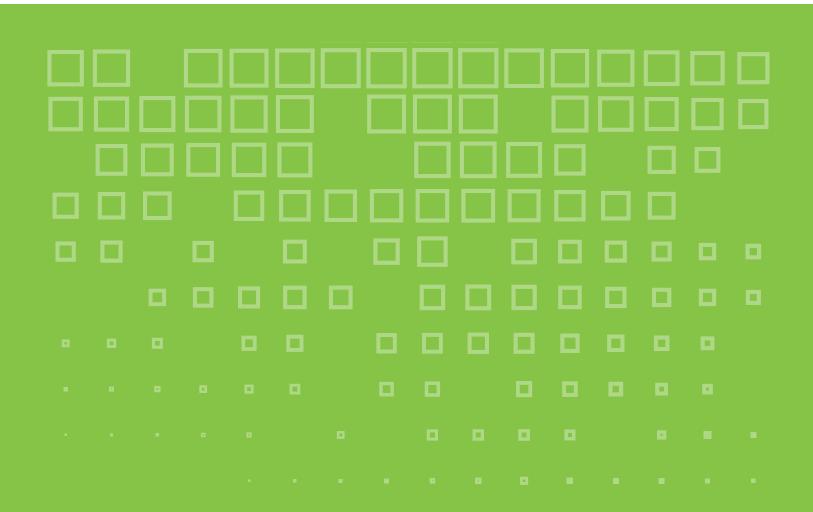
JANUARY 2023

Health Care Imperatives for the 2020s

2023 Update: Embracing Whole-Person Health



Health Care Imperatives for the 2020s

In January 2021, Manatt Health described ten health care imperatives essential for improving our health care system and advancing health equity in the decade of the '20s. Our 2022 update, "Navigating Through the Surges" recognized the extraordinary challenge of simultaneously improving the health care system while navigating the exigencies of the pandemic, and highlighted the problems presented by erosion of trust, the epidemic of behavioral health disorders, persistent and widening disparities, and chronic workforce shortages and stresses. We recognized gains made through federal and state action to improve coverage and access and industrywide attention to addressing inequities.

2022 again proved challenging. While enrollment in Medicaid reached an all-time high of 90 million, access to abortion care was sharply curtailed with Dobbs. Commitments to health equity met backlash from "antiwoke" advocates. Safety net facilities struggled with rising demand and declining payments, including loss of federal COVID-19 relief funding. The rapid spiral upward in labor and supply costs combined with compressed reimbursements resulted in massive losses for many hospitals. The worsening children and youth mental health crisis overwhelmed health services. Amidst this dark landscape, there were glimmers of light. Telehealth continued to demonstrate its potential with digitally enabled care models. Innovative solutions integrating health and social services were meaningfully launched in several states to meet the health-related social needs (HRSNs) of enrollees. Recognizing these important opportunities, we have chosen "Embracing Whole-Person Health" as the theme for our annual update, and we have added an 11th imperative: Innovating and Advancing Care at Home.

As a unifying theme, Embracing Whole-Person Health establishes a "north star" for the alignment of needs across the health system. Our individual ability to live a healthy and productive life depends to a great extent on drivers of health, including housing, food, safety, education, help at home, transportation and coordination of care across the continuum. The concept of whole-person health recognizes the benefit of aligning services from wellness through primary care to acute and post-acute care. It also embraces the need to focus public and private resources on aligning downstream health care services with upstream social and community resources. This alignment benefits from health care coverage and the intensive coordination of primary care, hospital, behavioral health, pharmacy, retail, social and educational services to improve the health of individuals, families, communities and populations. States are implementing these coordinated solutions through their Medicaid agencies and managed care contracting practices. Retailers are integrating health care and pharmacy services with expansive digital platforms. Health plans are building out extensive primary care platforms and taking steps to integrate social care into health care delivery. Health tech companies are rapidly evolving and introducing capabilities that facilitate coordination of services. And health systems are expanding their ambulatory, digital and community benefit investments to achieve similar goals.

Innovating and Advancing Care at Home has long been a critical missing link in the alignment of the health care system around those who need it the most, particularly the aging and those suffering with chronic and debilitating conditions. Advances in technology, including telehealth, remote patient monitoring, smart sensors, Al and medication administration, along with payment models piloted during the pandemic, have made care provided in the home far more available to millions of people and a desirable alternative to institutional care. Medicare Advantage plans, in coordination with community-based organizations (CBOs) and health systems, are likely to be significant leaders in advancing care at home. Our imperative reinforces the need to modernize the legal, datasharing and regulatory frameworks that govern home care and the reimbursement schemas that pay for it.

2023 Health Care Imperatives



Ensure Access to Coverage and Care

Improve access to needed services at every point in the health care system. Minimize coverage losses due to the end of the federal continuous coverage requirements.



Achieve Health Equity Through Collective and Sustained

Work upstream to solve structural issues of social need while continuing to improve access to and quality of health care.



Stabilize the Safety Net and Rebuild Public Health Capacity

Deploy financing solutions that allow safety net facilities to remain open and enable them to stabilize their workforce, invest in outpatient services and access capital for needed



Address Social Drivers to Improve Health for All Americans

Embrace whole-person-health strategies and engage enrollees in new ways to address their health-related social needs.



Help Our Children Reach Their Full Potential

Leverage policy and financing strategies to build partnerships between health care institutions, schools, and community organizations to develop life skills, enhance mental health knowledge, provide early intervention and connect youth in need with more intensive services.



Innovate Long-Term Financing and Care Models to Promote Living Longer, Healthier Lives with Dignity

Expand and support the long-term care workforce and improve access to noninstitutional and home-centric care models for older adults and people with disabilities.



Innovate and Advance Care at Home

Modernize legal and regulatory frameworks that govern home care and the reimbursement schemas that pay for it to remove barriers to innovation.



Accelerate Digital Health

Tightly integrate technology and clinical models to improve experience and clinical outcomes, implement strategies to incorporate AI, and design payment policies to stimulate further adoption.



Advance Academic Medicine

Accelerate repositioning strategies: expand ambulatory and community locations, invest in population health and value-based payment strategies, integrate community health into academic programs, extend digital offerings, and become vastly more efficient.



Deliver Breakthrough Treatments Affordably

Engage with FDORA (Food and Drug Omnibus Reform Act) to optimize new therapy review and launch.



Secure Health Data and Put It to Work

Execute a unified, cross-agency, comprehensive national framework to protect consumer health information held outside the traditional health care system. Ensure data strategies account for new federal and state data-sharing requirements.



Lead for Change: Environmental, Social and Governance

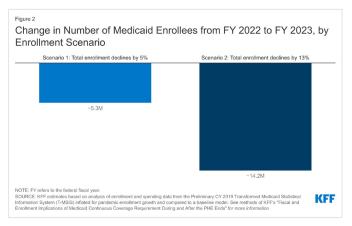


Ensure Access to Coverage and Care

Over the last three years, access to coverage has been strengthened by federal policy requiring states to continuously maintain Medicaid coverage without terminations in order to receive enhanced federal funding. These "continuous coverage requirements" are slated to end on March 31, 2023, and states will begin redetermining the eligibility of over 90 million Medicaid enrollees, threatening the historic coverage gains that were achieved during the COVID-19 public health emergency (PHE).

2022 Recap. Medicaid enrollment reached new highs-increasing by nearly 20 million since the start of the pandemic in early 2020—while states across the country prepared to resume redeterminations in anticipation of the end of continuous coverage. Marketplace enrollment also grew, and in signing the Inflation Reduction Act of 2022, President Biden extended for three more years the enhanced subsidies for purchasing coverage on the Marketplace, making commercial coverage more affordable for millions of people. While access to coverage surged, access to abortion care hit a major wall. The Supreme Court's June decision in Dobbs v. Jackson Women's Health Organization—and the subsequent action by more than a dozen states to prohibit all or most abortions—created an enormous barrier to accessing abortion services for pregnant people who experience unwanted or nonviable pregnancies and left in their wake a rapidly changing and uncertain landscape for patients, providers, payers, employers and Community Benefit Organizations (CBOs). The new reality is a highly complex patchwork of state laws impacting access to abortion care.

2023 Priorities. Millions may lose their Medicaid coverage this year; history proves that Medicaid eligibility redeterminations can cause coverage loss, even among eligible individuals. The Biden Administration has made minimizing coverage loss one of its highest priorities and has been releasing voluminous guidance on potential mitigation strategies states can take—working in partnership with managed care plans, providers and CBOs-to ensure eligible individuals continue to have access to coverage. By the end of this year, look for the Biden Administration to finalize a proposed rule intended to make longer-term changes to improve Medicaid and CHIP eligibility and enrollment processes. The Administration is also expected



Source: Jennifer Tolbert and Meghana Ammula. "10 Things to Know About the Unwinding of the Medicaid Continuous Enrollment Provision." KFF. Kaiser Family Foundation, January 11, 2023. https://www.kff.org/medicaid/issue-brief/10 things-to-know-about-the-unwinding-of-the-medicaid-continuous-enrollment-

to finalize a proposed rule that would create an easier path to Marketplace enrollment for people who lose Medicaid coverage, but the transfer of account information between Medicaid and the federal and some state-based Marketplaces continues to present a challenge to seamless coverage transitions.

Ahead of resuming all Medicaid redeterminations, states should work to maximize their ability to redetermine an individual's eligibility based on available data without requiring information from the individual (also known as "ex parte") and clearly communicate with enrollees and key stakeholders (including plans, providers and community partners) the actions needed to keep individuals enrolled in coverage. Managed care plans in particular should work closely with their state to help minimize coverage loss through targeted outreach to their members, and providers and CBOs will want to support these efforts by, for example, ensuring patients are aware of potential coverage changes and that their contact information is up to date.

To preserve access to abortion care, the abortion rights community and health care advocates will continue to focus on addressing barriers to access and assisting providers in understanding and navigating legal risks and implications of delivering both medication and procedural services. Providers of abortion services may need to adjust their business practices to mitigate their own risks while continuing to maintain access to services. A high priority in 2023 will be accelerating the secure and confidential delivery of direct-toconsumer information and telehealth services to facilitate access to medication abortion.



Achieve Health Equity Through Collective and Sustained Actions

Health equity means everyone has a fair and just opportunity to attain their optimal health regardless of factors such as race, ethnicity, socioeconomic status, gender identity, sexual orientation and disability. Many health care institutions and organizations have embraced the importance of advancing health equity; it plays a central role in federal policymaking and is a pillar of the work of the Centers for Medicare & Medicaid Services (CMS).

2022 Recap: In 2022, CMS released its 2022–2032 Framework for Health Equity with the following priorities:



Source: "CMS Framework for Health Equity 2022–2032." CMS. Centers for Medicare & Medicaid Services, April 2022. https://www.cms.gov/about-cms/agencyinformation/omh/health-equity-programs/cms-framework-for-health-equity

In parallel, many provider organizations amplified their health equity efforts, beginning to include equity objectives in their approach to community engagement, addressing bias and disparities in care delivery, and building representative workforce and leadership teams.

2023 Priorities: Macroeconomic headwinds will test the commitment of organizations and participants in the health system to prioritize health equity. The economic roots of many of the disparities in our nation call to our policy and health care leaders to look upstream to larger structural issues by making investments in affordable housing, job creation, transportation, education, and other social needs. Continued and expanded insurance coverage and improved access to and quality of care are also fundamental components of achieving health equity, as are investments in affordable housing, education, and other social drivers of health. These are all fundamentally resource allocation decisions. Certain states are facing organized backlash to their health equity work. Institutions working toward health equity will need to remain steadfast in their commitment to investing in upstream solutions while building diverse boards, leadership teams and workforces; embedding equity as an organizational value and priority; collecting, looking at and acting on data on disparities; engaging with community partners to shape health system priorities; and setting bold goals for progress.



Stabilize the Safety Net and Rebuild Public **Health Capacity**

Safety net hospitals are essential providers of services in vulnerable communities, with payments provided largely by Medicaid or Medicare. However, many facilities are failing because of the structural weaknesses in the financing system, with Medicaid covering only 88% of costs (with wide variation across states) and Medicare covering 84%. Consequently, hospitals are in financial distress and lack margin to invest in services their communities need. Many hospitals have closed in recent years, with 140 rural hospital closures alone since 2010. These failures constrain access and perpetuate disinvestment in vulnerable communities, which continue to suffer from chronic disease and worse health outcomes.

2022 Recap. Perfect storm conditions affected safety nets in 2022: rapid escalation of costs due to workforce shortages, ongoing pandemic-related demands, increasing restrictions on 340B drug discounts and reductions in government relief funding.

2023 Priorities. Policymakers at the federal and state levels must develop financing solutions that not only allow these facilities to remain open but also enable them to stabilize their workforce, invest in outpatient services (including, but not limited to, behavioral health) and access capital for needed investments (e.g., facility modernization, quality improvement). To achieve this goal, three priorities are needed. First, a consistent safety net definition must be established. Numerous safety net hospital definitions exist, but there is not a universally accepted definition across states. A common definition based on key factors such as payer mix can help policymakers target reforms directed to safety net facilities. Second, safety net hospital leaders and advocates should build coalitions on a regional or statewide basis to draw attention to the structural failures and build support for payment reforms. Third, states can expand their reform efforts through tools

like Medicaid-directed payments, which allow them to enhance payments to providers under managed care contracts and, in some cases, receive higher federal financing than disproportionate share hospital payments. CMS has approved an estimated \$20 billion already in directed payments. The regional average commercial rate can act as a benchmark for policymakers and providers for the level of funding required to cover hospital costs and correct for decades of disinvestment.



Address Social Drivers to Improve Health for All Americans

While attention to the impact of social drivers on health and well-being has steadily grown over the past decade, the COVID-19 pandemic accelerated investment strategies to address "whole-person health." The Medicaid and Medicare programs are expected to continue this focus as traditional health care providers and CBOs seek to collaborate and engage patients in new ways to address their HRSNs.

2022 Recap. In 2022, CMS signaled strong federal support for addressing HRSNs by authorizing ambitious 1115 waivers in Arizona, Arkansas, Massachusetts, Oregon and Vermont that advance the type of HRSN services covered via Medicaid and by releasing guidance on the use of "in lieu of services" as a mechanism to finance evidence-based HRSN initiatives. Also in 2022, California began delivering HRSN services statewide, and North Carolina launched its HRSN pilot program in three areas of the state. Both initiatives provide members with services such as housing deposits, caregiver respite and healthy food boxes while investing in the community's capacity to deliver services and participate in Medicaid.

Medicare Advantage policy also encourages a range of supplemental benefits that address HRSNs, with onefifth of these plans now providing one or more nonmedical benefits (e.g., food, nonmedical transportation). And in 2022, CMS launched its Realizing Equity, Access, and Community Health (REACH) Model to test an innovative accountable care payment approach to support integrated, whole-person care delivery and coordination for patients in underserved communities.

Examples of SDOH Services Covered in Recently Approved (AZ, MA, OR, VT) or Launched (CA and NC) 1115 Waiver Initiatives*

Housing	Food	Transportation	Interpersonal Safety/ Toxic Stress	Other
 Housing navigation, support and sustaining services Asthma remediation Short-term post- hospitalization housing Rent/temporary housing for months for specific populations 	 Nutrition and cooking education Fruit and vegetable prescriptions Healthy food boxes/ meals Medically tailored meal delivery 	Reimbursement for transportation including bus passes, taxi vouchers, ride sharing credits	 Parenting programs Home-visiting services Case management for victims of violence 	 Caregiver respite Linkages to legal services Sobering centers Community transition services

Note: Not every service is covered by each state. Source: Manatt Health Analysis

2023 Priorities. As Medicaid and Medicare expand their focus on HRSNs, expectations and opportunities to address these needs grow for managed care plans, providers, technology vendors and CBOs. Plans are seeing increasingly prescriptive social determinants of health (SDOH) requirements from state Medicaid agencies (e.g., requiring partnerships with CBOs), some of which are translating to provider requirements (e.g., use of ICD-10 Z codes to capture data on social need). With a key success factor being CBOs' capacity to deliver HRSN services, states, plans and health care systems must contemplate how to scale up successful pilot programs and help foster community-led networks of CBOs-including through the use of community care hubs that help organize and support CBO networks and technology vendors with closed-loop referral capabilities. Stakeholders will also continue identifying opportunities for sustainable financing for HRSN services and initiatives.



Help Our Children Reach Their Full **Potential**

While promising policies and strategies began to emerge in 2022, more will need to be done quickly to address the mental health challenges children and youth are facing. Leaders need to leverage existing policy and financing strategies and enact new ones; incentivize partnerships between health care institutions, schools and community organizations; and implement proven interventions and innovations to reverse the current trajectory. This is particularly important for the vulnerable children enrolled in Medicaid and CHIP, which together cover more than half of all Black and Latino children in the country, making racial equity a central concern.

2022 Recap. In 2022, COVID-19 vaccines became available to all children 6 months and older, schools and daycare centers resumed somewhat normal business, and by May 2022, enrollment in Medicaid and CHIP grew by 5.6 million, providing comprehensive health coverage to half of the nation's children. In many ways, these advances were overshadowed by the worsening children and youth mental health crisis gripping the nation, dominating news media and straining a health care system ill-equipped to deal with the emerging crisis even before the pandemic.

2023 Priorities. Schools are a critical setting for mental health prevention and will continue to be a focus in 2023. If appropriately resourced, comprehensive school mental health systems will work in partnership with youth, families, communities, health systems and managed care plans to develop life skills, enhance mental Racial and ethnic disparities contribute to disproportionately troubling mental health and wellness conditions among children of color. A 2022 report by the Annie E. Casey Foundation shows that almost 10% of high schoolers overall attempted suicide. The percentage increased for students of color, with over a guarter of American Indian or Native Alaskan high schoolers attempting suicide. Further, among LGBTQIA+ young people, nearly a quarter of gay, lesbian or bisexual students attempted suicide as compared with 6% of their heterosexual counterparts.

health knowledge, provide early intervention and connect youth in need with more intensive services. In addition, given dire mental health workforce shortages, states should leverage their Medicaid plan or seek a state plan amendment to expand telehealth mental health (TMH) in schools. Mental health workforce shortages are ubiquitous, and states, health systems, payers, agencies, schools and other stakeholders will all need to invest in recruiting, training and retaining a robust and culturally diverse workforce, including behavioral health providers and coaches, community health workers, and peers. Pediatricians and primary care physicians will also need training and adequate payment structures to assess and treat mental health conditions. And children's hospitals lack adequate beds to serve a growing number of patients with mental health and substance use concerns. The problem is particularly acute for individuals who lack access to community- or family-based care options and who frequently wait long periods of time for available psychiatric beds. In these situations, institutionalization, hospitalization and justice system involvement should be prevented whenever possible, and policy and financing strategies will need to reinforce and support this shift.

The youth and family voice will need to be lifted in designing appropriate strategies to address the youth mental health crisis.



Innovate Long-Term Financing and Care Models to Promote Living Longer, Healthier Lives with Dignity

By 2030, all of the nation's 74 million baby boomers will be age 65 or older. Baby boomers are also entering their senior years with more chronic disease than prior generations, including a growing population with dementia and Alzheimer's disease that will need advanced levels of care. An analysis by the Urban Institute found that 70% of adults who survive to age 65 will need some type of long-term services and supports (LTSS) in their lifetime, and at least 20% will need LTSS for longer than five years.

2022 Recap. The Biden Administration announced a lengthy list of nursing home reforms and policy priorities, including minimum staffing requirements, that are expected to take shape in the coming months.

In response to the pandemic, several states, including Massachusetts, New Jersey and New York, have also turned their sights to increased oversight of nursing home ownership (in an industry where 70% of nursing homes are for-profit), requiring increased staffing requirements and new financial transparency standards. A few states enacted laws or regulations mandating increased nursing home wages. Addressing shortterm funding needs for Medicaid enrollees, CMS extended the time period states have to use funding made available by the American Rescue Plan (ARP) for Medicaid home and community-based services through March 31, 2025.

2023 Priorities. In 2023, health care industry leaders must expand and support the long-term care workforce and improve access to noninstitutional and home-centric care models for older adults and people with disabilities. They must concurrently plan for a sharp increase in the need for nursing home care (for both post-acute/rehab services and residential care).

Federal and state policy efforts must focus on strategic and sustainable approaches and public-private partnerships for growing the workforce, which is disproportionately women, people of color and foreignborn. Efforts must include pipeline growth, recruitment, retention and workforce extension; workforce stability through wage, benefit and training supports; and workforce sustainability through clear and accessible career pathways and opportunities. Five states— California, Colorado, Massachusetts, Minnesota and Texas—have established Master Plans for Aging, which take a whole-person-health perspective and define road maps for the coordination of services and infrastructure required to support healthy aging.

In parallel, policymakers must continue to remove barriers to accelerated expansion of home- and communitybased services to enable more people to age and manage disabilities at home; reimagine and modernize skilled nursing and institutional care models to improve quality and resident satisfaction; invest in technology to better link LTSS to clinical care; and address the lack of alignment, conflicting incentives and inadequate financing models in public health payment systems that are not well-positioned to handle the coming challenge.



Source: "Master Plan for Aging." Master Plan for Aging. January 2021.



Innovate and Advance Care at Home

Catalyzed by investments and advances in technology that can now be deployed at scale, regulatory and payment flexibilities implemented under the COVID-19 PHE, and increased acceptance by providers and growing preference by patients, services delivered into the home are a rapidly expanding frontier for innovation. Emerging segments include remote patient monitoring, home urgent care, home diagnosis and testing, and acute care hospital admissions at home. However, home visits by clinicians, home infusion and multiple varieties of care at home remain rapidly growing, particularly for specialty services such as cancer care.

2022 Update: As of September 2022, a total of 253 hospitals had been approved to treat patients with inpatient-level care at home. The federal omnibus spending bill signed into law on December 29, 2022, directed CMS to extend its Acute Hospital Care at Home program through December 2024. Big hospital systems are beginning to make significant commitments to in-home care.

Interest in in-home health was front and center for big retail. Walgreens announced it would fully acquire the post-acute and home care platform CareCentrix. CVS outbid Amazon and United Health Group to acquire Signify Health for \$8 billion. Signify Health provides health risk assessments during home visits and connects patients to medical and community-based services. Best Buy continued its strategy to invest in remote patient monitoring (RPM) and senior care with the cloud-based RPM IT platform Coeus. Walmart partnered with Avanlee to help families and caregivers buy and deliver groceries for remote seniors to support aging-inplace.

The nation's largest insurance company, United Health Group, acquired home health care provider LHC Group in a deal worth \$5.4 billion. In-home and remote care continued to be an area of focus for private equity, with major investments completed in Biofourmis, Medically Home, Dispatch Health and CareBridge among others.

"Shifting the site of healthcare to the home and scaling home-based care will meaningfully decrease healthcare expenditures while affording additional benefits to patients through an improved patient experience, including the ability to be surrounded by family and friends and be more active in the comfort of a home setting. Research shows that home-based care can provide more patientcentered and satisfying care, lower complication rates, reduce **Emergency Department utilization** and lead to improved patient outcomes for patients who can safely be transitioned out of a hospital setting. It also results in fewer readmissions, one of several ways Mass General Brigham is addressing the ongoing hospital capacity crisis."

Mass General Brigham-August 2022

2023 Priorities: Advancing and sustaining home-based care models will require building, training, and retaining a diverse and skilled workforce adept at supporting different levels of intensity and acuity of need at different times. It will also require modernizing legal and regulatory frameworks that govern home care and the reimbursement schemas that pay for it to remove barriers to facilitate innovation, the provision of highly specialized care and initiatives that address whole-person-care needs.

Federal telehealth and hospital-at-home flexibilities have been extended for just two years; significant progress must be made on permanent policy change and associated quality and accountability approaches.



Accelerate Digital Health

The transformation of health care through information technology continues to accelerate, although effective and adequate payment for virtual modalities is highly variable. Artificial, or augmented, intelligence solutions are now being embedded in diagnostic and care delivery products, which is likely to further accelerate digital health adoption.

2022 Recap. Virtual care adoption stabilized in 2022—with telehealth now representing about 50% of behavioral health care, 10% of primary care and 5% of specialty care nationally. With this stability, providers began to shift their focus to embedding telehealth into everyday care through the creation of digitally enabled care models. In the end-of-year spending bill, Congress extended pandemic-era Medicare telehealth flexibilities through the end of 2024, which will provide much-needed (though ultimately short-lived) predictability to health care providers.

2023 Priorities. Partnerships between payers, health systems, employers and health tech companies will increase in importance during 2023 with a determined focus on return on investment (ROI) and optimization of digital tooling and infrastructure. Many health tech companies are likely to shift their focus from direct-toconsumer models to partnerships with payers, providers, or pharma through which they can demonstrate shortterm clinical and financial ROI.

Many Al companies have technology solutions that are ready to be deployed at scale in health care environments. While some health systems are looking to proactively adopt these solutions, most will need to begin designing strategies to incorporate Al-including addressing the legal, ethical and value implications while securing clinical buy-in. Of particular concern is that Al engines will reflect the biases of the inputs on which they have been trained.

Tightly integrated technology and clinical models driving improved member experience and clinical outcomes will be the most valued in moving digital health forward. Amazon's pending acquisition of One Medical, Tia's partnership with CommonSpirit and UCSF, and the



How will Al improve health care, as a poem



With data vast and knowledge deep, AI in health care will take its leap, Analysing patterns, finding cures, For illnesses, both known and obscure.

It will assist doctors in their quest, To diagnose and treat the sick and stressed, By sifting through mountains of data fast, And pinpointing what must be addressed.

It will streamline processes and reduce wait, For patients in need of care so great, And help to personalise treatment plans, For individual needs of every man.

Al in health care, a boon so true, Will improve lives, and make the world anew.

Source: Musings from ChatGPT, January 26, 2023.

consortium of 15 health systems General Catalyst has assembled to partner with portfolio companies are three models for providers partnering with health tech companies to deliver a unique product experience in their markets with tight clinical integration.

For those states that have not yet implemented permanent telehealth policies, we expect many to align with Medicare's policy and temporarily extend broad telehealth coverage and reimbursement for the next two to three years. We also expect to see states pass legislation and implement new telehealth policies related to payment parity, tele-medication abortion, cross-state licensure, coverage of audio-only telehealth services and network adequacy, among others.

The digital divide continues to be a priority for policymakers, health systems, payers and other stakeholders. Progress in digital health adoption has been limited by broadband access and affordability, and a lack of human-centered design practices within health tech models. New efforts are necessary to address health equity and social barriers limiting digital health access, including digital literacy, access to devices and language translation services.



Advance Academic Medicine

Academic health systems are once again at an inflection point in their long and productive history. Crosssubsidization from commercial payments to support the academic missions has long been a central pillar of academic medicine financing. The significant growth in Medicare and Medicaid enrollees now served by academic health centers, combined with a flattening of commercial rates, significantly weakens this longstanding pillar.

2022 Recap. In 2022, many academic health centers experienced operating losses due to cost increases, labor shortages and ongoing pandemic challenges. Workforce and pandemic challenges have continued to affect hospital and elective surgery capacity and thus revenue, escalated staff and faculty burnout, and led to significantly higher labor costs. Private sector disrupters are targeting high-margin services and offering patient convenience to attract commercially insured patients offered at a lower cost for patients and insurers. Regional and national consolidation of health plans and community-based provider systems is beginning to pose a threat to the referral of specialty cases upon which the fragile economics of academic centers rests. The increasing consolidation of primary care into national retail chains will also disrupt prevailing market structures and relationships with specialists.

2023 Priorities. These factors are necessitating an acceleration of strategies that academic centers have been pursuing in recent years: expansion of ambulatory and community locations, investing in population health and value-based payment strategies, integrating community health into their academic programs, extending their digital health platforms, and becoming vastly more efficient. Leaders are also diversifying their sources of future income with commercialization initiatives and joint ventures. Thoughtful increases in training programs will also be needed, particularly for primary care, nursing and allied health, to support the future workforce needs. In the domain of research, the policy imperative and increasing regulation to increase accrual of diverse patients to clinical trials will require new and rapid progress. Academic medical centers (AMCs) should continue their community engagement efforts to reach diverse populations and work to improve the efficiency and cost-effectiveness of their clinical trial operations to make it easier for faculty to engage in research and improve access for patients. Financial pressures are leading to higher productivity targets that, if not well managed, can be counter to sustaining a clinical practice culture that motivates physicians to participate in research and accrue patients to trials.



Deliver Breakthrough Treatments Affordably

In recent years, scientific discoveries have led to a dazzling array of new therapies. There are now 27 approved cellular and gene therapies in the United States. Advances in the generation and cellular delivery of RNA have enabled the development of lifesaving mRNA vaccines for COVID-19 and hope for their use in cancer and other diseases. Al is increasing the accuracy of diagnosis and treatment, driving improved outcomes, predicting infectious disease spread and showing potential for enhancing drug development. These sophisticated advances come with a high price tag, particularly in the case of cell and gene therapies, which are especially complex and difficult to manufacture.

2022 Recap. In 2022, Congress took significant action that will impact the trajectory of these life sciences advances for years to come. After decades of consideration, Congress passed the Inflation Reduction Act (IRA), which gives CMS the authority to regulate the prices paid by Medicare for older drugs and biologics. 2022 also saw Congress extend the Food and Drug Administration's (FDA) medical product user fee programs and enact a package of laws with major impacts on FDA's authorities and responsibilities (the Food and Drug Omnibus Reform Act, or FDORA).

The reauthorization of FDA's various user fee programs and FDORA provide FDA with critical new tools and resources to ensure new therapies are efficiently reviewed and the agency's regulatory practices keep pace with the ever-changing state of science, including an influx of resources to oversee the exponentially increasing gene and cell therapy submissions, a new requirement for the submission of diversity action plans detailing how clinical trial sponsors intend to ensure participation by diverse and underserved patient populations, and new tools for overseeing drugs approved under the Accelerated Approval pathway.

2023 Priorities. The IRA will have an immediate and substantial impact on life sciences companies, not only on those with currently marketed products that the law will directly impact but also on current R&D decisions and the valuation of early-stage companies. Companies may need to scale back research on new uses for current products, reduce investment in emerging companies, reorient research away from small molecule drugs and toward biologics, and prioritize research spending away from products intended for Medicare populations.

FDA will be actively implementing FDORA's many provisions for months and years to come, and life sciences companies must be prepared to engage and help shape these policies through public comment opportunities as it does.



Secure Health Data and Put It to Work

Federal and state policies continue to liberate an unprecedented volume of data with the goal of strengthening care delivery, fostering market transparency and competition, and enhancing health system oversight. A vast amount of digital consumer health information held outside the traditional health care system and therefore not protected by HIPAA, the nation's primary federal privacy law, also continue to proliferate. The June 2022 Supreme Court decision in Dobbs v. Jackson Women's Health Organization shone a painfully bright light on the vulnerabilities of highly sensitive health data—and the dire consequences of not protecting it better. Yet comprehensive federal data privacy legislation remains just out of reach.

2022 Recap. In 2022, federal interoperability and information-blocking rules continued to unlock clinical data previously siloed in health system electronic health records (EHRs), while the Trusted Exchange Framework and Common Agreement (TEFCA) drew closer to offering national governance and standards for health information exchange among participating networks. Federal price transparency rules required hospitals and payers to publicly disclose their negotiated service rates in machine-readable file formats, allowing for their future use in contract negotiations—a use case that is already being tested. States, meanwhile, continue to invest in health system data and analytic capacity, with Texas, Georgia, Indiana and Alaska joining 18 other states in establishing an All-Payer Claims Database (APCD) and California joining nine other states in establishing a cost growth benchmarking program, resulting in 1 out of every 5 Americans being covered by a program that seeks to contain health care cost growth through spending transparency and accountability.

States Covered by APCDs

Current States	Expected	Gap	
18 states with an operating APCD (Pop: ~103m)	6–8 states with an APCD in development (Pop: ~94m)	24–31 states without an APCD (Pop: ~129m)	

Source: McAvey, Kevin. "Realizing the Promise of All Payer Claims Databases." Manatt. Manatt Health, December 2022. https://www.manatt.com/insights/whitepapers/2022/realizing-the-promise-of-all-payer-claims-database

Congress came close to passing data privacy legislation, with the American Data Privacy Protection Act (ADPPA) making it through the House Energy and Commerce Committee before stalling, in part because of significant resistance from the state of California, which claimed that the bill would preempt arguably more protective California state laws.

The FTC advanced further into the consumer health space with the release of an Advance Notice of Proposed Rulemaking (ANPRM) that will explore rules to "crack down on harmful commercial surveillance and lax data security," as well as a new enforcement action against data brokers for selling geolocation data that could be used to track movements of individuals to and from sensitive locations, including reproductive health clinics.

2023 Priorities. In 2023, health care organizations will need to orient their data strategies to comply with new federal and state data-sharing and -reporting requirements, and to take advantage of new data resources that could preserve or strengthen their market positions. As public concerns grow over health care affordability, more states will likely invest in benchmarking programs and APCDs to better understand their region's cost drivers, likely fueling new debates on health system prices and spending.

As more health data continues to be unlocked and exchanged, Manatt believes that a unified, cross-agency, comprehensive national health data trust framework will be essential to promote data utility while protecting it from unintended use. This will improve consumer protection, shore up the cybersecurity of the nation's health care system and incorporate SDOH data into our data protection strategy while improving the provision and quality of behavioral health care.



Lead for Change: Environmental, Social and Governance

As 2022 opened, we advanced the view that responding effectively to the erosion of trust in health care institutions will be a defining characteristic distinguishing leadership in this decade. We cited three dimensions of trust as essential to address the health and health care challenges ahead: trust within historically disenfranchised communities to achieve equity, trust in science and scientific innovation, and trust in health care organizations. We believe that implementing an environmental, social and governance (ESG) framework can bridge the gap between health care organizations and all their stakeholders in order to build a better, more equitable health care system moving forward. While public, private and not-for-profit health organizations have different drivers for adopting an ESG framework, they all serve communities that are increasingly aware of what responsible business looks like and have elevated expectations for the organizations with which they engage.

ESG provides a framework for organizations to integrate their sustainability (e.g., environmental performance), corporate social responsibility, community benefit investment, and diversity, equity and inclusion initiatives. We also believe it creates a framework for advancing whole-person health in the manner most suited to the organization's priorities. Among the critical issues that health systems, health plans and state Medicaid agencies are addressing:

- Housing solutions for the homeless
- Food insecurity
- · Racial disparities
- Access to education
- Climate change—carbon neutrality
- Supplier diversity and local sourcing

Further, government, regulators, investors, donors and other stakeholders critical to their operations are playing a major role in driving the ESG dialogue within health care.

ESG principles provide a basis for leading the change needed in health care. Developing and executing a strong ESG framework has significant community benefits, including building trust; improving outcomes such as the promotion of diversity, access, equity and inclusion; improving workforce health and safety; and reducing greenhouse gas emissions.

Resources From Manatt Health

To access all Manatt Health insights: Manatt Health—Manatt, Phelps & Phillips, LLP

Ensuring Access to Coverage and Care	 How Differential Health Insurance Payment Rates Impact Access, Health Equity and Cost Vital Access: How Policymakers Can Streamline the Cancer Care Journey The Chaotic Health Care Landscape in a Post-Roe World Post-Dobbs Considerations for Provider Organizations: Navigating State Restrictions on Abortion
Achieving Health Equity Through Collective and Sustained Actions	The Role of State-Based Marketplaces in Advancing Health Equity State Strategies to Improve Maternal Health and Promote Health Equity Compendium Expanding Equitable Telehealth Access: Federal Funding Opportunities to Support Universal Broadband
Stabilizing the Safety Net and Rebuilding Public Health Capacity	Stabilizing the Safety Net: Challenges and Solutions for Saving Our Anchor Institutions
Addressing Social Drivers to Improve Health for All Americans	Integrating Community Care Hubs into Efforts to Address SDOH: A Playbook for State Medicaid Agencies In Pursuit of Whole-Person Health: A Review of Drivers of Health Initiatives in Medicaid Managed Care What Health Plans Should Know About Federal Changes for Dual Eligibles
Helping Our Children Reach Their Full Potential	The Substance Use Disorder Epidemic Among Youth: Responding to a Growing Crisis Strategies to Ensure Continuous Coverage for Children at the End of the Public Health Emergency
Innovating Long-Term Financing and Care Models to Promote Living Longer, Healthier Lives With Dignity	 Innovating Digitally Enabled Home-Based Care: Promoting Longer, Healthier Living Sustaining Flexibilities in Medicare and Medicaid Leveraging Federal and State Authorities to Ensure Access to LTSS: Resource Guide and Update
Innovate and Advance Care at Home	Designing and Launching Hospital-at-Home Models: Strategic Imperatives for Health System Leaders
Accelerating Digital Health	Closing the Digital Health Disconnect: A Blueprint for Optimizing Digitally Enabled Care Accelerating and Enhancing Behavioral Health Integration Through Digitally Enabled Care Maintaining Telehealth Access to Medicaid-Covered Pediatric Services After the End of the PHE
Advancing Academic Medicine	Creating Successful Integrated Service Lines: A Guide for AMCs On the Path to Health Justice—Opportunities for Academic Medicine to Accelerate the Equitable Health System of the Future The Impact of Dobbs on Medical Education and the Pipeline From OB/GYN Training to Clinical Practice
Delivering Breakthrough Treatments Affordably	 Achieving Clinical Trial Diversity: An Overview of the Policy Landscape and Ongoing Challenges Positioning for Value-Based Cancer Care: Lessons and Opportunities Delivering Breakthrough Treatments Affordably Reimagining Medicine: Can Policy Keep Pace With Scientific Advances?
Securing Health Data and Putting It to Work	 Protecting Consumer Health Data: FTC and State Actions to Close the Privacy Gap Realizing the Promise of All Payer Claims Databases: A Federal & State Action Plan Privacy Considerations in an Era of New Health Data Custodians

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About This Report

This report was prepared by Manatt Health professionals to share with clients and friends. For more information, contact Ilene Siegalovsky at isiegalovsky@manatt.com.

About Manatt Health

Manatt Health integrates legal and consulting services to better meet the complex needs of clients across the health care system.

Combining legal excellence, firsthand experience in shaping public policy, sophisticated strategy insight and deep analytic capabilities, we provide uniquely valuable professional services to the full range of health industry players.

Our diverse team of more than 180 attorneys and consultants from Manatt, Phelps & Phillips, LLP, and its consulting subsidiary, Manatt Health Strategies, LLC, is passionate about helping our clients advance their business interests, fulfill their missions and lead health care into the future. For more information, visit https://www.manatt.com/Health.

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