employers may also choose to adopt a pull-through strategy whereby the employer pushes for the PDT intervention as a less invasive initial strategy due to cost-effectiveness, at-home options or the desire to support less reliance on drugs. Alternatively, employers could demand PDT as a more effective option after a patient has relapsed or attempts at drug-based therapies have failed.

Additional support for PDTs may be leveraged through occupational medicine physicians as early adopters. Physicians who perform random drug tests would be able to identify patients who could benefit from PDTs.

The sidebar describes how one health and welfare fund implemented a PDT benefit.

Summary and Concluding Remarks

When determining whether to utilize prescription versus non-PDTs for beneficiaries, it is critical to keep the main differences between PDTs and non-prescription mobile health apps in the forefront. In a recently released article on the value of PDTs, thought leaders at the

Greater Philadelphia Business Coalition on Health drew comparisons that offer an excellent summary of the similarities and differences between PDTs and mobile apps as shown in the table.

In recent years, major trends have emerged that PDTs can help address, including:

- The growing burden of disease
- Health care provider shortages
- Increases in the use of telemedicine
- The growing pervasiveness of technology.¹⁴

In December 2020, the Centers for Disease Control and Prevention (CDC) issued a Health Alert Network (HAN) advisory regarding a concerning ac-

TABLE


Comparing Prescription Digital Therapeutics With Mobile Apps

Prescription Digital Therapeutics	Mobile Health Apps
Are evidence-based, having been assessed for efficacy through clinical trials	Provide easy access to information related to conditions or treatments
Target a specific disease or disorder	Help health care professionals improve and facilitate patient care
Go beyond routine patient monitoring	Promote health and wellness
Undergo Food and Drug Administration (FDA) evaluation for authorization as medical devices	Not FDA-regulated and do not require FDA authorization
Require a prescription from a provider	May not be rigorously evaluated, with findings subject to external review
Provide 24/7 access to clinically validated treatment	

Source: J. Mak. (2022). “Prescription Digital Therapeutics: Evidence-Based, FDA-Approved.” Greater Philadelphia Business Coalition on Health: Employer Action Brief. www.gpbch.org.

celeration of fatal drug overdose deaths between March and May of 2020. The HAN cited COVID-19 lockdown and isolation measures as a main driver of the spike.¹⁵

The 12-month period ending in May 2020 recorded a staggering 81,230 drug overdose deaths. (It should be noted that the lockdowns were not occurring during the previous year, in 2019.) This represents the highest number of annual drug overdose deaths in the U.S. ever recorded.¹⁶

As stated at the beginning of this article, increases in drug overdose deaths began over 20 years ago, in 1999.¹⁷ Health care industry leaders are now presented with an opportunity to respond to the rapidly growing alarm of SUDs. Provider shortages have undoubtedly contributed to the problem. The growing acceptance of digital technology and telemedicine might well represent a viable strategy in helping to quell the tragic consequence of addiction. Everyone knows that there is no “magic bullet.” Still, PDTs have a place in the arsenal of efficient and effective treatment strategies. 

The authors acknowledge the contributions of Mary Seery of Pear Therapeutics to this article.

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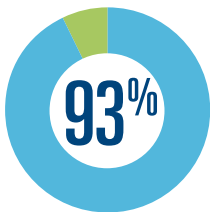
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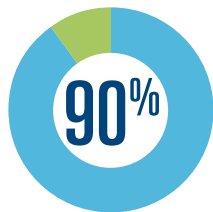
Millennials and Health Care

Almost half of Millennials don't have a primary care provider even though they would like to have one, author Melina Kambitsi, Ph.D., writes in her article "Advanced Primary Care: Meeting Millennials' Needs and Reducing Health Care Costs" on page 26. Kambitsi details the challenges that exist for increasing Millennials' use of primary care and suggests that advanced primary care is one model to consider to overcome those obstacles.

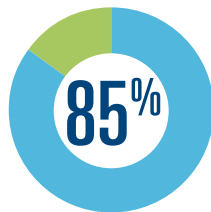
Millennial Health Care Attitudes*



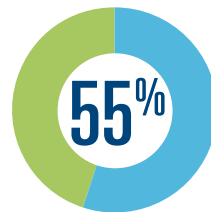
want to establish a primary care relationship



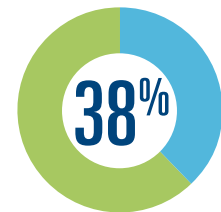
want mental health support from their doctor



believe providers only care about them when they're sick



say online information is as reliable as their doctor



trust their peers more than their physicians

Challenges for Increasing Millennial Utilization of Primary Care

- › Lack of trust
- › Low or no access to care
- › Fragmented care
- › Lack of cost and quality information

Advantages of Advanced Primary Care Models

- › Lower costs
- › Built-in care navigation
- › Enhanced patient access to physicians
- › Evidence-based medicine
- › Risk-stratified care management
- › Care coordination
- › Behavioral health integration
- › Realigned payment methods



*Statistics derived from a variety of sources cited in "Advanced Primary Care: Meeting Millennials' Needs and Reducing Health Care Costs."

Advanced Primary Care: Meeting Millennials' Needs and Reducing Health Care Costs

by **Melina Kambitsi, Ph.D.** | *The Alliance*

Millennials (those born between 1981 and 1996) make up nearly a quarter of the entire U.S. population. It's not surprising, then, that they are projected to spend an estimated \$3.4 trillion¹ on health care in the future. But their participation in the current health care marketplace is lacking due to—among other contributors—obscure pricing, poor convenience, lack of informational tools and an outdated patient experience.

This article will take a deeper look into the future of health care, how Millennials might influence it and how advanced primary care (APC)² may help in unlocking Millennial trust.

Personalized Primary Care

A Kaiser Health Foundation study³ found that almost half of adults ages 18 to 29 did not have a primary care provider (PCP). And because so few of them have an established PCP when compared with older generations, experts previously speculated that they were simply not interested in primary care—that they only value convenience.

On the contrary, Welltok⁴ found that 93% of Millennials do want to establish a PCP relationship. So why aren't those connections happening? While it's true that Millennials want health care that's fast, effective and convenient, they

also want health care that's personalized. In that same survey,⁵ 85% of respondents said providers only care about them when they're sick.

AT A GLANCE

- Millennials make up nearly 25% of the U.S. population and will soon account for a large portion of future health care costs, but their participation thus far in the current health care system has been lacking—specifically within the realm of primary care.
- Although primary care should be used by patients first and most frequently, primary care utilization is trending downward, and Millennials—among other factors, such as consolidation and diversification of primary care—play a large part in that downward slide.
- Advanced primary care (APC) may be one solution to increasing primary care utilization among Millennials while lowering costs for employers. It also may improve employee health and well-being as well as engagement and satisfaction with their health plans.

Convenience and personalization are just two pieces of the puzzle. Millennials also prefer a holistic approach to health care: A whopping 90% say they want mental health support from their doctor.

In other words, Millennials care about building an equitable relationship with their PCP and want to feel supported in improving their physical and mental health. More than 80% of respondents said their doctor would serve them better if the doctor understood them on a personal level, including their goals and interests.

The Issue of Trust

For Millennials, that perceived lack of personalization seemingly produces mistrust with physicians. Per *Forbes*,⁶ “38% [of Millennials] say they trust their peers more than their physician. Additionally, over half (55%) said the information they find online is ‘as reliable’ as their doctor.”

Similarly, Millennials don’t believe that their insurers have their best interests at heart either. In a 2019 HealthEdge survey⁷ of more than 5,000 Millennials, over half of them graded their current health plan as an “F” with just 53% believing their current health plan is the most effective option in administering their benefits. Meanwhile, 62% found their health plan’s communications satisfactory, ranking them a “D.”

Low or No Access

Consolidation remains the leading cause of the loss of independent PCPs and private practices;⁸ the percent of PCPs who worked for large health systems jumped from 28% to 44% between 2010 and 2016 alone.⁹

Then, from 2016 to 2018,¹⁰ roughly 14,000 independent physicians left private practice to work in hospitals. Because primary care practices rely heavily on fee-for-service payments, the pandemic has likely added fuel to the fire, exacerbating the rate of consolidation. Hospitals see primary care as a feeder into specialty care, with PCPs diagnosing issues and sending patients to a specialist for treatment. And since specialties are generally more profitable, more money and resources are devoted to them than to primary care, meaning there’s even less focus on prevention.

According to the Health Resources and Services Administration (HRSA), more than 80 million people live in what

they consider a *primary care shortage area*,¹¹ meaning the supply of PCPs does not meet the needs of the local population. The criteria are based on a 3,500:1 ratio of patients per physician. Nearly 20% of the U.S. population¹² resides in a health professional shortage area; the majority of these areas are dominated by rural counties.

Because primary care practices are being consolidated or closed, there’s a lower supply of PCPs that, coupled with their uneven geographic dispersal, leads to an inadequate supply of appointments. This is especially true for last-minute appointments—a type of consumer-convenient appointment that’s highly prized by Millennials.¹³

Fragmented Care

Not only is primary care being offered in fewer places and used less by patients, it’s also often organized in a way that prevents physicians from understanding and addressing the situational factors in patients’ lives.

Today’s health care system offers more flexibility and financial opportunities for physicians who practice within specialty care, which is partially why specialties within primary care itself (family medicine, internal medicine, general pediatrics, geriatrics, etc.) are growing in combination with other niche medicine specialties (sleep medicine, sports medicine, etc.).

Previously, PCPs approached patient needs from a generalist standpoint; they addressed a broad variety of symptoms and focused on holistic care—what Millennials actually value—rather than seeing patients for individual health concerns.

Lack of Cost and Quality Information

Several price transparency problems¹⁴ face health care today, and Millennials, perhaps more than any other generation, value accurate cost estimates before undergoing treatment. In fact, Millennials are almost twice as likely as Baby Boomers to shop for cost estimates online.

Still, high prices, surprise billing¹⁵ and lack of quality, accessible information are thwarting their confidence. Seventy-nine percent of Millennials found health care too expensive, and 77% said costs were too unpredictable. That lack of confidence has caused nearly half of Millennials to delay treatment¹⁶ or, even worse, forgo it altogether.

Priority No. 1: Improving Price Transparency

For health care providers, breaking down these barriers is the key to unlocking that \$3.4 trillion worth of future care. So how can they do it?

As a start, health care providers and insurers can work together to become more transparent and offer adequate information that's conducive to "shopping." Knowing the total price of care before a patient receives treatment would go a long way toward getting Millennials to seek more care. In addition, creating tools that allow users to search providers by doctor ratings, facility quality and more would improve the patient experience.

Health care providers would benefit by catering to Millennial preferences; offering accessible, easy-to-digest information on price and quality would boost consumer confidence and increase health care utilization long term. More health care consumers would equate to more money for health systems and better health outcomes for individual consumers—a win-win.

But while price transparency is gaining national attention (see RAND Corporation's Hospital Price Transparency Project)¹⁷ and bipartisan legislative support (see the Transparency in Coverage ruling from the Centers for Medicare & Medicaid Services (CMS) and other federal rules),¹⁸ health care providers are strongly resisting or outright refusing to comply thus far.¹⁹

Advanced Primary Care as a Solution

The fragmented, impersonal and sometimes inaccessible primary care options wrought by the pandemic have highlighted the need for a new primary care solution—one that focuses on the whole person and places an emphasis on preventive care. APC is one such option that employers have turned to.²⁰

The goal of APC (also known as *direct primary care*) is to improve patient health and lower the total cost of care. Its main features also may heavily appeal to Millennials. APC is often offered through a clinic that provides holistic, patient-centered care that combines physical, mental and nutritional health. Its goal is to create a trusting patient-physician relationship while utilizing an alternative payment method (a flat, monthly membership fee) with the goal of improving individual access to high-quality care.²¹


Advantages of APC clinics for Millennials and employers include the following.²²

- **Lower costs:** APC measures success by a patient's health status rather than the revenue generated from visits, tests and procedures. And by not simply treating acute symptoms and placing a larger focus on preventive health, physicians seek to help patients become less likely to experience worsening symptoms and prevent more serious problems down the line. The hope is that the need for costly specialty care should become less likely as patients' issues are treated and managed by their primary care doctor.
- **Built-in care navigation:** When a physician does have to refer a patient to a specialist, they can work with their team to make a high-value decision and help the patient navigate their in-network options. APC physicians use a narrow list of specialists to refer care to and remain in contact to develop a cohesive treatment plan.
- **Enhanced patient access:** The APC model calls for physicians to spend more time with patients and offer an enhanced scope of services, more immediate care availability (like same-day appointments) and availability outside of clinic operation hours.
- **Evidence-based medicine:** Care teams avoid test orders not linked to evidence and only refer care to specialists when absolutely necessary. For example, a clinic is more likely to refer patients who need magnetic resonance imaging (MRIs) to a freestanding clinic instead of a hospital, which usually results in a cost savings.
- **Risk-stratified care management:** Each patient receives care based on their unique needs, including extended office visits, care manager guidance, monitoring and tracking, phone checkups, etc.
- **Care coordination:** Care teams engage in outreach, including chronic condition management, coordination of care and work to ensure patient understanding of medications, orders, adherence expectations, etc.
- **Behavioral health integration:** Using patient records, care teams can identify patients who may need outreach to assess mental health needs, supporting patients through ongoing treatments.

- **Realigned payment methods:** The care management team is rewarded based on quality of care—patient experience, resource use and referrals—instead of volume of care (fee for service).

The Issue With Advanced Primary Care

So why aren't all employers jumping to provide their employees with APC? The short answer is that it isn't easy to find. While some high-quality health systems provide excellent primary care, there is often a breakdown in what happens after the visit. Finding networks that offer more independent physicians that work outside the health system can also be challenging.

As a result, an increasing number of employers are opting to open their own clinics, either independently or with partners that have expertise in providing APC. This is generally a type of primary care offered directly to employers or consumers and is independent of a larger hospital system. This type of care utilizes an alternate payment method, most often capitated with a monthly cost. The goal is to improve access to high-quality care by offering a flat, affordable membership fee and with little to no cost for employees. Removing that financial barrier should increase the patient's utilization of high-quality care and, as a result, patient groups could be expected to report higher levels of engagement and satisfaction. Because the clinic is typically near (or at) an employer's worksite, the patient doesn't need to commute to their appointment and, if they do, almost all APC clinics offer a form of telehealth services. 

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Pushing the Boundaries: Emerging Global Health Care Needs for a Work-From-Anywhere Culture

by **Noelle Weinrich** | *GeoBlue*

Remember missing the train? Rush hour traffic? Changing out of your pajamas? What a nightmare. Even if you're still going into the office every morning, millions of others are joining the "great cubicle exodus" in exchange for a more flexible, remote lifestyle. The trend had already begun before anyone mentioned the COVID-19 pandemic. Technology was advancing, communication platforms were popping up left and right, and the next generation of employees was stepping into their roles already groomed for a virtual workspace. The pandemic just served as the final push for many of us hanging onto our name tags and key fobs. There is no question; remote workforces are here to stay. But an important question remains—Are employers ready? As the world becomes more adept at hosting virtual meetings and managing employees via dashboards and portals, the workforce will continue to push the boundaries—literally and figuratively—and move toward a work-from-anywhere culture. Remote workers are looking beyond their home offices, kitchen tables and spare bedrooms to find that remote opportunities truly open a "world" of possibilities.

Who Are These Digital Nomads?

Employees are redefining what it means to work remotely. According to the 2020 *State of Independence in America Re-*

port, digital nomads make up almost 11 million people in the United States.¹ Within that group, traditional workers who now identify as being "location independent" nearly doubled from 3.2 million in 2019 to 6.3 million in 2020.² Over the next two or three years, that number is expected to rise,

AT A GLANCE

- Employees are demanding more flexible working arrangements, with remote work being redefined to include working from anywhere in the world. Many employers are left to figure out how to manage this growing trend to attract and retain talent.
- Employee health benefit requirements for the globally mobile are different than for a U.S.-centric workforce. Relying on a domestic health plan can create financial and health care benefit-related issues, as well as undue stress and burden for employees and employers since domestic policies do not translate seamlessly abroad.
- Employers should consider the flexibility of their carrier's plans and seek out carriers that can support globally mobile populations with benefits that are designed for international travel and work outside the U.S. and plans that can be provided as either employer-sponsored or voluntary benefits.

signaling a growing trend. And, one in four (24%) U.S. digital nomads said they plan to travel internationally over the next year.³ But who exactly are these digital nomads? The answer isn't as cut and dried as employers may hope.

Remote workers are a unique breed compared with both a traditional workforce and each other. Some nomads have worked remotely for years, building their careers around a lifestyle that lets them travel the world without missing a single Monday morning meeting. Others look for short-term opportunities known as “work-cations.” However, both groups are seizing the opportunity to control how nomadic they want to be. While some find a single country to build a base in, others remain on the move—chasing new adventures every chance they get.

As a cohort, Gen Xers (age 41 to 56) are more likely than any other generational group to seek out job opportunities that have flexible schedules and enable them to work remotely.⁴ Millennials (age 25-40) also remain a key demographic since 42% of digital nomads are in the Millennial cohort.⁵

How Do Employers Respond?

Employers are faced with the difficult task of attracting, supporting and maintaining a remote workforce and developing capabilities to keep them engaged. They are also left to figure out what the work-from-anywhere trend means for their existing remote work policies, specifically the role employers should play in helping employees care for and maintain their health when they independently decide to work re-

TABLE I

Key Considerations for Employers

<p>Do you have highly skilled workers in technical and creative roles?</p>	<p>It's no surprise that digitally savvy workers with job functions such as IT, web design, digital marketing, creative design and engineering are most likely to seek location-independent status. Companies with a high concentration of technical work teams may be experiencing a surge in employees going global.</p>
<p>What type of international travel policy do you have?</p>	<p>Travel accident and travel medical policies are different, with travel medical policies providing primary medical coverage (including medically necessary evacuations) when outside the employee's home country. Both may only cover employees who are officially traveling on company business, not those who desire to be location independent.</p>
<p>If you have an international travel medical policy, does it cover leisure or vacation travel?</p>	<p>International travel medical policies may not cover leisure or vacation travel, which is how employers tend to view independent global mobility. Employees who independently decide to live and work outside their home country may assume they are covered but end up paying for their own medical expenses, including medically necessary evacuations if their condition calls for it.</p>

motely outside the U.S.—as a benefits sponsor or as an advisor to employees to choose international health coverage on their own.

The health benefit requirements for an international workforce vary greatly from those of a U.S.-centric workforce. Employees who are not offered international policies are forced to use their domestic plans overseas, which can create financial and health care benefit-related issues since domestic policies

do not translate seamlessly abroad. Benefit needs also vary depending on the length of time that employees plan to work away from the office. Those differences require employers to understand their options when proposing and negotiating benefits to current and future employees.

Following are some considerations about U.S. health plans and the potential pitfalls of applying a U.S. health plan for use internationally.

- If companies do not have proper international health coverage in place, employees could be left to rely on their U.S. health plans if they get sick or injured while outside the U.S. Health care systems vary by country and, in many countries, the government pays for health care. U.S. health care plans that include employee cost share—deductibles, copays and coinsurance—make it difficult for international providers to collect payment. As a result, employees may end up paying hundreds or thousands of dollars in health care costs that might not be reimbursed. Worse, they may be denied care until payment is rendered.
- U.S. health plan benefits are rooted in networks with negotiated rates

between the carrier and provider that are beneficial to the employee. Employees typically pay more out of pocket for out-of-network claims and, in some instances, out-of-network claims are not covered at all. A U.S. health plan policy may default international health-care claims to an out-of-network status, driving employees to pay more out of pocket, which may lead to the employee becoming dissatisfied with their benefits.

- Most U.S. health plans do not cover important services that are a must for international travel, such as medically necessary evacuation and repatriation. If an employee has a health event that requires a medically necessary evacuation and does not have adequate inter-

national travel medical coverage, this can result in undue financial and emotional burden for employees and possibly the employer (if the employer is self-insured and bears the health claims risk for their employees).

A Range of Solutions for Employers to Consider

Employers should consider their employees’ health insurance needs, even if they don’t plan to provide employer-sponsored health insurance. There are opportunities to steer employees in the direction of individual international policies that can provide the proper protection and mitigate the stress and financial burden of dealing with an unexpected health event in an unfamiliar health care system.

TABLE II

How International Health Care Plans May Benefit Globally Mobile Employees

Without an International Health Care Solution	Recommended Capabilities of an International Solution
<ul style="list-style-type: none"> • Risk burden falls to the employer or domestic health plan. • Domestic telemedicine services may not extend globally. • Medically necessary evacuations are typically not covered, resulting in thousands of dollars that may not be reimbursed. • Plans risk noncompliance in countries with specific health insurance regulations. • Employees pay up-front for care that may not be reimbursed. • Domestic medical plans operate during U.S. business hours, which can result in delays in validating benefits and authorizing care. 	<ul style="list-style-type: none"> • The plan assumes 100% of the risk for claims. • Global telemedicine services are available, allowing worldwide access to doctors by mobile phone or video. • Medically necessary evacuation coverage is a benefit option. • All provided coverage satisfies visa requirements. • The carrier arranges for direct payment with providers, reducing the burden of out-of-pocket costs to employees. • Multilingual support is available 24/7/365 from an integrated customer service and medical assistance team.

Consider these examples from two employers that, as of this writing, are currently building policies to empower worldwide location flexibility and support their employees' work-from-anywhere wishes:

- A large, well-known retailer is testing the waters before possibly embarking on a more permanent work-from-anywhere policy and employer-sponsored benefits that support worldwide location flexibility. This retailer allowed 2,000 of its employees to work from anywhere in the world during the month of July. The retailer plans to educate employees on the importance of travel medical insurance and promote travel medical policies for individuals/families as part of its education campaign.
- A global hospitality company recognized that its U.S. health plan did not sufficiently cover employees who wanted to independently travel and work internationally. As such, the company is offering a discount for U.S. employees who want to purchase an individual travel medical policy to help cover the gaps and limitations. For example, international health claims would be considered an out-of-network expense on the employer's U.S. health plan that may or may not be covered. Employees who opt to purchase a well-designed international travel medical plan have peace of mind knowing that they have coverage for medical services outside the U.S. without having to worry about any potential constraints brought on by a U.S. benefit plan design.

When looking for benefit solutions, employers should consider the flexibility of their carrier's plans and seek out carriers that are ready and willing to support a workforce that will undoubtedly continue to explore their options outside of the office and the U.S. This is judicious even if the employer is not ready or in the position to provide an employer-sponsored solution.


Employers that are ready to add international health coverage to their employee benefits in support of a work-from-anywhere culture should consider an international travel medical policy that covers employees for any type of international travel or add coverage for leisure travel in addition to a short-term business travel medical policy as a possible solution. Even if employers choose not to spon-

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sor health insurance for these digital nomads, providing educational opportunities on the potential risks as well as information on individual travel medical policies from a carrier experienced in covering members abroad will help employees protect themselves.

Global telemedicine services are another key benefit worth considering for international travel. Just like the telemedicine services inside the U.S., global telemedicine services provide users with the ability to virtually connect with a doctor. It's often the first line of defense for nonemergent, acute medical events such as a sore throat, the flu, a skin rash or even early COVID symptoms. With global telemedicine services, users can access doctors from their location wherever they are in the world. Users don't need to worry about having to search for and travel to a local doctor in an unfamiliar locale. Instead, doctors are available virtually to speak or video chat with anywhere. 

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Identity Authentication Versus Criminal Counterinnovations: Pension Account Security

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Identity authentication is an essential element of most financial transactions. Whether it occurs in person or online, *identity authentication* is the process that occurs when a person or computer confirms that another person is who they say they are. Common examples of identity authentication include entering a password to access an online bank account or visiting a notary to verify signatures on documents. Pension plan sponsors must ensure that they have adequate systems and procedures to protect against cybersecurity breaches and to verify participant identities (Geller, 2020). Without these protections, criminal actors can more readily obtain information about participants and then drain their accounts (Lawton, 2020).

The pandemic has led more people to use online services rather than in-person interactions. More people have been working from home and have chosen online financial services, such as robo-advisors instead of human advisors (Fisch, Laboure and Turner, 2019; Senders, 2021). It has also caused a change in how identity authentication is done for some pension decisions.

Another issue of increasing importance is the need for greater cybersecurity. With more participants performing pension transactions online, more people working from

home and increased digitization, there is an increased demand for remote identity authentication systems. Increased cybercrime has also placed pressure on companies to upgrade their protections. Losses from identity theft in 2020 totaled \$712.4 billion (Burt, 2021).

AT A GLANCE

- COVID-19 and the growing popularity of online financial services have emphasized the importance for pension plans and participants to employ strong cybersecurity systems to protect identities, data and assets.
- Remote identity authentication for pension plans and participants may involve online identity authentication, telephone call identity authentication, remote online notaries, biometric identification, video call options and audio/video-conference technology.
- Plan sponsors should be aware that the Employee Retirement Income Security Act (ERISA) presents issues for remote identity authentication and that criminal counterinnovations are creating a cybersecurity “arms race” between those trying to protect versus those trying to gain access to personal identity information.

The need for pension plans to manage identity authentication is part of cybersecurity. It is no longer sufficient to use only a password for identity authentication. All this has resulted in growth in identity management companies that provide participant identity authentication and access management protections (Metinko, 2021).

This article focuses on remote identity authentication for pension participants and pension plans. These approaches include electronic signatures, remote notarization, biometric identification and other techniques. The article first considers remote identity authentication for access to a plan account, such as for when a participant requests a distribution. It then considers remote identity authentication when notarization is needed. The article ends with a discussion of recent innovations and how criminals have developed new ways of breaking through cybersecurity protections, followed by concluding comments.

Remote Identity Authentication

Identity authentication is a widespread practice in modern societies to protect financial and other assets. People have government-issued photo IDs such as driver's licenses and passports. However, it is necessary to verify that these documents are genuine and belong to the people who present them. In-person identity authentication is done when another person compares the image of the person with the actual person.

McGlone (2021) argues that cybersecurity strategy involves three steps: (1) identify possible threats, (2) take ac-

tion to protect against them and (3) be prepared to deal with the consequences of successful attacks. This article focuses on the first two steps.

Remote identity authentication occurs when an account holder is not physically with the person or entity responsible for identity authentication. People have passwords to access numerous accounts and services, but this approach has proven to be vulnerable. One problem is that people often choose weak passwords that can be easily guessed or they use the same password for many accounts. To protect against such vulnerabilities, the minimum length has generally increased from four to sometimes more than ten characters. There also has been a move toward more complex passwords, with more requirements for the elements of passwords in terms of letters, numbers, capitalization and symbols. Passwords must now meet standards for complexity, with security questions and other identifying information used for further verification in some uses. However, there has also been a move away from passwords and toward other forms of identity authentication, such as *biometric technology*—the use of fingerprints, facial recognition and eye scans.

To counter security risk, account holders are asked questions about knowledge that other people generally do not have about them, which is called *knowledge-based authentication*. Their computers and mobile phones can be a supplemental identifier of who they are, with two-step authentication that sometimes involves a one-time code that is sent to their preidentified device,

either as an email or a text message. A text message to a predetermined cell phone number can be accessed by a single device, while an email message is less secure because it can be accessed from multiple devices. Cell phones have identity verification systems. These so-called *digital certificates* are used to verify the identity of the device itself (AppviewX, 2021). Thus, device identification becomes an important element of online identity authentication.

Identity authentication relies on data that is difficult to produce except by that specific person (Trulioo, 2018). Experts classify remote identity authentication according to three types of questions: (1) something only the person knows, such as a password, the last digits of their Social Security number, the town where they met their spouse or the person's high school mascot; (2) something the person has, such as a one-time authentication code sent to their cell phone or computer; or (3) a biometric identifier, such as their fingerprint or facial/voice recognition (Fallon, 2021). Identity authentication can also involve aspects of their physical behavior, such as their stride or the way they tap their cell phone to enter data on a phone (Barnett, 2021; Muchmore, 2021).

Notarization

The COVID-19 pandemic has been an impetus for technological and social innovations. During the pandemic, it is often no longer possible to walk into a bank to have a document notarized. The participant needs to contact the branch to make an appointment. Because banks have limited their hours

and closed some branches, the participant may need to wait a week or longer for the appointment. With all these ways of personal authentication, financial technology needs to adapt to the changes people have made in reaction to COVID-19.

It can be difficult for individuals to manage a typical pension plan transaction by traditional means. During the COVID-19 pandemic, some people, particularly older people who are more vulnerable to the virus, may be reluctant to have documents notarized because it would require them to go to a bank or another business to have an in-person, indoor meeting with a notary. This section discusses options for authentication of a person's identity that would work during the pandemic and would also be more efficient. Signature witnessing is a common type of notarization by which an in-person notary visually verifies the person's identity. The notary witnesses the individual while they sign the document after the notary compares the individual's photo ID with their face (Liveoak Technologies, 2020).

Notarizing a pension document can be complicated. For example, to make a required minimum distribution (RMD) from the Georgetown University pension plan, a participant must contact Fidelity, the plan administrator. The participant needs to request that a document requiring notarization be mailed to them because this plan will not allow emailing the document. This step can be made more complicated because the Fidelity agent, who deals with numerous plans, generally will

not know the details of the Georgetown University plan. Once the participant receives the document in the mail, that person needs to notify their spouse that they need to go to a bank or other location to have their signature notarized to indicate that they approve the participant receiving the mandatory withdrawal.

This traditional approach to identity authentication, which has been used for decades, remains highly secure. But it is inconvenient, time-consuming and (during a pandemic) risky to one's health. New financial technologies promise to provide similar levels of security but with more convenience.

All forms of identity authentication, both traditional and new, generally involve comparing two sets of data: the actual person and a certified image of the person or a biometric identifier, such as fingerprints. Some states allow an exception—If the notary has personal knowledge of the person, no form of identification is required (Corey Stapleton, 2020). With the growing problem of identity theft, identity authentication methods are needed that are not susceptible to identity theft and that protect against it.

Online Identity Authentication

Developments in ID technology have enabled personal identities to be authenticated online. The certified image of an individual does not need to be a physical copy, such as a driver's license or passport; rather, an image can be certified in a computer system. Computer ID technology does not require a human to verify the matching of

the two data sets and, arguably, it does not require a notary.

In recent years, there has been a move toward using third-party identification services. These services, which use identity authentication software, are responsible for the infrastructure required to authenticate each user's access to a computer system (Bhargava, 2021). These systems often rely on photographs taken by the account holder (i.e., a "selfie"), which is arguably more reliable than a password, two-factor authentication and knowledge-based authentication systems (DeNamur 2019).

The start-up company Neuro-ID analyzes "digital body language" to verify identities. The system assesses the ways by which users scroll, type and tap on phone keypads and uses that data to identify fraudulent users (Balogh et al., 2021). This technology could be applied to protect the accounts of pension participants.

Telephone Call Identity Authentication

A relatively recent innovation is voice recognition software, which can be used for telephone transactions. Once the pension provider has verified a person's identity by traditional means, the account holder's distinct voice characteristics can be analyzed with voice recognition software to make secure transactions during subsequent calls.

Problems With Notaries

A notary offers an impartial screening of a person's identity, willingness to sign and awareness of the document's content (DocuSign, 2020). In-person

notaries, however, can be considered an outdated, less-convenient approach. They are only available during business hours. Small bank offices might not have a notary or may only have one available during limited hours. Relying on a notary costs time and requires the inconvenience of going to an office.

During a pandemic, seeing a notary in an indoor setting involves a health risk. As more people work from home, they have less access to workplace notaries. In addition, the ability to digitally sign documents has become more prevalent. For these reasons, remote online notarization (RON) is becoming more popular.

Remote Online Notary Laws

Until recently, notarization was generally performed in person based on legislative requirements state by state. Several states have passed legislation that permits remote electronic notarization (sometimes called *webcam* or *online notarization*) that uses a technology platform and identity-proofing process approved by the state. States that permit remote notarization—and the date their law was passed—include Virginia (2012), Montana (2015), Ohio (2017), Nevada (2018) and Texas (2018) (Liveoak Technologies, 2020). The National Notary Association (2020) indicates that, due to the pandemic, many states passed temporary laws permitting remote notarization in 2020. Pennsylvania passed a law in 2020 that permanently allows remote notarization (Passman, 2021).

Remote notaries notarize documents electronically. Remote online notaries use the following technology to go through the traditional notary steps (Liveoak Technologies, 2020): digital signature, digital notary seal, digital document and digital certificate. The online company Notarize advertises that a person can have a document notarized within five minutes without leaving home. There is at least one company that provides technological support to notaries who wish to offer remote notarization (CISION, 2021).

Remote notaries use audiovisual recordings of each transaction that can be used as evidence in fraud cases, which serves as a deterrent against fraud. For this reason, remote notarization is arguably more secure than in-person authentication.

Videocall Options and Audio/Videoconference Technology

Remote notarization could be implemented in various ways. For example, individuals could use a video call to apply online for a pension. The person would scan and email a copy of their photo ID. The pension plan employee could verify the person's identity by comparing the photo ID with the video image of the applicant. This could also be done with videoconference software (e.g., Zoom).

These technologies could also be used as an online alternative for notarizations. The remote notaries would still be able to satisfy the requirements of verifying each person's identity. Or the process of identity authentication could be handled by a pension plan representative without a notary. Using a personal computer recognized by the company doing the authentication would provide additional verification of the person's identity. With global positioning technology, the person's location could be used as identifying information.

ERISA Issues

In 2020, the Internal Revenue Service (IRS) issued a temporary exception to the Employee Retirement Income Security Act (ERISA) requirement for in-person notarizations for pensions. The IRS recognized that in-person notarizations might be impractical or involve health risks during the COVID-19 pandemic. In December 2020, the IRS extended that exception to June 30, 2021 (IRS, 2020). The IRS subsequently extended the exception to June 30, 2022 (IRS, 2021) and then to December 31, 2022.

For a plan subject to the ERISA joint and survivor distribution requirement, any plan distribution in the form of benefit disbursements or a loan requires that the spouse notarize a spousal consent form or waiver if a joint and survivor option is not selected. Notarization is also required for distributions related to COVID-19, such as through the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Alternatively, a notary is not needed if a plan representative witnesses the spouse signing the consent form.

If state law permits, the person could use remote electronic authentication without being physically present in the same room with the notary or other authenticator. Instead, this

task could be done through an audiovisual online meeting. Pension plan representatives can qualify for this approach under certain conditions. The individual signing must provide a valid photo ID during the audiovisual conference. The conference must be live and allow for interaction between the individual and the plan representative. A legible copy of the signed document must be faxed or scanned and emailed to the plan representative on the same day it is signed. The plan representative must acknowledge that the signature has been witnessed under the terms of *IRS Notice 2020-42* and transmit the signed document with the acknowledgment back to the individual electronically (Perkinson, 2020).

This temporary relief applies to any participant election that must be notarized or witnessed by a plan representative. The IRS (2021) has received requests to make this relief permanent.

Biometric Identification

An alternative approach to password identity authentication is to use biometric identification. Using facial recognition software is one method. Other biometric techniques use fingerprints, scans of the iris or retina, and voice recognition. With biometric methods, the match must be near but not identical. To require an identical match would increase the risk of false negatives. Biometric identification is commonly recognized as being more reliable than conventional forms of identity authentication (Soni, 2021).

Facial recognition software, in contrast with using a live video and hard copy ID, uses a previously recorded electronic image of the individual. Technologies vary, but the following steps are typically used with facial recognition software (Norton, 2020).

1. A picture of the person's face is recorded.
2. The facial recognition software reads the geometry of the person's face. Key factors include the distance between the eyes and the distance from forehead to chin. The software identifies facial landmarks—one system identifies 68—that are key to distinguishing a face. The result is the person's facial signature.
3. The facial signature, encoded as a mathematical formula, is compared with an official ID.
4. A determination is made.

To implement this technology, employers could provide the photo IDs of employees to their pension service providers. Facial recognition software could be combined with video calls or online video meetings to authenticate an individual's identity without a notary. This could be part of a trend to reduce costs by cutting out notaries as middlemen.

Facial recognition software could also be used to prevent the theft of pension participants' money through fraudulent online transfers (Clark and Edwards-Franklin, 2019). Facial recognition on a mobile device or personal computer provides a second level of authentication, with the first level being the possession of a device that is known by the pension plan to be associated with the individual.

This approach could reduce or eliminate the need for security questions, two-factor authentication, passwords and PINs. Complex passwords improve security, but they are easier to forget. As a result, people often need to answer security questions and reset old passwords. In addition, it is difficult for people with many online accounts to choose a unique password for each website. They often use the same password for many sites, which increases the risk that hackers will access multiple accounts belonging to the same person.

Local governments in some Chinese provinces have introduced terminals and mobile apps that use facial recognition technology for pension payments. For example, the facial recognition mobile app Laolai, which is designed to enable older citizens to prove their identities, is used by China's Ministry of Human Resources and Social Security to ensure pension payouts and avoid fraud. About 250 million retirees have used this app (Hadass et al., 2020).

Facial recognition software has been criticized when used by U.S. police departments because, critics argue, it too often misidentifies people with darker skin and thus contributes to racial discrimination. When police departments use this technology, people tend to believe false-positive results (Ovide, 2020). This tendency could also be a problem when facial recognition software is used to prevent cybercrime, particularly when it involves people with darker skin.

Biometric authentication has other possible uses in pension administration. One company actively working to

bring back tontines is the Gibraltar-based Tontine Trust (2020). This company's mission is to create secure, low-cost, highly transparent lifetime income solutions via tontines invested passively in a highly diversified set of exchange-traded funds (ETFs). The firm utilizes blockchain technology with pseudonymous immutable ledgers and biometric authentication as a means of providing account participants with transparency about each transaction while also protecting their privacy. This authentication approach uses cell phone technology and 3D facial maps of a live account holder (not a photograph) to confirm the person's identity and that the image they are confirming is that of a live person rather than a photograph.

To enable fingerprint authentication, cell phone designers place sensors under cell phone screens that can scan fingerprints. Apple is developing new patents for in-display sensors designed for fingerprint identity authentication. Apple's current Face ID uses laser technology to create 3D maps of users' faces (MobileIDWorld, 2021).

As with all forms of identity authentication, it is necessary to take steps to protect the information from hackers. Just as cryptography is used to protect text, biometric hash is a technology similar in concept to cryptography that is used to protect biometric data (Chan, 2021).

Collaboration in Counterinnovations: The Cybersecurity "Arms Race"

Technological advances in identity authentication are designed to protect investors from cybercriminals who want to steal their investments or identities. However, these advances will be countered by increasingly sophisticated efforts by cybercriminals to overcome those advances. Cybercriminals are investing in deepfake technology to make authentication bypass campaigns more effective (Hill, 2021).

Deepfake technology is an escalating cybersecurity threat. In deepfake technology, cybercriminals invest in artificial intelligence (AI) and machine learning to create synthetic or manipulated digital content, including images, video, audio and text for use in cyberattacks and fraud. This fake content can realistically replicate a person's appearance, voice, mannerisms or vocabulary to trick the targets into believing that what they see, hear or read is authentic (Hill, 2021).

The ability to create fake facial images presents a serious challenge to facial recognition technology. The new technology used to produce false facial images is based on an AI development called an *adversarial generative network* (Tumin and Levitt, 2020). A programmer inputs a large number of photographs of real people. The program studies them and produces fake photographs while also trying to detect which images are fake. The AI engages in machine learning, which means that the AI gets better over time at creating fake images. This technology could be used to create fake identities and to detect which images of people are fake.

Facial recognition is among the most convenient biometric approaches, but because there are so many facial images of people on the internet, it does pose a risk of impersonation when the authentication is being done by a computer, given the availability of facial images of people on the internet. A hacker could try to use a picture of someone they wish to impersonate, called a *spoof*. It is essential for legitimate facial recognition authentication systems to detect spoofs by assessing the "liveness" of the image (Aware, 2020). This challenge is avoided when identity authentication occurs online between two people—for example, through a video meeting.

Cox (2021) describes a security weakness in systems that use identification codes sent by text messages. He explains how hackers can reroute text messages to themselves. Once the hacker receives the account holder's text message, by sending log-in requests, they can easily hack into other accounts associated with that phone number.

Cybercriminals have an incentive to overcome protective barriers. They have used AI to create voice cloning. For example, in 2020, criminals cloned the voice of a business executive in the United Arab Emirates and managed to steal \$35 million from the company (Brewster, 2021).

"The absence of face-to-face contact under lockdown has made it easier than ever for fraudsters to get past standard identity checks. We're now seeing an uptick in deepfake tech and service offerings across the dark web, where users are sharing illicit software, best practices and how-to guides," said Stephen Ritter, an expert on deepfake technologies. He continued, "All of this demonstrates a concerted effort across


the cybercrime sphere to sharpen deepfake tools, which in turn points toward the first signs of a new wave of impending fraud” (Hersey, 2021). Cybercriminals have used the dark web to offer customized services and tutorials that incorporate visual and audio deepfake technologies designed to defeat security measures (Hill, 2021).

Technological counterinnovations are not the sole strategy of criminals. In Argentina, a 2021 hack of government records allowed a criminal to access the identifying information of nearly every citizen in the country. The information included social security numbers and government photos. The hacker has offered to sell that information online to anyone. He claimed that his success was due to “careless employees” (Nash, 2021).

Conclusions

Remote identity authentication can be accomplished with passwords, security questions, security codes sent by text message and biometric measures.

Some people, particularly those who are of retirement age and have health risks, may be reluctant to have documents notarized by an in-person notary during a pandemic. This article discusses options that would make it possible to have signatures authenticated remotely, with or without a notary. In addition to reducing health risks, these options would also be more efficient, convenient and cost-effective in the future, not requiring people to spend the time and incur the transportation costs currently involved. These innovations would be useful in the context of pensions, where a person has an ongoing relationship with an employer or financial institution, but they could be used for any situation where a person needed to have their identity verified or a signature notarized. These innovations could reduce or eliminate the need for in-person trips to a bank or store to have a document notarized. Identity authentication innovations can also improve security on websites that contain pension participant information used for online pension transactions.

However, pension plans and participants must be aware of the broader issues related to remote identity authentication and the criminal counterinnovations designed to gain access to personal identity information. 

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Plan's Lower Reimbursement Rates for Outpatient Dialysis Do Not Violate Medicare Secondary Payer Act

Marietta Memorial Hospital Employee Health Benefit Plan v. DaVita Inc. No. 20-1641, 2022 WL 2203328 (U.S., June 21, 2022).

The U.S. Supreme Court held that a group health plan that provides uniform benefits for outpatient dialysis to individuals with and without end-stage renal disease (ESRD) does not violate 42 USC § 1395, the Medicare Secondary Payer Act (MSPA). Because the defendant employer-sponsored group health plan provided equal, albeit limited, benefits for outpatient dialysis, the plan did not violate MSPA.

Employer-sponsored group health plans can choose to provide limited benefits for outpatient dialysis as long as benefits are equal for individuals with and without ESRD, says the U.S. Supreme Court. MSPA was passed to alleviate the federal government's rising health care obligations, making Medicare a secondary payer to an individual's existing insurance plan for medical services like dialysis when the plan covered the same services. To prevent plans from avoiding their primary payer obligations, the statute imposed two constraints on group health plans: (1) a plan could not differentiate in the benefits it provides between individuals with ESRD and those without it and (2) a plan could not take into account an individual's Medicare eligibility due to ESRD. The defendant, Marietta Memorial Hospital Employee Benefit Plan, provided limited benefits for outpatient dialysis but provided the same coverage to all individuals.

In 2018, the plaintiff, DaVita Inc., one of two major dialysis providers in the country, filed suit against the plan, alleging that the plan violated MSPA by (1) differentiating between individuals with and without ESRD and (2) taking into account Medicare eligibility for individuals with ESRD. The district court dismissed DaVita's claims, finding that the plan's uniform application of benefits to all individuals meant that the plan was not differentiating between individuals or taking into account Medicare eligibility. The U.S. Court of Appeals for the Sixth Circuit reversed, holding that MSPA authorized disparate impact liability and that the plan's limited outpatient coverage disparately impacted individuals with ESRD. Because the Sixth Circuit's holding conflicted with

several district court holdings and with a later Ninth Circuit decision, the Supreme Court granted certiorari.

The Supreme Court agreed with the original district court decision and held that MSPA was not violated when the plan provided the same outpatient dialysis benefits to all plan participants. Without the provision of different benefits for individuals, the plan did not differentiate between individuals with ESRD and those without it or take into account the Medicare eligibility status of individuals. The Court rejected DaVita's argument that the statute authorized disparate impact liability for several reasons. First, the Court found that the text of the statute asked whether plans provided different benefits rather than asking about the effects of the provided benefits. In addition, the Court felt that requiring courts to evaluate a plan's coverage for outpatient dialysis compared with other services would prove unworkable and effectively mandate some minimum level of benefits for outpatient dialysis, an outcome neither required nor called for by MSPA.

In dissent, Justice Elena Kagan, joined by Justice Sonia Sotomayor, also rejected the disparate impact theory but was persuaded by DaVita's "proxy" theory. Kagan believed that outpatient dialysis was "an almost perfect proxy" for ESRD, such that providing limited benefits for outpatient dialysis meant providing different benefits for individuals with ESRD. Kagan pointed to the fact that 97% of people diagnosed with ESRD without kidney transplants underwent dialysis, while 99% of outpatient dialysis patients have or develop ESRD. In Kagan's view, by allowing group health plans to provide limited benefits for outpatient dialysis—simply because plans targeted dialysis rather than individuals with ESRD—the Court was rendering MSPA useless and shifting costs back onto the federal government.

This case tells employer-sponsored group health plans that they are free to provide whatever benefits they choose for outpatient dialysis, provided that plans do not provide different benefits for individuals with ESRD and those without it. Because MSPA does not impose a minimum level of benefits for outpatient dialysis, plans can choose to cover as much as they desire, and Medicare will step in to cover the rest for eligible individuals. It also tells Congress that if legislators want to shift costs back onto group health plans or mandate a minimum level of benefits, Congress must amend MSPA or pass a new statute altogether.

Supreme Court Rejects HHS Prescription Drug Medicare Reimbursement Rule for Certain Hospitals

American Hospital Association v. Becerra, 142 S.Ct. 1896 (June 15, 2022).

The Supreme Court struck down the Department of Health and Human Services (HHS) rule providing lower prescription drug reimbursements under Medicare for hospitals serving low-income and rural patients.

Since 2006, HHS has reimbursed hospitals for the cost of certain outpatient prescription drugs provided to Medicare patients. The Medicare statute provides HHS with two mechanisms by which it can calculate the reimbursement rate for these drugs.

First, HHS may conduct a survey of hospitals' acquisition costs for the prescription drugs and set the reimbursement rates based on the hospitals' average acquisition costs. This option (Option 1) explicitly permits HHS to verify the reimbursement rate by hospital group at the HHS secretary's discretion. The second mechanism (Option 2) applies when acquisition cost data is not available. In these situations, HHS may calculate the reimbursement rate based on the average price charged by drug manufacturers for the prescription drug. Option 2 further provides that the reimbursement rate may be "adjusted by the Secretary as necessary for purposes of" the statute. From 2006 to 2018, HHS did not conduct any surveys of hospital acquisition costs and set the reimbursement rate for all hospitals using Option 2 at approximately 106% of the drugs' average price.

HHS practice from 2006 to 2018 resulted in what it considered to be "overpayments" to hospitals serving low-income or rural populations. These alleged overpayments resulted from the equal applicability of the standard reimbursement rate to all hospitals, despite federal law, which caps the cost of prescription drugs to hospitals serving low-income or rural populations (known as "340B hospitals"). In order to remedy this situation, HHS set two different reimbursement rates in 2018 and 2019 without conducting an acquisition cost survey under Option 1—one rate for 340B hospitals and a different rate for non-340B hospitals. While non-340B hospitals received the standard 106% reimbursement rate, HHS reim-

bursed 340B hospitals at 77.5% of the average sale price for the prescription drugs. The American Hospital Association, two hospital industry groups and several hospitals sued the HHS secretary in the U.S. District Court for the District of Columbia, challenging the lower rates for 340B hospitals.

HHS contested the suit on two grounds. First, HHS argued that its establishment of the reimbursement rates was not subject to judicial review. Second, HHS asserted that the language in Option 2 allowing the secretary to adjust the reimbursement rate "as necessary" permitted it to vary the rate for 340B hospitals despite not having completed a survey. The district court rejected both HHS arguments and struck down the varied rate. HHS appealed the decision to the U.S. Court of Appeals for the District of Columbia Circuit. The circuit court affirmed the district court's determination that the judiciary could review HHS's establishment of the reimbursement rate but reversed the decision on the merits, upholding the lower reimbursement rate for 340B hospitals. The American Hospital Association appealed the circuit court decision, and the Supreme Court agreed to hear the case.

In a unanimous decision, the Supreme Court found in favor of the American Hospital Association. First, the Court, in agreement with the district court and the circuit court, determined that HHS's establishment of the reimbursement rates was subject to judicial review. Next, the Court considered whether Option 2 permitted a lower reimbursement rate for 340B hospitals. The Court held that this was not permissible under the statute.

The Court's opinion rested largely on the plain language of the Medicare statute. The Court explained that while Option 1 explicitly permits HHS to vary reimbursement rates by hospital groups, Option 2 does not contain the same language. HHS argued that language in Option 2 allowing the HHS secretary to "adjust" the rate permitted this variable rate; however, the Supreme Court rejected this argument. To accept the HHS reading of the statute, the Court stated, would render meaningless the survey requirement contained in Option 1. This is because the HHS reading would permit the same variation by hospital group as contained in Option 1 without any of the procedural safeguards contained therein, including very detailed specifications outlining the process for surveying hospitals' acquisition costs.

HHS next argued that its interpretation was reasonable in light of the significant “overpayments” being made to 340B hospitals. The Supreme Court declined to give credence to this argument, stating that it was possible that Congress intended these alleged overpayments in order to subsidize the cost of providing health care to low-income and rural communities. If HHS did not want to overpay hospitals for the drugs, it could conduct a survey and then establish rates varying by hospital groups. Otherwise, this alleged policy determination would need to be remedied by Congress.

While the Supreme Court’s unanimous decision constitutes a win for hospitals serving low-income or rural communities, this win is tempered by HHS’s actions in subsequent years. Beginning in 2020, HHS undertook the requisite acquisition surveys and set lower reimbursement rates for 340B hospitals based on the outcomes of these surveys. The case also failed to address how these hospitals will be made whole as a result of the Supreme Court decision. According to the Supreme Court’s determination, the HHS rate resulted in underpayments to 340B hospitals of approximately \$1.6 billion annually in 2018 and 2019; however, the Supreme Court left the issue of how to remedy these substantial underpayments to the district court to address upon remand.

Federal Arbitration Act Preempts California Law’s Prohibition of Arbitration

***Viking River Cruises, Inc. v. Moriana*, 142 S.Ct. 1906 (June 15, 2022).**

The Supreme Court reaffirmed its strong protection of arbitration agreements under the Federal Arbitration Act (FAA), preempting a California law to the extent it prohibited arbitration of claims under the California Labor Code Private Attorneys General Act of 2004 (PAGA).

On June 15, 2022, the Supreme Court, in an 8-1 decision, considered the relationship between FAA and California’s PAGA. PAGA permits employees, as private attorneys general, to enforce California labor laws on behalf of the state. In order to do this, *aggrieved employees*, meaning those employees who have been harmed by an employer’s violation of the labor laws, may bring suit regarding the violations that harmed them but also with respect to violations experi-

enced by other employees. The employee who brings suit under PAGA is entitled to 75% of the final recovery, while the remaining 25% is distributed to employees affected by the violations.

The plaintiff in this case, Angie Moriana, was an employee of Viking River Cruises, Inc., who sued the company under PAGA, alleging untimely payment of wages. In addition, Moriana alleged a large number of violations against other employees that did not directly impact her but that were permissible under the provisions of PAGA, allowing the joinder of such claims. Viking River moved to compel arbitration of Moriana’s “individual” PAGA claim, meaning the alleged violation that she was directly harmed by, specifically the untimely payment of wages. The state courts in California refused to mandate arbitration, holding that the arbitration agreement could not divide Moriana’s individual claim from the claims she brought regarding the other employees. The Supreme Court agreed to hear the case.

In a decision drafted by Justice Samuel Alito, the Supreme Court reversed the California state court’s determination and held that Moriana could be compelled to arbitrate her individual claim against Viking River. The Court found that California’s interpretation of the law was preempted by FAA, which provides significant protections for arbitration agreements. A central tenet of FAA is that parties are free to determine “the issues subject to arbitration” and “the rules by which they will arbitrate,” emphasizing that “arbitration is a matter of consent.” The Court held that by refusing to separate Moriana’s individual claims from the other claims, the California courts required either that Viking River consent to arbitrate many additional claims (those of the other employees) that it had not agreed to arbitrate or forgo arbitration altogether. This choice, mandated by the California courts, violated FAA. As a result, the Court held that Viking River was entitled to enforce the agreement mandating arbitration of Moriana’s individual PAGA claim.

While not addressing the interaction between FAA and the Employee Retirement Income Security Act (ERISA), the Supreme Court decision in this case could have implications for the wide proliferation of suits that have faced this issue over the last few years. In fact, a petition for writ of certiorari filed with the Supreme Court just a few months later, on Sep-

tember 8, 2022, raised the question of whether agreements could compel the arbitration of claims under Section 502(a)(2) of ERISA. Section 502(a)(2) permits plan participants, beneficiaries or fiduciaries to sue for breaches of fiduciary duties on behalf of the plan. The petition for certiorari, filed following the Sixth Circuit's refusal to compel arbitration in *Hawkins v. Cintas Corporation*, likens suits under Section 502(a)(2) to claims brought under PAGA. Specifically, the petition states that suits brought on behalf of the plan under Section 502(a)(2) are equivalent to suits brought under PAGA where employees bring suit on behalf of the State of California. In light of the Supreme Court decision in *Viking River*, the petition for certiorari argues that the Sixth Circuit decision (and a previous Ninth Circuit decision) not to compel arbitration in these cases cannot stand. The Supreme Court has not yet determined whether it will hear the case, but even if it does not, the Supreme Court decision in *Viking River* is likely to be the subject of much more litigation around this matter in the future.

Sixth Circuit Rules on Two 401(K) Investment Option Cases

***Smith v. CommonSpirit Health*, 37 F.4th 1160 (6th Cir. June 21, 2022); *Forman v. TriHealth, Inc.*, 40 F.4th 443 (6th Cir. July 13, 2022).**

The Sixth Circuit decides two cases alleging breaches of fiduciary duties based on investment options provided by 401(k) plans.

On June 21, 2022, the U.S. Court of Appeals for the Sixth Circuit decided a case and set the standard for pleadings in cases involving high-fee investment options. In the case—*Smith v. CommonSpirit Health*—Yosaun Smith, a former employee of CommonSpirit Health and participant in its defined contribution 401(k) plan, sued CommonSpirit alleging a breach of fiduciary duty based on imprudent investment decisions. Specifically, Smith alleged that CommonSpirit acted imprudently by offering investments in the actively managed Fidelity Freedom Funds when a similar index fund offered higher returns and lower fees. CommonSpirit moved to dismiss Smith's claims. The U.S. District Court for the Eastern District of Kentucky first heard the case and ruled that Smith

had not alleged sufficient facts to support her claim. Smith appealed the district court decision to the Sixth Circuit.

ERISA plan fiduciaries have a duty of prudence that includes a continuing obligation to monitor the plan's existing investments and remove any investments that are imprudent. Whether an investment is imprudent depends on the particular circumstances that existed at the time of the fiduciary's decision to either add or continue to maintain a particular investment. The Sixth Circuit determined that Smith had not plausibly alleged a violation of this fiduciary duty in her complaint.

First, Smith alleged that CommonSpirit violated the Employee Retirement Income Security Act (ERISA) simply by including actively managed funds within its portfolio of investment options. Smith alleged that these funds generally include higher fees than their index fund counterparts and include greater risks for investors. The court rejected this argument, stating that actively managed investments are a common fixture of retirement plans. The court found that offering these options was a "reasonable response to customer behavior." In fact, the court speculated that not offering actively managed investment options might violate a plan's fiduciary obligations.

Smith next alleged that CommonSpirit violated its fiduciary duties specifically by offering the actively managed Fidelity Freedom Funds investment option to participants rather than the passively managed Fidelity Freedom Index Fund. In support of this argument, Smith noted that the index fund outperformed the actively managed fund over a five-year period while charging lower fees. The Sixth Circuit stated that it was not enough to "simply point[] to a fund with better performance," without providing further evidence that an investment "was imprudent from the moment the administrator selected it, . . . became imprudent over time or . . . was otherwise clearly unsuitable for the goals of the fund based on ongoing performance." The Sixth Circuit highlighted that the actively managed fund had distinct goals and risk profiles from those of the index fund. The court also relied on the fact that the actively managed fund was twice as popular as the index fund and actually had outperformed the index fund in more recent data. All of these facts, when taken together, demonstrated that Smith's claim of imprudence could not stand.

Less than a month later, the Sixth Circuit had the opportunity to review a similar case in which ERISA plan participants alleged that the plan administrator had acted imprudently through the plan's choice of investment funds. This time, the Sixth Circuit came to the opposite conclusion, permitting the participants' claim. The contrast between these two cases highlights the evidence that is required in order for plan participants to maintain a claim of breach of fiduciary duty based on allegedly imprudent investments.

In *Forman v. TriHealth, Inc.*, Danielle Forman, a former employee and 401(k) plan participant, as well as a number of other participants, sued TriHealth Inc., alleging that TriHealth's offering of certain high-cost mutual funds violated the fiduciary duty of prudence. Specifically, Forman alleged that TriHealth offered higher cost "retail" share classes rather than lower cost "institutional" share classes in the mutual funds. *Retail* share classes in mutual funds are those which are readily accessible to individual investors. In contrast, *institutional* share classes have high minimum-balance requirements and generally lower expenses.

Forman argued that TriHealth offered retail share classes in a variety of mutual funds, despite the fact that the plan's investments in these funds would meet the minimum-balance requirements to qualify for the lower cost institutional shares. The U.S. District Court for the Southern District of Ohio dismissed Forman's claims, finding that the complaint did not allege sufficient facts to support that TriHealth acted imprudently. Forman appealed the district court decision to the Sixth Circuit.

In contrast to its decision in *CommonSpirit*, in *Forman*, the Sixth Circuit found that the plan participants had sufficiently alleged a violation of the duty of prudence. This was because the participants relied not simply on the performance of the plans after the selection but on factors that existed at the time the fiduciaries made the decision to include the investments.

The Sixth Circuit stated, "Taken in their most flattering light, these allegations permit the reasonable inference that TriHealth failed to exploit the advantages of being a large retirement plan that could use scale to provide substantial benefits to its participants." Unlike the participants in *CommonSpirit*, who compared an actively managed fund with a distinct, though perhaps similar, index fund, the participants in *Forman* criticized the plan's decision to select a more expensive share class in the exact same fund, with the same investment strategy, portfolio and management team. The Sixth Circuit emphasized that "a claim premised on the selection of a more expensive class of the same fund guarantees worse returns." Such a guarantee did not exist with respect to the comparison made by the plan participants in *CommonSpirit*.

The Sixth Circuit was careful to highlight that permitting the plan participants' claims to move forward in *Forman* did not mean that the plaintiffs would ultimately be successful in their claim. The court indicated that there are a number of potential reasons why TriHealth may select a retail share over an investment share. For example, the plan may have a revenue-sharing arrangement in place that makes the retail shares less expensive. However, the court found that there wasn't sufficient information this early in the case proceedings in order to evaluate such an argument. Therefore, the participants' claim was permitted to proceed.

The Sixth Circuit's decisions in *CommonSpirit* and *Forman* highlight the process-based inquiry that the court will undertake in claims involving allegedly imprudent investment decisions. The good news for ERISA plans is that simply pointing to better performing, but distinct, investment options is insufficient under these decisions to support a claim. However, plan fiduciaries must be exceedingly cautious in light of the court's decision in *Forman* when selecting between retail and institutional classes because this may result in a viable lawsuit by plan participants.



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