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# Examining Healthcare

## Regulation and related implications for opportunistic allocation

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Examining Healthcare

Trends within the global healthcare space are often driven by intricately linked forces of burgeoning science and technology, changing customer behavior, and shifting government regulation. The resulting pace and scale of evolution within the sector presents dynamic opportunities for allocating capital.

**"An opportunistic and nuanced approach to the healthcare sector, including a thorough understanding of complex regulatory forces, requires a specialized team with deep healthcare investment expertise and training across a wide range of domains."**

Howard Rowe

Healthcare encompasses a wide array of interrelated sub-sectors, each with a different set of applicable trends and a resulting track record of divergent performance. Multiple factors can influence the competitive positioning of healthcare companies including the medical necessity of products, proprietary science and technology, intellectual property, and quality of company management. Additionally, regulation acts as a powerful force that can cut across the various differentiators and significantly alter the competitive landscape, both within and across healthcare sub-sectors.

In our view regulation can create both headwinds and tailwinds for healthcare investors. Shifting headwinds, when accompanied by uncertainty around the magnitude of potential changes, have the potential to render specific sub-sectors or niches within them problematic for a portfolio. The selection of regulatory forces we outline in this paper, for example, can drastically alter the profitability and staying power of healthcare services businesses, particularly ones involved in the provision of care. By contrast, the same regulatory forces can act as tailwinds, creating opportunities ripe for potential. In this paper we outline a range of examples where regulatory shifts have created additional upside to our investment thesis for companies with an existing competitive advantage. Whilst the focus of this paper is on regulation coming out of the United States, the general themes of trends around the world have been similar.

We believe a nuanced approach to the healthcare sector, including a thorough understanding of complex regulatory forces, can achieve an attractive return profile with asymmetric upside. A specialized team with deep healthcare investment expertise and training across a wide range of domains is required to uncover and track opportunities and strategically access them across the capital structure.

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# 1.

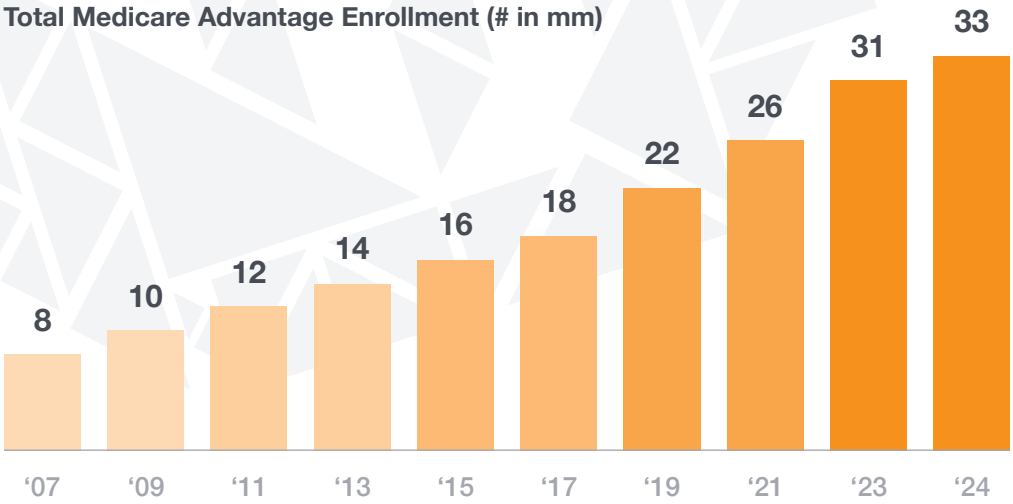
## Regulatory forces shaping the healthcare sector

# Profitability, already suffering from inflationary pressures, can be altered by the stroke of a pen

For healthcare services providers in the United States, prospects for profitability and long-term sustainability are in part shaped by actions of a network of payers including private insurance companies and the federal government. Medicare is the single largest payer for health care services in the United States and pays for most items by setting a fixed payment rate rather than reimbursing for full costs incurred. In most cases the fixed payment is updated annually and based on a formula calculating the relative average cost for performing a service. [1] However, payment rate increases typically lag industry trends and are not always in line with the cost of inflation.[2] Congress can enact legislation changing the formulas for Medicare payment rates, as it did in 2020 when it provided four temporary increases to fee schedule rates due to the COVID-19 pandemic, but, in general, is under pressure to keep overall Medicare spending in check.[3] This can be a difficult task when the price of medical care has shown a steady, upward trend since 2000 increasing 121.3% when, in contrast, the price for all consumer goods and services rose by 86.1% during the same period.[4]

Changes to Medicare's various fee schedules are a large determinant in the profitability of healthcare services providers across the continuum of care. Despite high medical care cost inflation, the payment rates set by Medicare can trend downward and can fluctuate, sometimes drastically putting a profit squeeze on provider businesses. Between 2012 and 2017 home health providers, for example, saw consistent Medicare payment rate cuts followed by only a very modest increase from 2018 through 2020. In 2012 skilled nursing facilities saw a massive net reduction in Medicare payments of 11.1% structurally changing the profitability and sustainability of many industry players.

**Total Medicare Advantage Enrollment (# in mm)**




**Source:**
KFF analysis of CMS Medicare Advantage Enrollment Files, 2010-2024; Medicare Chronic Conditions (CCW) Data Warehouse from 5 percent of beneficiaries, 2010-2016; CCW data from 20 percent of beneficiaries, 2017-2020; CCW data from 100 percent of beneficiaries, 2021-2022, and Medicare Enrollment Dashboard 2023-2024. Note: Enrollment data are from March of each year. Includes Medicare Advantage plans: HMOs, PPOs (local and regional), PFFS, and MSAs. About 61.2 million people are enrolled in Medicare Parts A and B in 2024.



1 https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment
https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2025-medicare-physician-fee-schedule-final-rule
2 https://gibbinsadvisors.com/healthcare-sector-bankruptcy-filings-have-slowed-but-financial-challenges-persist/
3 https://www.kff.org/medicare/issue-brief/what-to-know-about-how-medicare-pays-physicians/
4 https://www.healthsystemtracker.org/brief/how-does-medical-inflation-compare-to-inflation-in-the-rest-of-the-economy/

Over the years the combination of rate pressure from Medicare, cost inflation for healthcare services, and healthcare workforce shortages and wage increases has created tight operating margins for healthcare services providers and resulted in increased financial distress, restructuring, and bankruptcies. Healthcare bankruptcies, for example, surged across sub-sectors in 2023 and, for clinics and physicians, climbed even higher in 2024.[5]

### Salability and capital access can be altered by antitrust enforcement action

Market valuations and long-term exit strategies for healthcare investors can be limited by the regulatory climate, associated risk, and enforcement actions. In 2023 the United States Department of Justice (DOJ) announced the withdrawal of three antitrust policy statements related to enforcement in healthcare markets, noting the statements were too permissive and no longer served their intended purpose of promoting competition and transparency.[6] This action, partnered with a first of its kind compliant initiated by the Federal Trade Commission (FTC) against a private equity firm engaged in a Physician Practice Management (PPM) roll-up strategy, signaled the United States government's intention to more actively focus on competition in the healthcare services space and pursue antitrust enforcement through litigation.

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Public scrutiny around consolidation has centered on the idea that roll-up activity prioritizes owner profits over patient care. In 2024 the FTC and DOJ launched a formal inquiry to identify roll-up strategies by corporate actors, including private equity firms, that have potentially harmed competition and negatively impacted patients, workers, and innovation.[7] Around the same time the DOJ created a health care task force to address issues with competition in health care markets and guide policy updates and enforcement strategies.[8] This more stringent regulatory climate with an increased focus on enforcement can have direct impacts on healthcare provider sales, mergers, and acquisitions, including a shrinking pool of interested buyers and a lack of willingness amongst equity holders to provide further capital support. Ultimately, these impacts can be reflected in lower market valuations, potentially limiting lenders' ability to be made whole on their loans.



5 https://gibbinsadvisors.com/healthcare-sector-bankruptcy-filings-have-slowed-but-financial-challenges-persist/
6 https://www.justice.gov/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements
7 https://www.ftc.gov/news-events/news/press-releases/2024/05/ftc-doj-seek-info-serial-acquisitions-roll-strategies-across-us-economy
8 https://www.justice.gov/opa/pr/assistant-attorney-general-jonathan-kanter-announces-task-force-health-care-monopolies-and

### Complexities of regulation can incentivize exploitation of loopholes

As previously alluded to, complexities of regulation surrounding Medicare often create ripple effects throughout the healthcare sector. This has been particularly relevant in the healthcare insurance business, where Medicare Advantage plans aiming to improve patient choice, convenience, and affordability are offered by private insurance companies receiving payments from the United States government to provide Medicare-covered services. Medicare Advantage plans have grown in popularity, with enrollment accounting for more than half of the eligible population in 2023 and more than doubling between 2010 and 2023.[9]

Whilst enrollment has climbed and payments to Medicare Advantage plans have surpassed payments to traditional Medicare, scrutiny of Medicare Advantage has increased. Inquiries into practices such as falsifying risk score calculations, upcoding patients to more lucrative conditions or treatments, withholding care, or providing unnecessary care have led to claims of Medicare Advantage plan providers exploiting the Medicare system to increase their slim margins within the regulated cap. In 2020 the United States Department of Health and Human Services (HHS) released a report with concerns about Medicare Advantage plan providers based on data from the prior decade. The report concluded the complexities of the Medicare system may be creating financial incentives for private Medicare Advantage providers "to make beneficiaries appear as sick as possible."[10] Since the release of this report public and government scrutiny of Medicare Advantage providers has only increased, with the press releasing regular articles and detailed proprietary analysis to underscore the issue.

For investors in the healthcare insurance space Medicare Advantage issues highlight the opacity and complexity of the sub-sector, one facet of which being the large volume and protected nature of patient medical records. Verifying the quality of care, patient health outcomes, and isolating and calculating associated risks is, in our view, a nearly impossible task and therefore a significant barrier to investment, especially when considered alongside the tight margins in the space, which are only further limited by regulation. The sub-sector of healthcare insurance could become even more fraught in the coming years with increased oversight and further limits on Medicare Advantage providers' profitability, resulting in potential knock-on effects for other healthcare insurance and services providers.



9 https://www.kff.org/medicare/issue-brief/10-reasons-why-medicare-advantage-enrollment-is-growing-and-why-it-matters/
https://www.medicare.gov/publications/12026-Understanding-Medicare-Advantage-Plans.pdf
https://www.kff.org/medicare/issue-brief/10-reasons-why-medicare-advantage-enrollment-is-growing-and-why-it-matters/

10 https://oig.hhs.gov/oei/reports/OEI-03-17-00471.pdf

## Regulatory forces can act as strong and, in some cases, unpredictable headwinds, particularly for businesses involved in the provision of medicalcare services or insurance.

In our view these sub-sectors are less attractive than other areas of healthcare for two key reasons.

Firstly, given already slim margins, the profitability and salability of assets within care services and insurance can be drastically harmed by external forces of government regulation.

Secondly, sub-sector opacity around quality of patient care and health outcomes makes crucial issues extremely difficult to examine and measure during the investment due diligence process.

However, we believe some of these same regulatory forces can act as tailwinds for healthcare companies, especially for growth focused technology businesses where long-term success is more dependent on widespread adoption than on payer rates. In these select cases long-term regulatory shifts can create asymmetry to the upside for companies' return profile. Similarly, we see unique opportunities to access long-term structural and demographic trends through potentially lower regulatory risk channels in cases where growth focused healthcare companies offer non-medical services.

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# Regulatory forces as tailwinds

# Shifting regulations can accelerate market adoption of technology

For healthcare companies with established competitive advantages based on proprietary science and technology longer-term regulatory forces focused on patient safety outcomes, increased efficiencies, and resulting systemwide cost savings can positively enhance market penetration.

Healthcare technology or products that help achieve better safety and efficiency, especially those designed to address leading causes of death, are potentially positioned to benefit from regulatory tailwinds helping to speed market adoption over time.

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## Case study: Glytec

**Hyperglycemic and hypoglycemic events related to diabetes have long been common issues within hospitals and are associated with increased patient cost, length of stay, morbidity, and mortality.[11] Controlling blood glucose for hospital patients is a challenge due in part to human errors within the current paper-based standard of work.[12]**

In 2022 the United States Centers for Medicare & Medicaid Services (CMS) first included Severe Hyperglycemia and Severe Hypoglycemia in a group of clinical quality measures, with flexibility to choose if these measures were included in public reporting.[13] In 2024 CMS announced mandatory reporting requirements aimed at improving hyperglycemia and hypoglycemia measures to take effect beginning in 2026.[14] Under the new rule all hospitals are required to report on clinical quality measures for serve glycemic events as part of the Inpatient Quality Reporting (IQR) program. Non-compliance with the rule will result in financial penalties including reduced annual payments from the Medicare hospital Inpatient Prospective Payment Systems (IPPS).[15]

To comply with the upcoming reporting requirements more hospitals are looking for tools and systems to enhance glycemic control, such as those offered by Glytec. Glytec's key product, Glucommander, is part of an FDA cleared, cloud-based software platform designed to help hospitals manage patient glucose levels. The software monitors patient blood glucose, centralizes data to hospital electronic record systems, calculates and recommends patient insulin dosing.[16] Hospitals were previously interested in this type of system to improve patient outcomes. Now, the additional financial incentives resulting from regulatory changes is accelerating this shift to industry best practices.

11 https://pmc.ncbi.nlm.nih.gov/articles/PMC4153389/
12 https://glytec.com/2020/09/22/iv-insulin-pharmacys-role-in-reducing-risks/
13 https://glytec.com/guides/cms-fy22-ecqm-hospital-harm/#august
14 https://glytec.com/newsroom/glytec-recognizes-cms-for-new-mandatory-hyper-and-hypoglycemia-measures-for-u-s-hospitals/
15 https://www.federalregister.gov/documents/2024/05/02/2024-07567/medicare-and-medicaid-programs-and-the-childrens-health-insurance-program-hospital-inpatient
16 https://glytec.com/

## Case study: Heartflow

**Coronary artery disease is the leading cause of death in the Unites States. Invasive procedures such as bypass surgery and stenting have long been under public scrutiny, with claims of overuse due to higher Medicare payment rates.**

**"Non-medical services focused on activities of daily living are an alternative approach to capturing the trend of increased aging at home without requiring a specific investment in care providers and the associated regulatory headwinds."**

Andrew Merrill

Coronary artery disease is the leading cause of death in the Unites States. Invasive procedures such as bypass surgery and stenting have long been under public scrutiny, with claims of overuse due to higher Medicare payment rates. Technology, like that offered by HeartFlow, designed to detect coronary artery blood flow occlusion with a standard cardiac Computed Tomography (CT) scan rather than invasive tests can lead to more informed treatment plans and reduce the need for invasive procedures.[17] HeartFlow's key product, HeartFlow FFRCT, takes CT data, applies HeartFlow's proprietary analysis, and produces a digital 3D-model of the heart reflecting the impact of blockages on blood flow and helping to determine the best treatment plan. Treatment can range from lifestyle changes to medication, stenting, or bypass surgery.[18]

In 2024 CMS released several favorable coverage decisions relating to HeartFlow's products including increased payment rates via Medicare's Physician Fee Schedule (PFS) and doubled payment rates via the Hospital Outpatient Prospective Payment System (OPPS).[19] This decision follows ongoing advocacy and updated diagnostic guidelines from the American Colleges of Cardiology and Radiology promoting CT scans as the most effective way to assess people with chest pain whilst providing cost savings back to the medical system by avoiding costly interventions that put patients at risk.[20] These regulatory changes can financially incentivize healthcare providers to more quickly shift to this industry best practice.

### Finding lower risk channels for accessing aging population trends

Long-term demographic shifts and overall healthcare cost inflation are megatrends that have influenced the shifting regulatory forces discussed throughout this paper.
The United States government has been evaluating and collecting data on the potential cost savings of aging in place instead of a nursing home or medical facility for several decades, being encouraged by early evidence that programs supporting aging at home may yield savings for Medicare and broader health systems.[21]

Non-medical services focused on activities of daily living are an alternative approach to capturing the trend of increased aging at home without requiring a specific investment in care providers and the associated regulatory headwinds.

17 https://www.heartflow.com/newsroom/use-of-heartflow-planner-leads-to-change-in-treatment-strategy-in-nearly-half-of-patients-with-coronary-heart-disease/
18 https://www.heartflow.com/heartflow-ffrct-analysis-old/article/our-technology-core
19 https://www.heartflow.com/newsroom/medicare-medicaid-ccta-reimbursement-access/
20 https://www.acc.org/About-ACC/Press-Releases/2024/02/01/15/39/CT-Scan-is-Most-Effective-to-Assess-People-with-Chest-Pain
21 https://www.huduser.gov/portal/periodicals/em/fall13/highlight2.html

## Case study: Honor Technology/Home Instead

**Honor is the world's largest home care network supported by a proprietary technology platform aimed at personalizing relationships between caregivers and their clients.**[22]

This includes Home Instead franchise businesses providing non-medical care for seniors aging at home including meal prep, housekeeping, transportation, and medication reminders. The care is typically paid for directly by clients and their families instead of private insurance, Medicare, or Medicaid and is therefore relatively insulated from payer rate pressures often experienced in medical care. Key long-term success factors for Honor Technology will likely be based on accessing new markets and growing the client base rather than on regulatory forces, while aided by government initiatives to encourage aging at home.

**These case studies are emblematic of our approach to evaluating long-term trends, shifting regulatory forces, and the impact on competitive positioning of potential healthcare investments.**

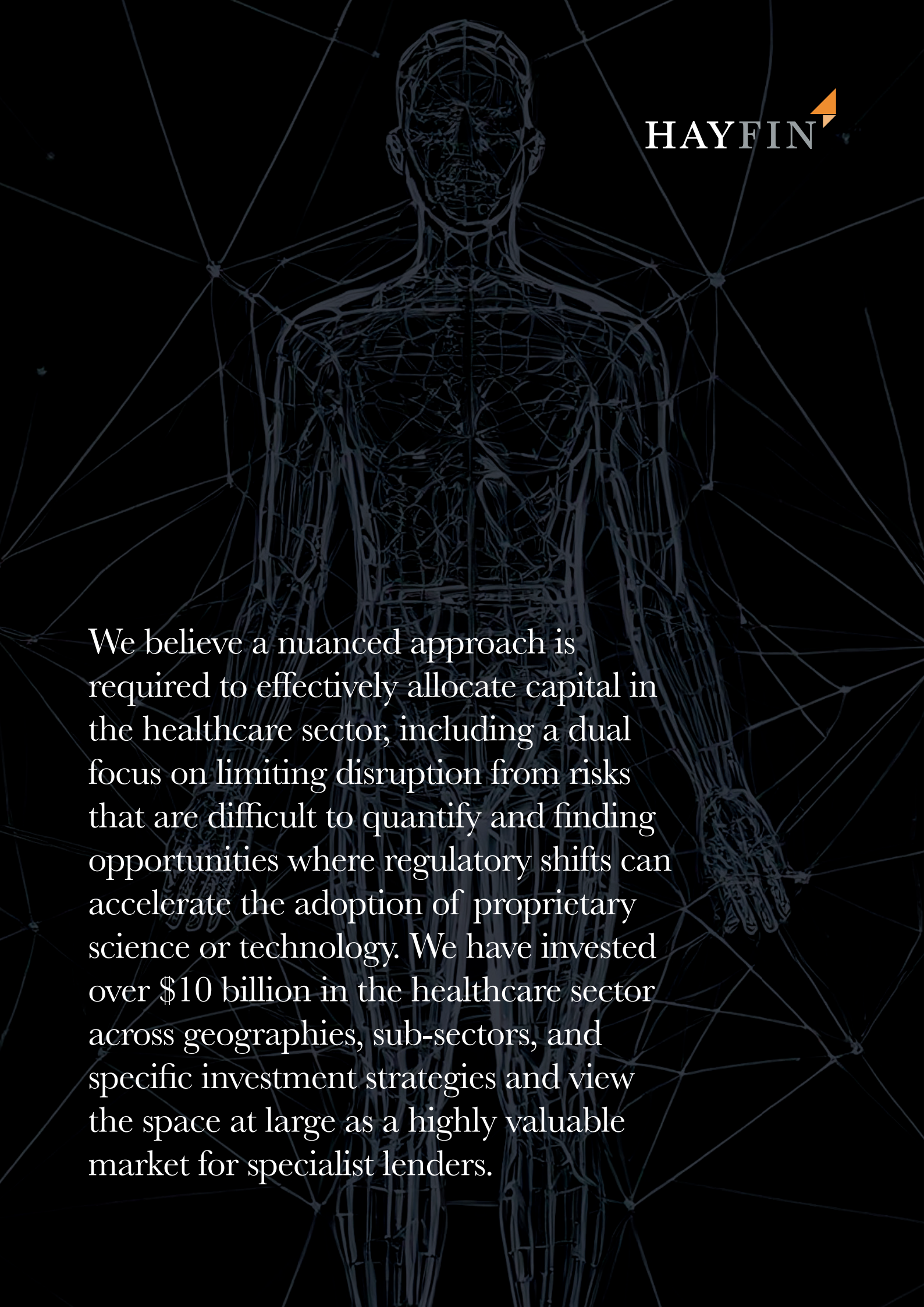
## Case study: PurFood

**PurFood provides seniors aging at home and their caregivers access to healthy meals that are convenient to prepare. It includes Mom's Meals, which delivers refrigerated ready-to-eat meals across the United States and offers meals developed to support common health conditions.**

Whilst clients typically pay for meals through Medicaid and, in select circumstances, Medicare, we see PurFood's long-term success as linked to their scale advantage and more dependent on growing the number of total clients served than on payer rates for the meals themselves.



22 https://www.honorcare.com/about-honor/



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We believe a nuanced approach is required to effectively allocate capital in the healthcare sector, including a dual focus on limiting disruption from risks that are difficult to quantify and finding opportunities where regulatory shifts can accelerate the adoption of proprietary science or technology. We have invested over $10 billion in the healthcare sector across geographies, sub-sectors, and specific investment strategies and view the space at large as a highly valuable market for specialist lenders.

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