

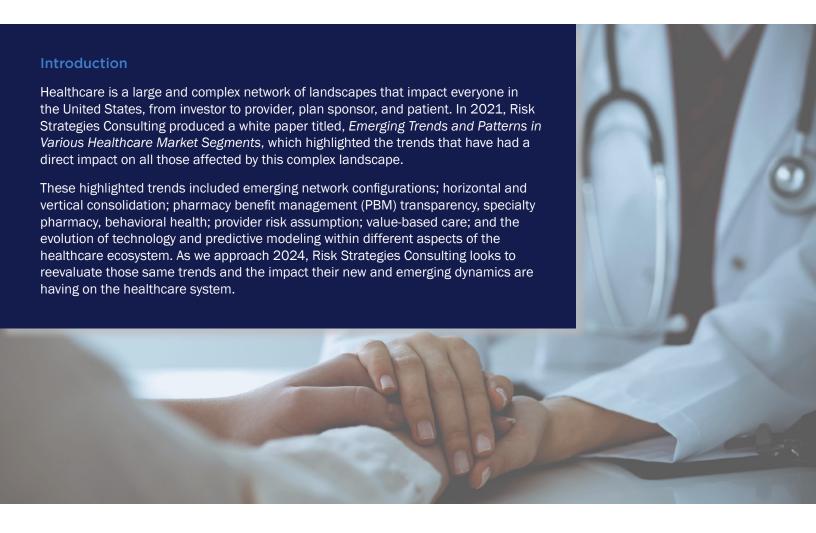
Emerging Trends & Patterns in Healthcare Market Segments

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In our 2021 piece, we explored the impact of the regulatory scene, highlighting at the macro level, the general influence that the Federal and State governments have on the design and consumption of healthcare. We also opined on the potential implications of multi-district Blue Cross Blue Shield litigation. Since the release of that publication, government and regulatory oversight has taken a larger stage in access to healthcare, rights of patients, pressures on ERISA exemption, and dramatic supply chain impact. As a result, in this edition of Emerging Trends and Patterns, we have delegated more space in helping to understand the broader impact these regulatory changes have on the market.

We also explored the trends in the vertical and horizontal consolidation of healthcare delivery systems within a growing number of geographic regions, where we saw a select number of large systems acquiring community-based and regional focused facilities to expand their footprint. These mergers continue to thrive in our environment today with non-traditional entities entering the healthcare field. In 2021, we discussed the need for vendors to evolve beyond the aggregation of competitive cost of goods as their value proposition. Pressure with the entry of disruptive players in the market such as Amazon with One Medical, is accelerating the market's evolution in vendors' approach to driving value beyond pricing discounts. We are seeing entities such as Walmart and Walgreens constructing partnerships with a broader ecosystem to deliver on framework representative of directional value-based care. In 2024 we anticipate these trends to continue, as the focus on transparency, disruptive new market players, and inflating healthcare costs, are creating a need for comprehensive value propositions that extend beyond offsetting trend discounts and savings.



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Additionally, in our previous publication, Risk Strategies Consulting highlighted the dynamics that were impacting the Pharmacy Benefit Management (PBM) industry via horizontal and vertical consolidation. These dynamics, while creating the potential for significant impact in trend management, have largely been focused on channel management and aggregation of goods for competitive pricing. With transparency at the forefront, we continue to see efforts on acquisition-based pricing, however there is need for clinical management strategies that provide an approach comprehensive of Total Medication and Therapy Management (TMTM) solutions.

Finally, in 2021's Emerging Trends and Patterns, we surfaced the growth in virtual and digital-based care as a trend, however, we did not elaborate on the explosion of healthcare solutions referred to as point solutions. In this white paper, we will discuss these healthcare solutions, the opportunities, challenges, and the crowded market, as evidenced by the behavioral health solutions available. With the outgrowth of these solutions within the ecosystem, there is a need to understand the return on investment (ROI), as well as impact, of these point solutions. Risk Strategies Consulting also sees the need for a 360-degree, or 'whole health' view that can integrate these and other solutions in the member's ecosystem to deliver clinical outcomes, optimize benefit design, and drive an impactful member engagement that overcomes the historical silos.



In our 2021 analysis, we briefly discussed the implications of government and regulatory action on the commercial market, however we have since witnessed a tidal wave of activity over the past two years that is resulting in reverberating effects on cost, affordability, access, and quality of care. Additionally, state pressures on ERISA exemption, the Inflation Reduction Act (IRA), Consolidated Appropriations Act (CAA), state/federal decisions on health rights, and focus on Pharmacy Benefit Manager (PBM) reform are top drivers of current and continued regulatory focus, as well as state departments of insurance regulatory differences, which must be considered for nationally focused healthcare entities.



CONSULTING **Emerging Trends & Patterns in Healthcare Market Segments**

Centers for Medicare and Medicaid Services (CMS) Impact

As we evaluate the interplay of CMS and the healthcare ecosystem, we examine the CMS rules and regulatory changes that will result in implications to health systems, providers, patients, and payors. In 2022 and 2023, much of the activity from CMS resulted in changes that affected healthcare macro-trends. We foresee the 2024 impending changes continuing this impact. These areas include:

- The reversal of 340B cuts to hospitals
- Passage of the IRA with the first 10 drugs selected for negotiation
- Reduction in CMS Medicare payment rates to providers
- Increases in CMS payment rates to Medicare Advantage (MA) plans
- Increases in Medicare Part B premiums
- Modifications of Medicare Advantage risk adjustment to take place in 2024, with over 2,000 codes removed
- Hospital and payor price transparency
- Continued push by CMS for advance payment models

340B

The 340B drug pricing program has been a highly contended topic in recent years, drawing support from those who see a continued need to support covered entities and their disadvantaged populations, as well as arguments of abuse of intended benefits, transparency in funds used, and duplicate discounts. 2023 was particularly impactful on the program, as the January 30 ruling by the US Court of Appeals of the Third Circuit in favor of drug manufacturers allowed the restriction of contract pharmacies that can dispense 340B drugs. It also brought a reversal to 340B Medicare payment cuts and introduced the Drug Pricing Transparency and Accountability Act.

These 340B reimbursement rate reductions resulted in impacts to health systems, and those that were able to weather the impact are now able to receive recuperation of funds; however, the rule is silent on how Medicare Advantage (MA) plans should address past payments to hospitals. Additionally, when the reimbursement cuts took place, the preface was to maintain budget neutrality. This resulted in payment increases, and now leaves the uncertainty of the remediation impact to health systems that were reimbursed under the outpatient prospective payment system.

As we look at the state of the 340B drug discount program in 2024 and beyond, we expect to see another impact that is tied to the convergence of hospital transparency requirements around pricing that go into effect in the coming year. The 2023 requirement set forth by CMS in the Consolidations Appropriation Act (CAA) prohibits gag clauses in contracts between insurance plans, providers, and insurance issuers allowing for transparency on provider specific costs and quality of care information to plan sponsors.^{1,2} In consideration of all the transparency requirements, there will be clearer insights to negotiations for provider services and rebate opportunities that were negated by 340B drug pricing discounts. Risk Strategies Consulting expects to see some additional litigation regarding the flow of money and how contractual rebate requirements come into play. As we observe these current actions and impending changes, this highlights the need for evaluating the current framework for rebates, pricing, pharmacy networks, and the role of PBMs. We continue to see opportunities to align incentives across the value chain by focusing on a more transparent pricing model, which requires an understanding of the supply chain and is based on clinical performance, quality of care, physician prescribing patterns, and the real-world performance of pharmaceutical products.





2022 Inflation Reduction Act (IRA)

Another indirect impact on the commercial market is the continued focus by CMS on providing affordable and accessible prescriptions to its plan members. Enacted in August 2022, the Inflation Reduction Act (IRA) requires the Secretary of Health and Human Services to negotiate drug costs for some drugs covered by Medicare Parts B and D with pharmaceutical companies.3 Price negotiations began in 2023 but will not go into effect until 2026. For 2026, CMS selected the following 10 Part D drugs for price negotiation:4

- Eliquis
- Xarelto
- Farxiga
- Enbrel

- Jardiance
- Januvia
- Entresto
- Imbruvica
- Fiasp; Fiasp FlexTouch, Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill
- Stelara

Each year, the number of drugs eligible for negotiation will continue to increase, with 15 Part D drugs eligible for 2027, 15 Part D and Part B drugs for 2028, respectively, and 20 Part D and Part B drugs eligible for 2029 and beyond. By 2028, the cost of 60 total drugs will have been negotiated.4 The selection pool of 50 drugs have the highest total Medicare Part D and B spend, respectively, and should meet the following criteria.4

- Does not have therapeutically equivalent generic and biological products available (i.e., vaccines and gene therapies)
- Does not have an orphan drug designation
- Has been on the market for at least seven years (single source) and 11 years (biological)5
- Has resulted in Medicare spending above \$200 million



While these negotiations may save money for Medicare, the concessions on pricing create the risk of offsets realized by increased costs for the employer market. Risk Strategies Consulting anticipates that this impact will be seen much sooner than 2026, and expects to start seeing changes in 2024, such as setting the initial launch prices of drugs at a higher cost to ensure that price increases do not exceed inflation requirements and commercial price increases.

As we look at implications of the IRA, Risk Strategies Consulting anticipates a three-fold effect:

- An increase in commercial drug costs
- The contraction of MA prescription drug plans (PDPs)
- An incentive for manufacturers to focus on biologicals, rare disease, and drugs under the medical benefit, shifting costs from PBMs to health plans





Evaluating the PBM and medical drug strategy for plan sponsors is critical with these implications from both the IRA actions and pharmaceutical companies' reactions in an effort to manage profitability.

With specialty drug spend accounting for over 50% of drug spend with 40% under the medical benefit, and the implications of the IRA, Risk Strategies Consulting is vigilant in monitoring the drug pipeline consisting of over 6,000 products, of which oncology comprises 38%. With the growth of cell and gene therapies, and the shift of common conditions receiving specialty drug options for treatment, it is imperative to discuss the current and future role of the PBM.

In 2024, the five percent beneficiary coinsurance requirement above the catastrophic coverage threshold begins, and in 2025, the percentage of federal reinsurance is drastically reduced from 80% to 20% of allowed cost for applicable drugs. These IRA implications increase the financial burden of high-cost drugs shifting to MA plans from the federal funding and patient contribution. Thus, a greater risk is present to the MA plans, and arguably, will drive a contraction of the PDPs in the market. MA plans have the ability to leverage quality bonus payments and benchmark rebates on medical expenses to offset their impact in pharmacy costs unlike standalone MA PDPs and must remain relevant in a highly competitive MA market, where member benefits are key differentiators.

CMS will also be introducing changes to risk adjustment in 2024 that may have unintended consequences. These changes, in addition to a proposed three and three tenths' percent reduction to base payment for physicians, may lead to reduced access to care and higher cost shift to the commercial payor. This could result in a shift of focus for manufacturers with regard to research and development as we expect to see reduced emphasis in small molecules and biosimilars for products that have competition.

With all the potential impacts, it is important to highlight the implications of the IRA to commercial plan sponsors. The market has witnessed that whenever reimbursement reduction occurs in Medicare, as a balloon is squeezed, the cost is shifted to the commercial side. Risk Strategies Consulting expects to see a similar phenomenon from the IRA, with the negotiation of drug prices and costs shifted to the commercial payor and plan sponsors. Performance of utilization management, networks, and clinical programs will all be important considerations as plan sponsors will require levers beyond lower aggregate pricing and rebates to manage trends.





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2021 Consolidated Appropriations Act (CAA)

The Consolidated Appropriations Act (CAA) of 2021 went into effect in 2023, resulting in greater responsibilities and requirements being placed upon employers with regards to fiduciary responsibilities and obligations of their health plans. Specifically, self-funded employer-based health plans and insurance companies are now required to submit claims data to the Department of Health & Human Services, the Department of Labor, and the Treasury, in the name of transparency.6 CAA also requires that employer-based plans legally be considered the fiduciary, responsible for running the plan in their participants' best interests and ensuring that the funds associated with the plan are being used for the exclusive purposes of paying plan expenses and providing benefits. In order to successfully do so, health plans must provide sponsors with easy access to claims data.

This need for transparency is not new to healthcare, however with regulatory actions, there have been financial and legal implications across the ecosystem, which will continue as a trend. We expect 2024 to bring about the enforcement of the provision around hospital price transparency. With data requirements from the transmission of data-to-data exchange, there are costs that will be incurred by health systems. As costs increase, there is also the potential unintended consequence of the valve releasing into the market for recuperation through billed charges and contracting rates negotiated.

Additionally, the market has seen a dramatic increase in litigation in which health plans are being sued by plan sponsors for allegedly violating their fiduciary responsibilities and lack of transparency around claims data. Mass Laborers' Health & Welfare sued Blue Cross, alleging breaches of fiduciary duties under ERISA and violations of state law.8 In the same year, the Bricklayers and Allied Craftworkers Local 1 Fund (BAC Local 1) and Sheet Metal Workers Local 40 Fund (SMW Local 40) filed a class action complaint against Anthem. The complaint alleges that network access provider, Anthem, recently rebranded as Elevance Health, unlawfully refuses to allow self-funded health plans with which it contracts to access their own plan claims data in violation of federal laws,9 In 2023, Kraft Heinz Co. filed a lawsuit against insurer Aetna, accusing the company of breaching its fiduciary duties by leveraging its status as a third-party claims administrator to benefit itself financially.¹⁰ We anticipate a continuing trend of these types of lawsuits considering the CAA impact. The increase in transparency will provide an opportunity to support innovation for plan sponsors on quality as well.

While many of these cases are still in the initial stages of discovery, the impact on the relationships between plan sponsors and health plans is arising now. Risk Strategies Consulting believes that plan sponsors and health plans need to work together to find contractual language that protects all parties, while best serving members. Additionally, independently validated, and comprehensive audits across medical and pharmacy will be requisite as a means of verifying the efficacy of their contract, clinical programs, and claims adjudication processes. These audits, or inability to complete these types of audits, may lead to more scrutiny of health plans and PBMs. The removal of gag clauses and push for more transparency will result in opportunities to reevaluate networks. There is always the caution of pricing in isolation, as we need to ensure quality and outcomes are in concert for comparison.



Health Equity

With health equity in the forefront of care access, it is noteworthy to identify that in 2023, CMS released an updated Framework for Health Equity directly impacting the quality and efficacy of care and outcomes throughout the ecosystem. The framework outlines the following five priorities, aimed at helping reduce disparities across the care continuum:¹¹

- Expand the collection, reporting, and analysis of standardized data
- Assess causes of disparities within CMS programs, and address inequities in policies and operations to close gaps
- Build capacity of healthcare organizations and the workforce to reduce health and healthcare disparities
- Advance language access, health literacy, and the provision of culturally tailored services
- Increase all forms of accessibility to healthcare services and coverage

For 2024, the Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) final rule updates Medicare payments for quality measures that foster safety, equity, and reduce preventable harm in the hospital setting. As we see these endeavors from a CMS perspective take form, Risk Strategies Consulting also sees the need for similar requirements across commercial market healthcare solutions. With the growth of healthcare solutions, referred to commonly as point solutions, and bundled solutions for healthcare services and conditions, we find that there are opportunities to address social determinants of health, from overcoming access to care due to transportation and/or disparities in care, to addressing gaps in health and technology literacies.

With continued focus on quality of care and cost transparency, a critical lens on health equity data needs to be applied to ensure there is a comprehensive view of the challenges that remain to be fully understood. Real world data and the ability to drive integration of data sets through effective data logistics and management are paramount to driving actionable insights and dynamic analytics. With disparate systems and lack of interoperability as real threats to leveraging data effectively, Risk Strategies Consulting sees the need for those advising, supporting, or directly driving innovation to have experience with data management, data science, and proficiency with predictive modeling that leverages machine learning.

Decisions Regarding Health Rights

Addressing health equity is becoming more complex as real barriers yielding from current state and federal legislation are resulting in nuanced disparities to healthcare access. On June 24, 2022, the Supreme Court issued its decision in Dobbs v. Jackson Women's Health, overturning Roe v. Wade and Planned Parenthood v. Casey, eliminating the federal standard regarding abortion access. 12 Seventeen states have effectively banned abortion resulting in healthcare access issues for women, complexity in network design, and how benefits are offered to female employees across states. To provide context to additional rulings that are at risk it would be important to raise the case of Eisenstadt v. Baird, where the U.S. Supreme Court extended the right to privacy to individuals, effectively legalizing birth control for unmarried women, and the case of Griswold v. Connecticut, in which the Supreme Court ruled that a state's ban on the use of contraceptives violated the right to marital privacy.13,14

The inherent risks from the Dobbs decision lie in how far reaching the interpretation may become to include access to contraception. It is important to consider that Roe v. Wade, vulnerability to Griswold and Eisenstadt, can place the right to obtain contraceptives at risk.



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Risk Strategies Consulting has continued to see states enacting restrictions on healthcare that may subject providers to the risk of felony charges. There are over 19 states with laws that restrict gender affirming care. The impact of legislation in gender affirming care is exemplified by state laws enacted with NC House Bill 808, as an example. 15 This bill prohibits gender-affirming medical care for those under 18, including treatment advised by their doctors and to which their parents' consent. The law also prohibits state funds and Medicaid dollars, from being used for such care. Doctors providing such care could lose their medical licenses under the law. With the impact of these decisions, plan sponsors must ensure that they are evaluating network coverage to account for these new obstacles that can impact their benefit design by state and availability of healthcare resources.

Government and Regulatory Focus on PBMs

Government and regulatory organizations will also maintain their focus on pharmacy drug-spend and PBMs. One such entity proposing legislation is the Senate HELP (Health, Education, Labor, & Pensions) Committee. The Pharmacy Benefit Manager Reform Act, also known as Bill S. 1339, was introduced to the Senate by the Committee to Promote Comprehensive PBM Transparency.¹⁶ The legislation proposes banning spread pricing, which occurs when PBMs charge a plan sponsor more for a drug than the pharmacy charges. The pharmacy is reimbursed, and the PBM retains the "spread" for a profit, "...resulting in an overpayment by the plan."17 The Act also requires that PBMs pass along the rebates they get from the pharmaceutical manufacturers to plan sponsors, which would result in lower costs. Currently in the Senate, the bill has received bipartisan support¹⁸.

Pending and proposed state legislation is also targeting billing practices, which will directly affect the administration and cost of provider-administered drugs. Provider-administered drugs encompass various drug types including intramuscular drugs and intravenous (IV) infusions like chemotherapy. Currently, providers use a buy-and-bill model, where the provider buys and administers the drug to a patient. The provider is then reimbursed for the drug cost and administration under the medical benefit. However, two additional practices called 'white-bagging' and 'brown-bagging' are starting to see more traction. White-bagging refers to the scenario where a provider-administered drug is dispensed from a specialty pharmacy and is shipped directly to the provider for administration to a specific patient. Brown-bagging describes a situation when a provider-administered drug is dispensed through a specialty pharmacy and then shipped directly to the patient and the patient subsequently brings the medication to their provider for administration. In both white-bagging and brown-bagging scenarios, the specialty pharmacy charges the plan sponsor for the drug through the pharmacy benefit and the provider is reimbursed for the administration of the drug under the medical benefit. These arrangements are intended to decrease plan sponsor costs through competitive, pre-negotiated pharmacy pricing and rebates, as well as remove inventory and billing challenges to providers. However, the counterargument is centered on provider concerns of delays in treatment caused by pharmacy coordination issues, heightened potential for wastage resulting from last-minute treatment changes, and concerns about maintaining product integrity and proper storage conditions when employing brown-bagging, which remains out of the provider's oversight. As a result of these concerns, three states have laws restricting these policies, and 18 states have proposed similar legislation in 2023.19 Risk Strategies Consulting foresees other states continuing this trend, however the restrictions should be closely evaluated as the disparities in site of care costs due to horizontal consolidation threatens the sustainability of managing drug costs under the medical benefit.

The focus on PBMs and the management of drugs under medical benefit places a necessary scrutiny with transparency in the supply chain with the opportunity to shift these models to cost transparency with clinical management as the revenue driver. Aligning incentives across the medical and pharmacy benefits starts with models that rely on the clinical value and impact of services rather than the financial margin to gain off a drug. This raises the question of the clinical value of the drug rather than the margin gained from discount, fees, or rebates that can be obtained from supply chain obscurities. Risk Strategies Consulting sees a need for manufacturers to move from their pay-to-play strategies towards true value-based pricing arrangements.





Patient Assistance and Pressure/Litigation from Pharma

Patient assistance programs (PAPs) and copay assistance programs were developed by manufacturers to help individuals afford the cost of prescription drugs, but also increase utilization by circumventing plan sponsor benefit designs. PAPs are income dependent and offered by drug manufacturers, nonprofits, and government agencies, while copay assistance programs are offered regardless of financial status. Both types of programs can provide the medication at a lower cost or at a full discount. Historically, the amount contributed by the manufacturer for copay assistance programs have applied towards a patient's out-of-pocket maximum and deductible. PBMs have developed programs that identify and disallow pharmaceuticalpaid dollars from counting toward the member's portion of drug spend. An important difference in these programs to note is that maximizer programs, unlike accumulator programs, continue to provide support for the member's drug cost after copay fund exhaustion.

Recently, manufacturers such as Johnson & Johnson (J&J) and AbbVie have rejected PBM-led programs centered around the utilization of these types of financial assistance. In 2022, Johnson & Johnson filed a suit against the copay maximizer program SaveOnSP, who partners with Express Scripts International (ESI) and Accredo Health Group to administer the program.²⁰ J&J and other manufacturers are pushing back and claiming that these programs take assistance meant for individual members and utilize it to provide savings to reduce plan sponsor and PBM costs. The lawsuit is still in progress but will be watched closely as the decision could have a significant impact on how PBMs utilize these programs and the amount of savings associated with them.

The ruling by the U.S. District Court for the District of Columbia on the case brought forward by three patients, the HIV Hepatitis Policy Institute, the Diabetes Leadership Council, and the Diabetes Patient Advocacy Coalition against the Department of Health and Human Services—overturned a federal rule that allowed health plans to use copay accumulator programs to exclude drug manufacturer copayment (copay) assistance from a patient's out-of-pocket costs.²¹ Depending on the program design, the outcome of this ruling may have significant implications for the way health plans and PBMs operate and interact with patients and copay assistance programs.

Implications of these programs sunsetting or reducing their impact will result in reduced cost savings that were offsetting trend. As we look at the overall landscape, Risk Strategies Consulting sees the need to gain transparency on cost of goods across the supply chain, incorporate controls for audits of those costs, focus on clinical and quality measures, leverage real world data, and drive more participation of the ecosystem is paramount to success of managing trend.









With approximately 40-45% of specialty drugs covered under the medical benefit, managing costs and trend for specialty requires a strategy that encompasses both pharmacy and medical benefit.²⁶ Managing drugs under the medical benefit comes with a unique set of challenges including:

- Non-specific drug coding (HCPCS vs NDC)
- Delayed billing (can be several months)
- Inconsistency in claim processing standards
- Inconsistent pricing depending on provider and site-of-service
- Non-specific utilization management (UM) clinical criteria

Areas of focus in managing drugs under the medical benefit includes:

- Minimizing waste, channel management with pharmacy benefit optimization
- · Site-of-care redirection
- Ability to steer to lower cost alternatives
- Insight into provider prescribing patterns and contract pricing opportunities

Site of care costs can vary and are commonly up to 200% higher in a hospital outpatient department compared to the home. Risk Strategies Consulting predicts that with the growth of horizontal consolidation, specialty drug management can magnify with the providers' place of service changing from a physician-based site of service to a hospital site of service, increasing the cost of the drug by 68%-104%.²⁷



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Cell and gene therapies (CGT) have introduced the promise in curing chronic and rare conditions that utilize this advanced biomedical technology. Most of these newer CGTs are designed as one-time treatments that focus on correcting the root cause of the chronic condition at the cellular or gene level. CGTs focus on treating rare diseases such as hemophilia, Duchenne muscular dystrophy, and spinal muscular atrophy, though looking further into the pharmaceutical pipeline, CGTs are also being studied for more common conditions.²⁶

Payors may shoulder the costs and may or may not retain the member. Uncertainty around durability and the long-term efficacy of the CGT is an additional challenge, putting plan sponsors at risk for paying for therapy that may not work as intended. Solutions for managing the high costs, financial risk, and efficacy should include value-based contracting, comprehensive clinical management including long-term outcome tracking, provider network optimization, and solutions to prepare for and limit financial volatility. With innovative treatments such as cell and gene therapies falling under the medical benefit, Risk Strategies Consulting sees the criticality to ensure that financial frameworks for managing these treatments take into consideration place of service optimization, Diagnosis-related group (DRG) bundling/unbundling, total cost of care, member experience, and clinical outcomes.

Biosimilars

Biosimilars are biologic medications that are highly like their respective reference product (a biologic already approved by the FDA). Biosimilars, while just as safe and effective as the original biological ones, are often less costly and can result in savings for members and plan sponsors. As of May 2023, the FDA has approved 41 biosimilars across 11 original reference biologics.²⁹ Due to the increased competition within these classes of medications, there are significant decreases in the average sales prices of the biosimilar and the original biologic products.

The Humira biosimilar launch of 2023 has been the most anticipated and significant biosimilar launch to date, given the market share Humira has maintained for many years within the anti-inflammatory space and the number of biosimilar entrants, nine specifically, in a short timeframe.

In anticipating these approvals, Risk Strategies Consulting advises that payors ensure that utilization management (prior authorization, step therapy), formulary management, patient cost shares, and member disruption communications are all optimized to maximize savings produced by lower cost biosimilars. As we look at biosimilars, we must also consider market forces that impact utilization, and that can start with initiation of treatment in the hospital environment.

With the 340B health system, the financial incentive for brands may dissuade the use of biosimilars, as is projected with Humira. As we look at our ecosystem, each thread is closely woven to another with the ability to tighten the weave or loosen the knitting. With the introduction of Humira biosimilars, it is clear multiple variables needed to be anticipated and evaluated for an effective interception in cost. Formulary designs with product selections in chronic inflammatory diseases such as rheumatoid arthritis, dermatological conditions such as plaque psoriasis and gastrointestinal conditions such as Crohn's need to be evaluating the real-world performance of Tumor Necrosis Factor (TNF) inhibitors like Humira. These evaluations should include elements of how the medications are performing in the real world in the backdrop of formulary and benefit design. When we look at the persistence of a medication, it allows us to gauge how well those patients on the drug will remain on the preferred product or may need to move to a non-preferred product because of poor tolerance due to side effects and/or suboptimal clinical effectiveness. Considerations such as these are important components to an informed biosimilar strategy, as they aid in accounting for factors such as the number of individuals who may switch to a drug in a different, more expensive drug class, therefore impacting the ability to maximize the biosimilars exchanges.

The integration of formulary design with clinical management is critical to assessing the value and impact of these opportunities. These real-world data assessments combined with dynamic modeling for adoption provide the ability to assess the opportunity for newly diagnosed to existing populations that would gain from biosimilar adoptions.





Approaches to Lower Drug Costs

It is noteworthy to identify two market approaches intended to lower drug costs. The first being CVS's formation of Cordavis, to commercialize and co-produce biosimilars. The second being the establishment of the Synergie Medical Collective, a medication contracting organization formed by a consortium of Blue Cross Blue Shield plans.

The Cordavis approach creates a vertical integration in the supply chain that may face challenges in an era with focus on transparency. If the model is set up for auditability on the buy and sell sides, with all pricing, discounts, rebates, and administrative fee disclosures, there may be an opportunity to understand the value of this integration to plan sponsors. Additionally, as we look at the Institute for Clinical and Economic Review (ICER) and the need for cost thresholds that align to value, biosimilars offer us a window into brands that have taken price increases with no incremental value.

Synergie Medical Collective was founded by a group of Blue Cross and Blue Shield affiliated companies to serve Blues and select independent health plans to undertake the drug spend under the medical benefit. It will be important to understand how this Collective engages on the issue impacting accelerated growth and fast tracking into the commercial market for medical benefit drugs, from the clinical outcomes to the financial value, which can be passed to self-funded plan sponsors.

The future of PBMs' capabilities will be critical in managing this dynamic landscape with supply chain efficiencies, clinical integration, data robustness and stretching across medical drug costs. A need for anticipatory frameworks is key to ensuring that biosimilars and innovative treatments are effectively leveraged for optimal clinical and financial impact. Real world data will need to drive the strategy, assessment of value, and cost thresholds. In a supply chain that can have misaligned incentives, it is critical to understand that a product with conditional approval is priced similar if not more expensive than fully approved therapies, placing a significant cost burden on the plan sponsor to shoulder without a guarantee of clinical impact. The future PBM needs to be able to bring in a whole health strategy that leverages real world data for:

- Clinical value true outcomes vs. surrogate markers
- Health equity clinical trials that are not limited in population demographics with representation across races, ethnicity, and gender
- Clinical management addressing disparities in access/support in Clinical Trial vs. Real World data
- Robust data sets that integrate beyond medical/pharmacy such as non-traditional data (genomics, labs, etc.) for a 360-degree view





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Market Consolidation Impacts on the Healthcare Landscape

Healthcare and markets are becoming more consolidated across payors, hospitals, providers, and health systems. The consequences of these dynamics have resulted in a complex mix of advantages and disadvantages for the healthcare ecosystem. The realm of these market consolidations is attributed mostly to mergers and acquisitions (M&A), joint ventures, and strategic affiliations across provider groups, health systems, and payors. Consolidations can be either vertical (payor acquiring health systems) or horizontal (hospitals acquiring other hospitals).



Payor-based PBMs are expanding their footprint into the provider services domain, with every major PBM being affiliated with a variety of primary, specialty, and urgent care providers.30

Recent notable acquisitions in the sector comprise:

- Amazon acquired primary care platform, One Medical, in July 2022
- CVS Health acquired home health provider, Signify Health, in September 2022 and primary care provider, Oak Street Health, in February 2023
- Walgreens-backed VillageMD acquired primary, specialty, and urgent care provider, Summit Health, in November 2022
- Kaiser announced their acquisition of Geisinger Health in May 2023

Consolidations offer opportunities to drive a shift from the fee-for-service (FFS) models to value-based care (VBC) models. With financial and administrative pressures in delivering healthcare, consolidations, particularly amongst provider systems, offer the opportunity for waste reduction, decrease in costs, and improvement in patient outcomes. The benefits of these consolidations are seen particularly in rural healthcare systems, where hospitals have merged with another hospital or have been purchased by a hospital system.31 However, the data is less consistent across other aspects of the healthcare continuum including services such as skilled-nursing facilities and dialysis-centers as well as larger hospital systems.32

Vertical and horizontal consolidations offer the opportunity for interoperability, operational efficiencies, VBCs, and a whole health management approach. Effective coordination of care, addressing health equity, reducing provider administrative burden, and improving the member experience become potential realizable opportunities. At the core of delivering on these promises is the ability to leverage data and drive date fluency across the member journey to understand, validate, and valuate the clinical, financial, and experiential outcomes. While these are all opportunities, in the market there have been unintended consequences, increasing costs, reduced competition threatening opportunity for innovation, and inorganic assimilation resulting in growing pains of service, operational impact, and abrasion across their consumers and providers.³³



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It is important to consider the unintended consequences that are introduced by vertical and horizontal consolidation. With markets that are already dominated by set provider groups, while consolidation may result in improved efficiencies, there is a risk for contracting that limits the ability for insurers to tier or steer, creating limited options at potentially higher costs. Take, for example, the network construct and its underlying provider base. When we look at the ability to move from a broad network to quality defined high-performing networks (HPNs), it is important to drive steerage to those high-quality performance providers in those networks, which may be limited by these types of market strongholds. Additionally, as the ecosystem becomes consolidated and limited by constraints of access points, we need to account for the potential disruption with existing referral and admitting patterns, which could be difficult given the vertical and horizontal consolidation of health systems, which means the plausibility and nature of an HPN will vary by service area. Moreover, employees who tend to purchase the smaller, defined networks tend to be healthy, low utilizers or individuals who already use these providers, which does not provide the higher volume of services to the providers in these networks they are seeking. This can result in network providers viewing these arrangements less favorably, or they may compensate by increasing rates in the broader networks.

Risk Strategies Consulting believes that depending on the types of vertical or horizontal consolidations, there are unintended consequences and opportunities. As we look at vertical consolidations, there is an opportunity to improve interoperability, clinical care, and improve health outcomes. However, what we see is that while advances may present within the verticals, across the horizontals, there remains deficits in the exchange of data, coordination/transition of care, and a risk for poor member and provider experiences, We see tailwind opportunities for VBC arrangements within a vertical; however, this is dependent on the ability to create a whole health approach that drives an integration of data to support clinical outcomes, member experience, health equity, and financial value. Forward-thinking solutions will be important in reducing the impact these consolidations have on access, quality, cost, and affordability. The development of HPNs that emphasize positive health outcomes and leverage innovative and preventative care will be critical in managing trend in the face of market dynamics, particularly where network performance and access may be impacted by consolidations and rising costs.

Emerging Technologies and Solutions Impact on the Healthcare Landscape

In 2021, Risk Strategies Consulting (then Cambridge Advisory Group) began to emphasize the importance of taking a Whole Health, or 360-degree approach, to patient care. The COVID-19 pandemic accelerated the outgrowth of digitalization across the healthcare industry, and as a result, we continue to see an evolving landscape of virtual and digital care that requires better integration in the ecosystem and framework to assess the value of these solutions. horizontal (hospitals acquiring other hospitals).







Solutions within the healthcare ecosystem depend on services, products, and technologies that enhance the quality, accessibility, and delivery of care. These modes of delivery span across conventional and virtual channels including clinics, hospitals, and new innovations surrounding telehealth, which is defined as the remote healthcare world and services. Technology plays a critical role in helping healthcare organizations accommodate diverse patient populations and tackle gaps in care, while also providing innovations that improve medical practices, create new care delivery efficiencies, and aim to reduce costs for the ecosystem.

With the growth of these modalities, Risk Strategies Consulting sees the unintended consequences unfolding in three respects:

- Interoperability challenges translating into more data disparities in longitudinal view of patients
- More options that may cause fragmentation in care journey
- Introduction of costs that may not result in improved clinical outcomes

Virtual Medicine

COVID-19 saw an increase in the usage of telemedicine services, medical services provided using telecommunications devices, particularly around primary care, and behavioral services. Currently, providers are using telemedicine to increase communication and promote more opportunities for longitudinal care delivery across multiple specialties and disciplines as well as transforming care delivery through a blended approach of digital and conventional delivery. Hospitals and health systems are also inserting telemedicine modes for pre- and postambulatory virtual nursing, virtual emergency rooms, and for other virtual clinical related treatments.



Expanding telemedicine services among other specialties such as oncology, dermatology, and dentistry are also on the horizon. We have seen new service models that are integrating genomics, care navigation, and medical management with oncology virtual care. With the impact of populations in need of care access and navigating these options, plan sponsors need to ensure their strategy includes integration with the whole health of these patients as addressing the patient in a silo can result in poor outcomes.

Risk Strategies Consulting believes that additional work is needed to address interoperability and health equity which can be provided through a strategic alignment with integration of the virtual care solution to ecosystem place of services such as high performing networks. As we look at the tailwinds that virtual care can provide it is important to note that the requisite of broadband and technology resources as well as technology literacy training is critical in its success. These advances continue to set the stage for the need of robust data analytics that can be enriched by diagnostics for continuum from emerging risk to heavily comorbid burdened populations. Additional growth in home-based care opportunities continues to show as evidenced by M&A activity with over 46 transactions reported in the first (2) quarters of 2023.



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Digital at-Home Diagnostics

With the global market for direct-to-consumer lab services expected to reach \$2.4 billion by 2025, it is important to assess the impact of this trend. The integration of digital technology and diagnostics is facilitating new opportunities for improved patient experience and outcomes. Home medical tests, portable devices, smartphones, and other technologies have allowed for new ways to diagnose, monitor, and treat patients in the home setting. The digitization of at-home diagnostics can often facilitate disease diagnosis, remote monitoring, and overall chronic health management.

There are generally three types of at home diagnostics:

- Monitoring: Typically for measuring heart rate, vitals, blood pressure. and physical exercise
- Sample collection (external): Requires that the patient collect specimen (e.g., saliva, blood, stool), and send to a laboratory for analysis
- Sample collection (internal): Requires that the patient collect specimen and interpret results at home (e.g., pregnancy, COVID test)

Many telehealth solutions and/or providers are now offering at-home testing kits used to detect various conditions such as acute health issues, infectious diseases, allergies, pregnancies, and substance abuse. Devices and kits for certain chronic illnesses are also available. For example, diagnostics for glucose monitoring are among the most frequently utilized. Other devices allow for heart rate monitoring and blood pressure data to be transmitted to providers in real-time. Arrhythmia monitoring devices can now connect to a smartphone to perform electrocardiograms, which allows providers to analyze patterns and diagnose symptoms remotely as well. Genome sequencing is being leveraged to develop preventive health plans for patients by exposing risk factors for hereditary diseases. Additionally, there are specific applications for blood testing through finger pricking, which can translate to several different conditions for remote monitoring.

Related applications can analyze and compute the results and even provide medical advice accordingly with the designated healthcare professional. While these new diagnostic technologies enable alternative and efficient ways to diagnose, monitor, and manage patients, process deviations and/or inaccuracies can still occur. Also, not all insurers have adopted standard reimbursement policies for these modes of digital diagnostics, which could impact the scalability of these methods going forward.

With emerging risk populations and the growth of personalized medicine, diagnostics inclusive of next generation sequencing is critical for understanding the need and value of treatments and services. High-cost conditions with significant health impact are starting to see treatments that may improve the clinical outcomes, however as clinical trials are hindered in diversity of patients, there will be a need to validate the outcomes in a real-world population. The continued need for an integrated medical and pharmacy becomes critical as we look at the horizon in home-based care with opportunities to address health disparities and improve clinical and financial outcomes.



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Non-Traditional Care Locations

Telehealth and digital diagnostic solutions have also enabled a growing market of patients receiving care in places that traditionally they did not. One such example is in the hospital-at-home model. Through the partnership of technology and healthcare providers, medium acuity patients with well-defined treatment protocols can receive hospital grade care in their homes. In addition to in-person care and video visits, patients are continuously monitored through biometric devices.35 However, establishment and implementation of a successful program requires the investment of staff, technology, and financial resources, which can be barriers. Partnerships with outside home health companies and paramedics have eased some of these burdens. Additionally, many private payors do not cover the at-home model. CMS recently launched a waiver program to cover the cost of at-home hospital care. Risk Strategies Consulting anticipates that this will, in turn, cause private payors to reevaluate their own coverage policies around the model in the future and contract innovatively with providers for these arrangements.

Technology is also a driving factor behind the growth of the retail telehealth space by nontraditional players. Dollar General has begun to partner with DocGo mobile clinics. With over 80% of Dollar General's stores in rural areas with populations fewer than 20,000, the partnership clinics are intended to serve areas that may typically have limited access to care.³⁶

As we look at care in the home, we see an opportunity to drive integration and optimize care coordination across the member journey, addressing the whole health of the patient, unlike today's environment, where the focus is on the ailment at hand with a siloed approach to care.

Healthcare Point Solutions

Healthcare point solutions are services designed to provide a health, wellness, and/or condition-based service to supplement a benefits plan. These solutions address a specific condition and provide care or a program that meets a need in the healthcare ecosystem. As with digitization, COVID-19 helped accelerate the growth of the point solutions market. These solutions often harness the best of what technology's impact on healthcare has to offer; combining remote care solutions with wearable technologies and partnerships that look to emphasize patient outcomes.37 Healthcare solutions can be a standalone condition specific, offer broader condition inclusion with wellness, provider networks, or drive hybrid approaches. In behavioral health we have seen over 30+ solutions in the market that encompass condition specific solutions (i.e., areas such as depression, anxiety, autism, eating disorders, substance abuse), offer EAP, and/or provider networks. With behavioral health gaining more attention as a focus of health disparities, national self-funded employers have turned to behavioral health point solutions to provide quick access to a clinically robust network. Additional trending solutions emphasize musculoskeletal (MSK), cardiodiabesity, sleep health, and women's healthcare.

Risk Strategies Consulting sees an opportunity for these healthcare solutions to drive a sum broader than their parts, as today many plan sponsors have multiple point solutions, due to robust benefits offerings. This results in complex navigation for their members. A whole health approach personalized to the ecosystem is paramount to addressing the right care at the right time in the right setting. With the expected growth of healthcare solutions, Risk Strategies Consulting has designed comprehensive ROI frameworks to facilitate an assessment of these solutions to understand the value and impact discerning those solutions that can deliver on improved outcomes. Ensuring an understanding of how these solutions are engaging members from emerging risk to polychronic, delivering clinical outcomes, closing gaps in health equity, improving the member experience, and driving financial value is key to navigating this growing market for adoption of high value solutions.





Artificial Intelligence (AI), Machine Learning (ML) and Natural Language Processing (NLP)

Artificial Intelligence (AI), Machine Learning (ML), and Natural Language Processing (NLP) are being leveraged in multiple capacities to standardize operational efficiencies, predict adverse health outcomes, train medical professionals, and even augment the pharmaceutical discovery and development process.

Al is a collection of technologies including ML and NLP, which work to imitate human behavior. In healthcare, its capabilities are being used for clinical and clerical work. A branch of Al, ML, focuses on using data and algorithms to mimic the human thought process. Over time, the model "learns" from its trials and errors and improves its outcomes, making classifications, predictions, and more.³⁸ The algorithms utilized in ML vary in complexity, and in healthcare, can be used for practices like disease detection and selecting patients likely to have the most positive outcomes for pharmaceutical trials.³⁹

NLP gives computers the ability to interpret human language and manipulate and synthesize it into data that can be utilized by practitioners in treating patients. Examples include dictation software that converts spoken clinical notes to text, and data extraction that pulls key details from a patient's medical history, which in turn allows clinicians to quickly and analyze medical records for important takeaways and spend more time focused on the patients in front of them.⁴⁰

Together, these three components, which build off one another's capabilities, can revolutionize the ways in which healthcare is delivered and managed. The emergence of AI in healthcare has been groundbreaking and has redefined the pathways for diagnosis, treatment, and remote monitoring across the care continuum. The use of AI in healthcare has especially helped to interpret and analyze unstructured data, introduce automation, and facilitate new opportunities for predictive analytics. AI has the capacity to collect and aggregate data from multiple sources and can assess the prevalence and potential outbreaks of diseases at the population health level. ML algorithms can quickly process large amounts of clinical documentation, identify patterns, and make predictions about medical outcomes with precision and accuracy. Both AI and ML have also solved operational gaps in care delivery by standardizing processes such as patient intake, triage, and even translating provider notes, thanks to the use of NLP.

Risk Strategies Consulting believes with a framework that leverages clinical outcomes, member experience, and health equity within a whole health approach, Al and ML can support the patient journey across their ecosystem by identifying the emerging risk and using a personalized approach to managing/coordinating resources and care. Capturing broad data sets to inform diagnostic decisions that result in appropriate care management and coordination is essential, and by having outcomes at the forefront, with member experience as its copilot, we can provide more opportunity to identify and address health inequity, Harmonization of data with interoperability allows ML to identify opportunities for ecosystem performance improvement from activation to outcomes derived by treatment, provider, and place of service. Technology can successfully change how we approach patient outcomes and care navigation. The growth and implementation of telehealth components in today's healthcare ecosystem as well as the evolving use of Al, ML, and NLP provide opportunities for efficacy around cost and quality of care. However, we also believe that for technology's true impact to be felt within the ecosystem, there must be a push to provide patients with the resources, tools, access, and education necessary to successfully navigate this system.

Additionally, as technology takes a more formidable role in healthcare, more nuanced regulations and safeguards will need to be put into place. October 2023, saw the enactment of an executive order from President Biden establishing safety and security standards around AI- specifically implementing a safety program run within The Department of Health and Human Services to receive reports and provide remedy around harmful or unsafe practices within healthcare that involve AI. All March 2023 saw the announcement of a cybersecurity implementation guide, created by the Department of Health and Human Services in conjunction with the cybersecurity and preparedness focused working groups. The guide provides specific steps that members of the private and public healthcare ecosystem to mitigate cyber risks and is recommended for implementation by CMS. Risk Strategies Consulting believes that while these new security measures and system-wide updates are an integral part of technology's role in the healthcare ecosystem, we also recognize that they are costly and as a result, plan sponsors and patients may see a rise in costs to them.



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Innovative Financial Models' Impact on the Healthcare Landscape

As we look at today's mechanism for evaluating provider networks, the familiar uniform discount and data specification file has become the foundational tool, that on the surface provides uniformity. However, as we look at how this tool is riddled with limitations, it highlights the importance of new models for evaluating quality and cost performance of provider networks. There is a critical need to understand the case mix, severity of population, individual physician performance, facility usage, and measurable clinical impact to complement evaluation of the financial impact. Financial models require an understanding of the mechanics of incentives in our current healthcare delivery model and the need for changes.



In 2021, Risk Strategies Consulting looked at how the market was entering the early stages of a transition period by reconfiguring their network and reimbursement structures. In recent years, provider networks have come under intense scrutiny for a multitude of reasons including financial structures, care management strategies, and care metrics. The government and market have responded with the growth in VBC arrangements in which the reimbursement payments are tied to the quality of care and effectiveness of service. Participants can enter either a one-sided risk, also known as an upside risk arrangement, or two-sided risk, also known as a downside/ risk arrangement. In a one-sided risk arrangement, participants who successfully provide care at a lower cost may receive reimbursement from either the payor or CMS. In a two-sided risk arrangement, participants who successfully provide care at a lower cost may receive reimbursement from either the payor or CMS at an amount higher than in a one-sided risk arrangement however, they may also owe fees if those success rates are not met.⁴³ As of 2021, nearly 60% of healthcare payments had linkage to quality and value; however, only 20% had two-sided risk arrangements.⁴⁴

While traditional value, which is considered in part due to a combination of experience, cost, and quality, is process-based, a growing marketplace has resulted in its evolution to a more outcomes-based approach. Prior to the creation and implementation of VBCs, provider networks typically functioned in a FFS arrangement, whereby a provider would receive payment based on the number and types of services provided to patients, and if with VBCs in place, many of them are still sitting atop a FFS chassis. Effective and cost-efficient prescription drugs must be available, and for those that utilize telehealth services, reliable and affordable internet access, along with technology literacy must be addressed. As we look at the provider lens as identified in the quadruple aim, the reduction of administrative burden and experience is key to successful VBC arrangement. Interoperability is one key factor; however, consideration must be given to the requirements and alignment on clinical and financial outcomes. As VBC strategies impact revenue cycle management, it is key to have mechanisms within the framework on payment integrity that can facilitate transparency on outcomes with controls that allow providers to have ease of administration.

For VBCs to be successful, Risk Strategies Consulting believes constraints facing service, product perspective, and virtual and digital care offerings must be addressed. There must be clear, consistent, and accessible data points that need to be accessible for clinician buy-in. Success with providers hinges on ensuring consultants understand VBC, payment integrity, and are able to provide efficiency with transparency in audits.



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Conclusion

As we have highlighted the most impactful emerging trends in the healthcare ecosystem, we see headwinds building in healthcare costs, regulatory pressures, and complexity in benefit design for plan sponsors. However, there are tailwinds generated by the outgrowth of healthcare solutions, value-based care, and technological advances including Al and ML. With the need for transparency, Risk Strategies Consulting believes that comprehensive and scalable auditing solutions will be critical to navigate regulatory compliance, financial value, and clinical outcomes successfully and proactively across pharmacy and medical.

With increased costs to plan sponsors from legislative efforts supporting government pricing negotiation, specialty drug spend, and FDA accelerated approval pathways, it will be critical to have pharmacy benefit manager strategies that can address the growing needs on pipeline management (e.g., cell/gene therapy), formulary (performance, value), medical benefit drug management, and total person management with sophisticated data integration of traditional and non-traditional assets. With litigation settlements, horizontal consolidations, and increased facility charges from regulatory compliance efforts, it will be increasingly important to evaluate medical networks and their clinical, quality of care, and financial performance.

Network designs must be evaluated for quality of performance at the provider level, sustainability of those networks, potential disruption from market strongholds, and contracting hurdles that may prohibit steerage or tiering. Vertical consolidation offers the opportunity to improve interoperability, promote value-based frameworks, identify solutions for health equity disparities, and provide a schematic for horizontal impact. However, the critical to mass opportunity is incumbent on effectively managing, modeling, and curating real world data for a longitudinal view of patients, provider quality of care, network performance, pharmaceutical product value outcomes, and comprehensive return on investment analyses. As we look at the fragmentation of care, disparities in health equity and ineffectively managed populations across the risk stratum from emerging risk to high complexity risk, there is a need for solutions that drive ecosystem integration. This integration needs to be underpinned by predictive analytics and AI, providing a member journey that delivers support anchors for optimal clinical outcomes, addresses social determinants of health, and delivers on a patient experience that personalizes care across healthcare, benefit, and financial solutions.

Risk Strategies Consulting is continuously assessing market trends that are impacting plan sponsors and health plans. We have previously published pieces on behavioral health, network valuation and auditing. These are available on risk-strategies.com/consulting. In addition to publishing more in-depth analyses of the trends and topics covered above, our experts will also be providing critical insights and guidance on themes around payment integrity, women's health, and sleep care. As plan sponsors and health plans determine courses of action, the need for consultants with experience navigating these complex challenges and expertise across benefit, actuarial, and data science is paramount to ensuring effective outcomes and improved experience. Our team of experts leverage real-world data, market insights, and conduct comprehensive ROI with dynamic actuarial modeling to advise our clients on impactful strategies that solve for these upcoming challenges with considerations for their ecosystem.



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As a national consulting and actuarial services business, Risk Strategies Consulting provides hightouch consulting and state-of-the-art analytics services including strategy and consulting (encompassing health and welfare with deep pharmacy expertise, as well as mergers and acquisitions); actuarial services for plan sponsors, providers, and insurers; and benefit and claim audit services. Services are provided for a wide variety of industry segments including government entities, manufacturing and distribution, and self-funded organizations including corporations and trusts, healthcare organizations, national and regional insurance companies, and private equity firms, among others.

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