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INNOVATION TO INTEGRATION: LEGAL PATHWAYS FOR SUSTAINABLE HEALTH CARE COVERAGE

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ABSTRACT

Over the last several decades, the U.S. health care system has seen a substantial shift towards value-based care, creating an environment increasingly capable of supporting innovative, yet non-traditional, health care interventions. Despite strong evidence of improved outcomes and reduced costs, many of these innovative services, such as doula, community health worker, and nutrition services, have struggled to transition from community-based programs into sustainable, reimbursable benefits integrated within traditional health insurance systems. Absent integration, these services risk remaining trapped in short-term funding limbo, limiting their impact and long-term sustainability.

This Article examines why many promising, innovative services fail to achieve lasting coverage and argues that successful integration depends on alignment with the legal frameworks that govern health care coverage. Focusing on Medicaid, Medicare, and the Affordable Care Act, we argue that alignment is possible given the flexibility embedded into each program. To bridge the gap between health care innovation and governing legal infrastructures, we identify three recurring legal and structural barriers that inhibit integration: benefit design, provider credentialing, and billing and reimbursement. Through examples, we trace how and why these challenges arise, how each issue is governed under insurance program legal structures, and how some innovative programs and services have successfully navigated these barriers. In doing so, the Article reframes legal compatibility not as an insurmountable obstacle or late-stage hurdle, but as a critical design component at every stage of

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development. When stakeholders understand and proactively align service models with statutory and regulatory requirements, long-term integration is both achievable and consistent with the core attributes that drive innovative success.

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I. INTRODUCTION

Of all the high-income nations, the United States experiences the worst health outcomes.¹ This is both despite spending the most on health care, \$4.9 trillion or \$14,570 per person in 2023, and having record health insurance enrollment—92.5% in 2023.² Many commentators believe that these are the consequences of our “sick care” system of health care that primarily focuses on treating illness and disease after they occur, rather than proactively promoting health and preventing disease.³ The consequences of this system are not distributed evenly. Health outcome disparities exist and continue to persist along race, ethnicity, gender, geography, socioeconomic status, and more.⁴

However, over the past several decades, the United States health care system has slowly shifted toward value-based models that prioritize quality and patient-centered delivery.⁵ This shift has ushered in new approaches to care that move beyond mere disease treatment to confront the root causes of chronic diseases, promote whole-person care, and address the social determinants of

1. David Blumenthal et al., *Mirror, Mirror 2024: A Portrait of the Failing U.S. Health System*, THE COMMONWEALTH FUND (Sep. 19, 2024), <https://www.commonwealthfund.org/publications/fund-reports/2024/sep/mirror-mirror-2024> [<https://perma.cc/KP8C-X8VN>].

2. Anne B. Martin et al., *National Health Expenditures in 2023: Faster Growth as Insurance Coverage and Utilization Increased*, 44 HEALTH AFFS. 12, 12 (2024).

3. See Farshad Fani Marvasti & Randall S. Stafford, *From “Sick Care” to Health Care: Reengineering Prevention into the U.S. System*, 367 NEW ENG. J. MED. 889, 889–890 (2012) (advocating for reorientation of medical education and health care delivery toward homeostasis and prevention rather than disease treatment and diagnosis).

4. Nat’l Acads. of Scis., Eng’g & Med., *Communities in Action: Pathways to Health Equity* 2 (Alina Baciú et al. eds., Nat’l Acads. Press 2017), <https://www.nationalacademies.org/projects/IOM-BPH-15-15/publication/24624> [<https://perma.cc/SRM8-EQLM>].

5. See Michael E. Porter, *Value-Based Health Care Delivery*, 248 ANNALS OF SURGERY 503 (2008), https://journals.lww.com/annalsofsurgery/citation/2008/10000/value_based_health_care_delivery.1.aspx [<https://perma.cc/E34B-7H5F>]; *Value-Based Care*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/priorities/innovation/key-concepts/value-based-care> [<https://perma.cc/K5HP-4M5G>] (last updated Feb. 27, 2025) (“In value-based care, doctors and other health care providers work together to manage a person’s overall health, while considering an individual’s personal health goals . . . This approach to care also can help people avoid the emergency department and keep them out of the hospital.”); Hannah L. Crook et al., *A Decade of Value-Based Payment: Lessons Learned and Implications for the Center for Medicare and Medicaid Innovation, Part 1*, HEALTH AFFAIRS (June 9, 2021), <https://www.healthaffairs.org/doi/10.1377/forefront.20210607.656313/> [<https://perma.cc/MH3S-9ND2>]; see also Zahy Abou-Atme et al., *Investing in the New Era of Value-Based Care*, MCKINSEY & CO. (Dec. 16, 2022), <https://www.mckinsey.com/industries/healthcare/our-insights/investing-in-the-new-era-of-value-based-care> [<https://perma.cc/U7QQ-59FD>] (describing investment in value-based care (VBC) over the past 10 years and forecasted growth potentials); WENDY GERHARDT ET AL., DELOITTE CTR. FOR HEALTH SOLUTIONS, ROAD TO VALUE-BASED CARE (2015) (detailing the shift from fee-for-service to VBC in 2015, including that “some health care organizations are actively preparing for the transition to VBC while others are hesitating.”); Vaibhav Awasthi, *What is the History of Value-Based Care?*, INNOVACCER (Aug. 23, 2023), <https://innovaccer.com/resources/blogs/what-is-the-history-of-value-based-care> [<https://perma.cc/LAE4-AKXV>] (explaining broader trend towards VBC, including the coining of the term “Value-based Care” in 2006).

health.⁶ Parallel to this system transformation, numerous “innovative interventions”⁷—from doula services to nutrition and housing support services—have demonstrated their ability to improve outcomes, creatively address disparities, and lower costs by preventing the “compounding complexity and disease progression that drive the need for more care.”⁸ Some scholars, however, caution that the benefits of these interventions may be overstated.⁹

6. See, e.g., Exec. Order No. 14212, 90 Fed. Reg. 9833, 9833–36 (Feb. 19, 2025) (setting United States policy towards aggressively combatting chronic diseases by, *inter alia*, prioritizing research on root causes); *Strategic Direction*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/priorities/innovation/about/strategic-direction> [https://perma.cc/BC8P-85E2] (last updated Mar. 16, 2026, 7:11 PM) (outlining Innovation Center’s 2025 strategy of incentivizing preventive care to help people avoid illness and optimally manage chronic disease); Press Release, U.S. Dep’t. of Health & Hum. Servs., HHS Announces Transformation to Make America Healthy Again (Mar. 27, 2025), <https://www.hhs.gov/press-room/hhs-restructuring-doge.html> [https://perma.cc/8FR6-UBXL]. Chronic conditions impose substantial burdens on health outcomes and health care costs. These conditions, such as diabetes, heart disease, and cancer, are among the leading causes of death and disability in the United States. They are also the leading drivers of the nation’s annual \$4.9 trillion in health care spending. See generally *About Chronic Diseases*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 4, 2025) https://www.cdc.gov/chronic-disease/about/?CDC_AAref_Val=https://www.cdc.gov/chronic-disease/about/index.htm. [https://perma.cc/TD5J-LNVX]; see generally *Whole Person Health: What It Is and Why It’s Important*, NAT’L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH, <https://www.nccih.nih.gov/health/whole-person-health-what-it-is-and-why-its-important> [https://perma.cc/TM2B-FCN9] (last updated May 2021) (“Whole person health involves looking at the whole person—not just separate organs or body systems—and considering multiple factors that promote either health or disease.”); OFF. OF THE ASSISTANT SEC’Y FOR PLAN. & EVALUATION, U.S. DEP’T OF HEALTH & HUM. SERVS., BUILDING THE EVIDENCE BASE FOR SOCIAL DETERMINANTS OF HEALTH INTERVENTIONS (2021) (evaluating “the existing evidence for effective interventions to address social determinants of health (SDOH) and social needs and identify potential next steps for further developing the evidence base for effective interventions.”).

7. This paper uses terms such as “innovative interventions,” “innovative services,” and “non-traditional” care and services interchangeably.

8. See Elizabeth Teisberg, Scott Wallace & Sarah O’Hara, *Defining and Implementing Value-Based Health Care: A Strategic Framework*, 95 ACAD. MED. 682 (2019) (“A patient whose diabetes does not progress to kidney failure, blindness, and neuropathy is, over time, dramatically less expensive to care for than a patient whose condition continually worsens.”); see generally Allison Orris, Anna Bailey & Jennifer Sullivan, *States Can Use Medicaid to Help Address Health-Related Social Needs*, CTR. ON BUDGET AND POL’Y PRIORITIES (Feb. 27, 2024), <https://www.cbpp.org/research/health/states-can-use-medicaid-to-help-address-health-related-social-needs> [https://perma.cc/9X4S-CQT4]. For instance, reimbursement for nutrition support or housing assistance has improved health outcomes and lowered costs by addressing the underlying drivers of illness rather than merely treating the symptoms. See Alexandra Bryan et al., *Addressing Malnutrition Through Advances in Value-Based Care*, HEALTH AFFS. (Apr. 2, 2025), <https://www.healthaffairs.org/content/forefront/addressing-malnutrition-through-advances-value-based-care> [https://perma.cc/2VWD-H5N9].

9. See, e.g., Katherine Baicker & Amitabh Chandra, *Can Prevention Save Money?*, 6 JAMA HEALTH FORUM 1, 2 (2025) (“[P]resently, there is little evidence for lifestyle and behavioral health promotion programs that reduce future health care costs by enough for a large enough share of participants to save money overall—and many may not even improve health outcomes.”). Baicker and Chandra argue, thus, that innovations should be evaluated not based on whether they “save money” but “whether they improve health sufficiently based on their cost.” *Id.*

The rise of value-based payment models, expanded public and private funding for the piloting and development of non-traditional interventions,¹⁰ and bipartisan momentum for whole-person care¹¹ are converging to create an environment conducive to supporting the scaling of services that address the U.S. health care system's most pressing needs. Still, all these developments present a legal and administrative challenge: can innovative approaches, which often leverage non-medical professionals and deliver services beyond traditional clinical settings, be integrated into existing legal frameworks and coverage and reimbursement systems without sacrificing the very attributes that have made them successful?

Legal scholars have examined the statutory and administrative constraints on health care innovation, often focusing on the “purposes” of the U.S. health insurance systems, particularly in Medicaid. Many scholars have addressed how the statutory language and surrounding case law interpreting the Social Security Act do or do not allow for or constrain innovation, such as coverage of nutrition and housing supports or imposition of work requirements via Medicaid Section

10. Federal programs, states, and private insurers have formalized and expanded reimbursement pathways for several innovative services and payment models. See Sahil Sandhu et al., *Integrated Health and Social Care in the United States: A Decade of Policy Progress*, 21(4) INT'L J. OF INTEGRATED CARE 1, 2 (2021), <https://pmc.ncbi.nlm.nih.gov/articles/PMC8570194/pdf/ijic-21-4-5687.pdf> [<https://perma.cc/GTF3-4MF3>] (“Innovative approaches to integrate health and social services expanded rapidly with the shift towards value-based payment models and the growing evidence that adverse social determinants of health (SDOH) are major drivers of poor health.”); see Alice T. Chen et al., *The Community as a Full Partner: A New Model for Public Health*, 43 HEALTH AFFAIRS 805 (2024), <https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2024.00033> [<https://perma.cc/K7PR-HY25>] (advocating for continued support for community-based partnerships post-pandemic); see, e.g., Amy Chen, *State of the States (November 2024): Efforts to Expand Access to Doula Care in Medicaid and Private Insurance*, NAT'L HEALTH L. PROGRAM (Dec. 6, 2024), <https://healthlaw.org/resource/state-of-the-states-november-2024-efforts-to-expand-access-to-doula-care-in-medicaid-and-private-insurance/> [<https://perma.cc/6H2L-XUU6>] (collecting data on eighteen states that have implemented Medicaid doula coverage and eight states which require private health plans to cover doula care); U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., SHO# 21-001 RE: OPPORTUNITIES IN MEDICAID AND CHIP TO ADDRESS SOCIAL DETERMINANTS OF HEALTH (SDOH) (2021) (identifying key federal authorities that can be used to support innovative strategies to improve care and reduce costs, in the context of addressing Social Determinants of Health); Exec. Order No. 14212, 90 Fed. Reg. 9833, 9833–36 (Feb. 19, 2025) (directing agencies to “ensure the availability of expanded treatment options and the flexibility for health insurance coverage”); *Coverage of Health-Related Social Needs (HRSN) Services in Medicaid and the Children's Health Insurance Program (CHIP)*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (2023), <https://www.medicaid.gov/health-related-social-needs/downloads/hrsn-coverage-table.pdf> [<https://perma.cc/FSE6-ELYG>] (identifying opportunities for states to address health-related social needs through Medicaid authorities); but see U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., RESCISSION OF GUIDANCE ON HEALTH-RELATED SOCIAL NEEDS (2025) (rescinding November 2023 guidance but restating commitment “to working with states to help identify strategies to support innovation and improvement in Medicaid and CHIP.”).

11. See Exec. Order No. 14,212, 90 Fed. Reg. 9833–36 (Feb. 19, 2025); U.S. Dep't of Health & Hum. Servs., *supra* note 6.

1115 demonstration waivers.¹² Others have focused on structural barriers to the development of responsive services within our health care systems. These commentators have highlighted how front-end inhibitors, such as weak market incentives and insufficient evaluative mechanisms, direct innovation away from “socially valuable” services.¹³

Today, the innovation landscape has evolved. Many programs have overcome early-stage barriers, leveraging grant funding and community-based efforts to fill gaps left by traditional health care delivery and develop effective service models.¹⁴ However, this bottom-up approach to service innovation and development presents new challenges of navigating health care integration at scale. As these initiatives seek to pursue health care reimbursement, the tension between innovative, value-based care models and health insurance statutory frameworks has become more salient. Many of these innovative services are currently functioning as pilots—e.g., via Medicaid Section 1115 demonstration authority—and struggle to transition to fully covered benefits, a critical legal distinction that implicates long-term sustainability.¹⁵ The consequences of this struggle for integration are particularly acute for patients. When services are not covered by health insurance, patients—especially those in need of care the

12. See, e.g., Laura S. Richman & Barak D. Richman, *The Objectives of Medicaid: The Legal Definition Behind America's Most Important Health Program*, GW L. FAC. PUBL'NS (2024), <https://dx.doi.org/10.2139/ssrn.5067576> [<https://perma.cc/L9EB-96T2>]; Kristen Underhill, *Purchasing Health? The Promise and Limits of Public Health Insurance*, 119 COLUM. L. REV. F. 302 (2019); Nicole Huberfeld, *Medicaid Waivers, Administrative Authority, and the Shadow of Malingering*, 49 J. L., MED. & ETHICS 394 (2021).

13. See, e.g., Daniel J. Hemel & Lisa Larrimore Ouellette, *Valuing Medical Innovation*, 75 STAN. L. REV. 517, 520–21 (2023) (“the system fails to provide adequate incentives . . . to invest in the medical innovations that would do the most to improve health”); Rachel E. Sachs, *Integrating Health Innovation Policy*, 34 HARV. J.L. & TECH. 58, 61 (2020) (“private market signals may distort innovative activity away from a class of therapies that would be highly socially valuable”); Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L.J. 1900, 1956 (2013) (raising concerns that the complexity and costs of evaluating the success of non-medical interventions “may ultimately prove insurmountably high” because of confounding variables and nonquantifiable outcome measures).

14. Rachael Zimlich, *Community-Based Care Programs Fill Gaps in Traditional Health Services*, MANAGED HEALTHCARE EXEC. (Jan. 3, 2019), <https://www.managedhealthcareexecutive.com/view/community-based-care-programs-fill-gaps-traditional-health-services> [<https://perma.cc/Z27G-6D8C>] (referencing Carrie E. Fry et al., *Evaluating Community-Based Health Improvement Programs*, 37 HEALTH AFF. 22 (2018)); see also Amelia Whitman et al., *Addressing Social Determinants of Health: Examples of Successful Evidence-Based Strategies and Current Federal Efforts* 13, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION (Apr. 1, 2022), <https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf> [<https://perma.cc/CMG8-LD9Y>] (identifying CDC's “REACH” grants, pilot projects, and other investments into community-based services); see also Katie Garfield, Julia Koprak & John Haughton, *Addressing Nutrition and Food Access in Medicaid*, THE FOOD TR., https://thefoodtrust.org/wp-content/uploads/2022/07/report_addressing-nutrition-and-food-access-in-medicaid_2021.original.pdf [<https://perma.cc/E34J-V5MW>] (last visited Apr. 5, 2026) (detailing food and nutrition interventions, grant funders such as HHS, USDA, states, and health care entities).

15. See, e.g., 42 U.S.C. § 1315(f)(6).

most—may be unable to pay for the services out-of-pocket and therefore may not be able to access them.¹⁶

This Article argues that, despite seeming facial incompatibility, the U.S. coverage systems—structured under Medicare, Medicaid, and the Affordable Care Act (ACA)—are flexible enough to support the sustainable inclusion of innovative services. But successful integration requires proactive alignment with the legal frameworks that govern these systems.¹⁷ By clarifying the statutory and regulatory contours of the three major U.S. coverage pathways, this Article seeks to bridge the gap between health care innovation and the legal infrastructure that governs it.

Armed with the knowledge of how their interventions may be evaluated, measured, and reimbursed by insurers, drivers of innovation can proactively structure their services to maximize scalability and future coverage opportunities. Full integration of these community-based services into traditional coverage frameworks not only enhances access and financial sustainability but also amplifies the core goals of value-based care: improved health outcomes, cost reductions, and greater satisfaction among patients and providers.¹⁸ Even if not every innovator, service provider, or stakeholder seeks to secure long-term health care funding, structuring programs in alignment with existing legal standards will promote stability and consistency across programs while keeping long-term coverage opportunities on the table.

This Article proceeds in three parts. Part II outlines the innovative service “life cycle” from community-based program to sustained health care reimbursement. Part III draws distinctions between traditional and innovative service models and identifies the structural and legal misalignments that often inhibit long-term health care integration and coverage. The section then examines three recurring barriers to integration that arise from this misalignment: benefit design, provider credentialing, and billing and reimbursement. By drawing on examples, it analyzes how these barriers emerge

16. Grace Sparks et al., *Americans’ Challenges with Health Care Costs*, KFF (Jan. 29, 2026), <https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs> [https://perma.cc/6U4J-K4M3] (“[36% of] adults say that in the past 12 months they have skipped or postponed getting health care they needed because of the cost . . . [75% of uninsured adults under 65] say they went without needed care because of the cost.”); see, e.g., Rory Peters & Alexis Robles-Fradet, *2024 Update: Medicaid Coverage for Doula Care Requires Sustainable and Equitable Reimbursement to be Successful*, NAT’L HEALTH L. PROGRAM (Jan. 23, 2025), <https://healthlaw.org/2024-update-medicaid-coverage-for-doula-care-requires-sustainable-and-equitable-reimbursement-to-be-successful/> [https://perma.cc/WRG5-84SW] (explaining how out-of-pocket costs for Doula care can be unaffordable for low-income families).

17. See, e.g., *Healthy Opportunities for All: A Practitioner’s Recommendations for Success*, REINVESTMENT PARTNERS 14 (Oct. 2022), https://static1.squarespace.com/static/6525b3af3afe0f0c191f9b5f/t/675ab65c0f9ab67d2584138c/1733998173019/Healthy+Opportunities+for+All_1_final.pdf [https://perma.cc/X3D2-22NE] (concluding that—in the context of a state-based pilot which provides food, housing, and transportation assistance to eligible Medicaid beneficiaries—making improvements early in the development of the pilots will increase their likelihood of becoming covered benefits).

18. *Value-Based Care*, *supra* note 5.

and how stakeholders have successfully aligned innovative services with the Medicaid, Medicare, and the Affordable Care Act legal frameworks to promote coverage compatibility. Finally, Part IV offers practical guidance for providers, funders, and policymakers seeking to support the sustainable development and integration of innovative care.

II. THE ROAD TO COVERAGE: THE LIFE CYCLE OF INNOVATIVE SERVICES

Innovators have leveraged a variety of established pathways to secure both short and long-term coverage and reimbursement for services. For example, community health workers (CHWs), frontline public health workers who serve as intermediaries between communities and health and social services, have been funded by Medicaid state plan amendments (SPA), Section 1115 demonstration waivers, managed care organizations (MCOs), and the Medicare Community Health Integration (CHI) program.¹⁹ Food is Medicine (FIM) programs, which provide certain patients with chronic illnesses with nutrition support services such as medically tailored meals, medically tailored groceries, and produce prescriptions, have accessed coverage through several Medicaid authorities, including Section 1915(c) home and community-based services waivers and Section 1115 demonstration waivers.²⁰ And non-emergency medical transportation services (NEMT), which provide Medicaid beneficiaries with transportation to and from medically necessary health care services, have transitioned from a federal “administrative requirement” to a covered Medicaid benefit.²¹

Although services leverage a variety of funding options, many follow a

19. See *Community Health Workers*, AM. PUB. HEALTH ASS'N, <https://www.apha.org/apha-communities/member-sections/community-health-workers> [<https://perma.cc/BB3V-TH26>] (last visited Apr. 5, 2026); see generally *State Community Health Worker Policies*, NAT'L ACAD. FOR STATE HEALTH POL'Y, <https://nashp.org/state-tracker/state-community-health-worker-policies/> [<https://perma.cc/G89Y-JFHW>] (last visited Apr. 5, 2026); Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program, 88 Fed. Reg. 78818, 78920–21 (Nov. 16, 2023) (to be codified at 42 C.F.R. pts. 405, 410, 411, 414, 415, 418, 422, 423, 424, 425, 455, 489, 491, 495, 498, & 600).

20. See generally Dariush Mozaffarian et al., “Food Is Medicine” *Strategies for Nutrition Security and Cardiometabolic Health Equity: JACC State-of-the-Art Review*, 83 J. AM. COLL. CARDIOLOGY 843 (2024); FOOD IS MEDICINE: A STATE MEDICAID POLICY TOOLKIT, CTR. FOR HEALTH L. & POL'Y INNOVATION OF HARV. L. SCH. & FOOD IS MED. COAL. 5–22 (July 2024) (detailing four Medicaid/CHIP authorities states can use to pay for and deliver FIM services).

21. *Non-Emergency Medical Transportation*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/medicare/medicaid-coordination/states/non-emergency-medical-transportation> [<https://perma.cc/DV37-ECPJ>] (last visited Apr. 28, 2025); 42 C.F.R. § 431.53 (As an “administrative requirement,” states were required to ensure necessary transportation to and from providers for Medicaid enrollees to receive Medicaid reimbursement); Consolidated Appropriations Act of 2021, Pub. L. No. 116-260, § 209, 134 Stat. 1182, 2988 (2020) (codifying NEMT as a Medicaid Mandatory Benefit); see also MEDICAID & CHIP PAYMENT & ACCESS COMM'N, MANDATED REPORT ON NON-EMERGENCY MEDICAL TRANSPORTATION 154 (2021).

similar trajectory as they transition from community-based interventions to integrated components of health care coverage. This path typically unfolds in three stages: (1) grant-funded community-based provision, (2) piloting and experimentation within formal systems, and (3) full integration as a covered benefit.

A. Phase One: Grant-funded Community-based Provision

Government and private grants and local funding provide critical resources for seeding, evaluating, and expanding access to interventions.²² For example, Wholesome Wave is a community-based nonprofit that pioneered several innovative interventions to address nutrition insecurity.²³ One such intervention is the produce prescription, which enables medical professionals to provide patients with funds to purchase fruits and vegetables.²⁴ These prescriptions increase access to healthy foods and reduce downstream health care costs associated with diet-related illnesses, particularly chronic diseases.²⁵ Like many other groundbreaking interventions, this program has been supported by grants from the federal government, nonprofit foundations, and local funders and partners.²⁶ Similarly, doula services²⁷ have been sustained and expanded

22. See, e.g., ADVANCING A HEALTHIER WISCONSIN ENDOWMENT, *Community-Led Seed Grants* 3–4 (June 2024) (offering private grants to “support[] community-driven efforts to conduct initial exploration and test innovative ideas to serve as a foundation for future larger, sustainable efforts to improve health.”); *How We Work*, ROBERT WOOD JOHNSON FOUND., <https://www.rwjf.org/en/about-rwjf/how-we-work.html> [<https://perma.cc/LF4T-HVEL>] (last visited Apr. 5, 2026), (supplying private grants for innovative strategies to create lasting change for health equity); Natasha Singer, *Eat an Apple (Doctor’s Orders)*, N.Y. TIMES (Aug. 13, 2010), <https://archive.nytimes.com/www.nytimes.com/2010/08/13/business/13veggies.html> [<https://perma.cc/49CQ-BSYY>]; *Wholesome Wave Awarded USDA Grant*, WHOLESOME WAVE (Dec. 21, 2022), <https://www.wholesomewave.org/news/usda-grant-awarded> [<https://perma.cc/G6PP-BGLT>] (federal government grant awarded for FIM service); see also Food Justice, *2021 Farmers Markets Coupon Program Launched*, CITY OF BOS. (July 2, 2021), <https://web.archive.org/web/20260303172240/https://www.boston.gov/news/2021-farmers-markets-coupon-program-launched> [<https://perma.cc/U4Q3-Y6WJ>] (exemplifying collaboration between nonprofit organizations and state and local governments to develop farmers market nutritional benefits programs).

23. Wholesome Wave, *supra* note 22.

24. See generally *Improving Health by Embedding Produce Prescriptions (PRx) into Healthcare Practice*, NAT’L PRODUCE PRESCRIPTION COLLABORATIVE, <https://nppc.health/> [<https://perma.cc/H6KS-JJHT>] (last visited Apr. 5, 2026).

25. Kurt Hager et al., *Food is Medicine Research Action Plan*, ASPEN INST. 84 (2024), <https://aspensfood.org/wp-content/uploads/2024/04/Food-is-Medicine-Action-Plan-2024-Final.pdf> [<https://perma.cc/9YYS-JTPR>].

26. See *supra* note 22 and accompanying text.

27. Doulas are “non-medical professionals who provide emotional, physical, and informational support and guidance” before, during, and after labor and birth.; *Doula*, CLEV. CLINIC, <https://my.clevelandclinic.org/health/articles/23075-doula> [<https://perma.cc/RT4L-GVD6>] (last updated Jan. 15, 2025); see also *What Is a Doula*, NAT’L HEALTH L. PROGRAM (2020), https://healthlaw.org/wp-content/uploads/2020/04/WhatIsADoula_4.16.2020.pdf [<https://perma.cc/F27B-L7D7>].

through funding from foundations, nonprofit grant makers, departments of public health, and federal grants, which have increased access to culturally competent, supportive care for pregnant individuals.²⁸

Although these early funding streams are instrumental in the initial development of innovative services, they are not long-term or statewide solutions.²⁹ As services develop and demonstrate their capacity to improve health outcomes, reduce costs, and/or address health care disparities, forerunners often seek to expand beyond the community-based model, leading to phase two.

B. Phase Two: Piloting and Experimentation

The second phase involves piloting and experimentation, where innovative services leverage legal flexibilities—such as pilot programs and waivers—offered within traditional health care models.³⁰ These mechanisms permit states and insurers to fund novel, evidence-based interventions and service delivery

28. See, e.g., Press Release, BCBSMA Foundation, BCBSMA Foundation Announces \$360,000 in Grants for Perinatal Health (July 18, 2024), <https://www.bluecrossmafoundation.org/about-us/news-updates/bcbsma-foundation-announces-360000-grants-perinatal-health> [https://perma.cc/6NTH-2494] (providing grant funds for “supporting access to doula care for pregnant people in communities of color”); *Birth Justice Fund*, GROUNDSWELL FUND, <https://groundswellfund.org/funds/birth-justice-fund/> [https://perma.cc/B6UX-5BSQ] (last visited Apr. 5, 2026) (providing nonprofit grants “to make midwifery and doula care and training accessible to women of color, low-income women, and transgender people.”); *Doula Initiative*, COMMONWEALTH OF MASS., <https://www.mass.gov/info-details/doula-initiative> [https://perma.cc/4N4R-NW7Q] (last visited May 11, 2025) (the Massachusetts Department of Health “Doula Training Scholarship provides financial support for individuals pursuing doula training or continuing education”); Healthy Start Supplement: Community-Based Doulas, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/grants/find-funding/HRSA-22-148> [https://perma.cc/GC3K-6X3L] (last visited May 11, 2025) (providing federal supplemental funding to increase the availability of doulas in “areas most affected by infant and maternal mortality and to increase the number of women with a higher risk of poor birth outcomes receiving doula services.”).

29. See, e.g., Carl Rush, *Sustainable Financing of Community Health Worker Employment*, NAT’L ASS’N OF CMTY. HEALTH WORKERS 1 (2020), <https://nhchw.org/resource/chw-sustainable-financing-2020/> [https://perma.cc/9DDT-Y6Z7]; see also Molly Knowles et al., *Community Health Worker Integration with and Effectiveness in Health Care and Public Health in the United States*, 44 ANN. REV. PUB. HEALTH 363, 371 (2023) (“Lack of sustainable financing is consistently identified as one of the most significant barriers to CHW expansion and integration with health care.” (internal citation omitted)).

30. See, e.g., Alison Aubrey, *Fresh Food Advocate Links Farmers, Doctors, Low-Income Families*, NPR (Apr. 27, 2012, 11:53 AM), <https://www.npr.org/sections/thesalt/2012/04/26/151473374/fresh-food-advocate-links-farmers-doctors-low-income-families> [https://perma.cc/FU2Y-5SV4] (discussing interest in pilot program for produce prescription program with Wholesome Wave co-founder); Amy Chen, *Best Practices for Medicaid Coverage of Doula Care*, NAT’L HEALTH L. PROGRAM, <https://healthlaw.org/doulamedicaidproject-bestpractices/> [https://perma.cc/Y4EU-EBYV] (last updated Mar. 2026) (discussing pilot programs for doula services which allow “local, regional, and state actors to test out different types of doula projects”); *MTM Program Pilot Act*, FOOD IS MED. COAL., <https://fimcoalition.org/policy/policy-priorities/mtm-pilot-act/> [https://perma.cc/Z6NP-FDEG] (last visited Apr. 5, 2026) (supporting a bill to establish a Medicare pilot program for Medically Tailored Home-Delivered Meals).

approaches, sometimes by waiving certain legal requirements.³¹ For example, the joint federal-state Medicaid program, administered by the Centers for Medicare & Medicaid Services (CMS), is one of the leading drivers of innovation financing in health care.³² Some Medicaid financing options include Section 1115 demonstration waivers³³ and Medicaid Managed Care In-lieu of Services (ILOS).³⁴ With this more formalized support, programs can build the evidence base for broader expansion and integration into standard coverage pathways.

Importantly, while these options enable innovators to test, evaluate, and refine service delivery models, they are not meant to provide long-term coverage.³⁵ Medicaid Section 1115 demonstration waivers, for example, are typically approved for an initial five-year period.³⁶ Although there is no cap on the number of times a demonstration waiver can be renewed or extended, there is also no guarantee of reauthorization.³⁷ Moreover, eligibility for pilot programs or waivers does not ensure compatibility with the heavily regulated health care

31. *See, e.g.*, 42 U.S.C. § 1315(a)(1) (permitting HHS Secretary to waive certain Medicaid state plan requirements for experimental, pilot, or demonstration projects); 42 U.S.C. 1396n(c)(3) (permitting states to waive certain Medicaid program requirements such as state wideeness and comparability for Home and Community Based Services waivers); 42 C.F.R. §§ 438.3(e)(2), 438.16 (enabling states and Medicaid managed care plans to expand settings options and provide medically appropriate and cost-effective substitutes for state plan covered services).

32. *See* Sandhu et al., *supra* note 10 (in describing three major Medicaid policy initiatives in the past decade, noting that “[g]iven Americans covered by Medicaid face greater socioeconomic challenges compared to Americans with private insurance, and are traditionally at highest risk for unmet social needs and societal inequities, the Medicaid program has been uniquely poised and motivated to integrate social care into health care delivery”).

33. 42 U.S.C. § 1315(a)(1); *see also* *About Section 1115 Waivers*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.medicaid.gov/medicaid/section-1115-demonstrations/about-section-1115-demonstrations> [https://perma.cc/D5SR-LYVV] (last visited Apr. 6, 2026).

34. 42 C.F.R. §§ 438.3(e)(2), 438.16. ILOSs can be utilized by state Medicaid programs and their managed care plans to strengthen access to care by expanding service and settings options as alternatives to traditional Medicaid benefits.; *see also* Diana Crumley, *Using In Lieu of Services to Address Health-Related Social Needs: Upshots from the Recent Federal Rule*, CTR. FOR HEALTH CARE STRATEGIES (June 2024), <https://www.chcs.org/resource/using-in-lieu-of-services-to-address-health-related-social-needs-upshots-from-the-recent-federal-rule/> [https://perma.cc/9YN3-M9HB] (explaining the use of ILOS to cover health-related social needs).

35. *See* Garfield, Koprak, & Haughton, *supra* note 14 (“Federal, state, and philanthropic grant and pilot programs are often time-limited”); CTR. FOR HEALTH L. & POL’Y INNOVATION OF HARV. L. SCH. & FOOD IS MED. COAL., *supra* note 20, at 36 (summarizing approval periods for five main pathways); *see, e.g.*, Knowles et al., *supra* note 29 (documenting organizational advocacy for long-term sustainable payment for CHWs given limitations of waivers and ILOS).

36. *See* 42 U.S.C. § 1315(f)(6); U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 33.

37. Demonstration waivers can typically be extended in three-to-five-year increments. *See id.*; *see, e.g.*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., RE: DESIGNATED STATE HEALTH PROGRAMS AND DESIGNATED STATE INVESTMENT PROGRAMS (2025), <https://www.medicaid.gov/resources-for-states/downloads/dshp-dsip.pdf> [https://perma.cc/QT7X-YVQB] (determining that certain demonstration projects will no longer be approved nor renewed, given CMS’s concerns about the appropriateness of providing federal funding for such programs).

delivery and financing systems already in place.³⁸ As a result, many programs find themselves at the end of a grant or pilot period without a clear funding source or path to full integration.

The Strong Start for Mothers and Newborns Initiative serves as an apt example.³⁹ From approximately 2013 to 2017, this program tested enhanced prenatal care interventions, such as birth centers, for women at risk of having preterm birth.⁴⁰ Despite “exceptional” results in reducing racial inequalities, improving birth outcomes, and lowering costs, the initiative did not transition into a sustained, covered benefit.⁴¹ Multiple factors contributed to this outcome, including provider difficulties in contracting with MCOs, low Medicaid reimbursement rates, and lengthy Medicaid eligibility determination processes.⁴²

These challenges reflect a deeper structural issue, as many Strong Start interventions did not align with traditional Medicaid benefit categories or payment models. For example, the initiative followed a midwifery model of prenatal care, which, particularly at the time, differed significantly from the approach compatible with existing reimbursement structures.⁴³ Unlike discrete, billable services typically provided by obstetricians in hospital settings, birth centers offer comprehensive prenatal, delivery, and postpartum care, often requiring longer visits and extended support both pre- and post-delivery.⁴⁴

38. See, e.g., *North Carolina's Healthy Opportunities Pilots: Barriers and Pathways to Success*, REINVESTMENT PARTNERS 6–7, https://static1.squarespace.com/static/6525b3af3afe0f0c191f9b5f/t/675ab68693a5583f5ed9bbf6/1733998214541/NC+HOPS+Barriers+and+Pathways+to+Success_final.pdf [<https://perma.cc/QX2F-HQVK>] (last visited Apr. 28, 2025) (explaining the difference between assisting provider organizations in complying with pilot program requirements and preparing them to become vendors in the health care sector).

39. See generally *Strong Start for Mothers and Newborns: General Information*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/priorities/innovation/innovation-models/strong-start> [<https://perma.cc/8LSV-8UXH>] (last visited Apr. 6, 2026).

40. *Spotlight on Success: The Strong Start for Mothers and Newborns Initiative*, NAT'L P'SHIP FOR WOMEN & FAM. (Sep. 2020), <https://nationalpartnership.org/report/spotlight-on-success-the-strong-start-for-mothers-and-newborns-initiative/> [<https://perma.cc/B6JD-AMDL>]. There were three models of enhanced prenatal care: group prenatal care, birth centers, and maternity care homes. *Id.*

41. *Id.*; CTR. FOR MEDICARE & MEDICAID INNOVATION, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *STRONG START FOR MOTHERS AND NEWBORNS: EVALUATION OF FULL PERFORMANCE PERIOD 2* (2018), <https://www.cms.gov/priorities/innovation/files/reports/strongstart-prenatal-fg-finalevalrpt.pdf> [<https://perma.cc/48HS-X9P3>] (“Women who received prenatal care in Strong Start Birth Centers had better birth outcomes and lower costs relative to similar Medicaid beneficiaries not enrolled in Strong Start.”); see U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 39 (“The Strong Start initiative period of performance has concluded and is no longer active.”).

42. See IAN HILL ET AL., *STRONG START FOR MOTHERS AND NEWBORNS EVALUATION: YEAR 5 PROJECT SYNTHESIS VOLUME 1: CROSS-CUTTING FINDINGS* 143–44 (2018), <https://www.cms.gov/priorities/innovation/files/cmml/strongstart-prenatal-finalevalrpt-v1.pdf> [<https://perma.cc/G629-6NU6>].

43. See *id.* at 3.

44. See *id.* at 3–4.

Rather than emphasizing strictly medical interventions like pharmaceutically induced labor or continuous electronic fetal monitoring, Strong Start offered enhanced services such as peer counseling, health education, and psychosocial support—many of which were not reimbursable under Medicaid at all.⁴⁵ As a result, reimbursement rates for Strong Start providers were substantially lower.⁴⁶ For instance, one birth center in Charleston, South Carolina, reported receiving only \$1,600 from the state’s MCO despite the actual cost of care being approximately \$3,000.⁴⁷ Because Medicaid payments failed to cover the true cost of delivering care, many birth centers were unwilling or unable to serve Medicaid beneficiaries,⁴⁸ ultimately contributing to the program’s inability to transition into a sustained benefit.

The Strong Start example reflects a critical point: compatibility with existing coverage frameworks is not merely advantageous but essential. Without it, programs are stuck in short-term funding limbo, dependent on grants or pilot programs, in which even the most successful interventions may not access sustainable reimbursement mechanisms. Moreover, reliance on short-term funding can lead to service interruptions, high provider turnover, and wasteful reinvestment to meet shifting priorities.⁴⁹ Conversely, alignment with coverage structures and legal frameworks can unlock vital funding sources, allowing organizations and providers to deepen their impact while reducing the total cost of care and improving patient health.⁵⁰

45. *See id.* at 3–4, 42.

46. *See id.* at 42 (“birth centers paid as little as 15 percent of hospital rates for the same delivery, and between obstetricians and midwives’ reimbursement, with midwives paid 70 to 92 percent of physician rates for the same service”) (internal citation omitted).

47. *See id.* at 28.

48. *See id.*

49. *See, e.g.,* REINVESTMENT PARTNERS, *supra* note 38, at 1, 6–7 (explaining that failed pilots and unsuccessful integration into Medicaid managed care program will result in service disruption and loss of political and industry support); Knowles et al., *supra* note 29 (discussing provider turnover rates and service interruption); Rush, *supra* note 29 (identifying limits of short-term funding, including that it may be “subject to appropriations or private philanthropic decisions” which do “not afford CHWs or their employers the latitude to apply the full range of CHW capabilities to community needs”); *cf.* Georgia Health Policy Center, *Bringing the Future into Focus: A Step-by-Step Sustainability Planning Workbook* 4 (2011) (explaining how grant-funded programs may need to “scale back” the services provided or the coverage area in response to reduced financial support).

50. *See Investing in Social Services as a Core Strategy for Healthcare Organizations: Developing the Business Case*, KPMG 9 (Mar. 2018), <https://www.commonwealthfund.org/publications/other-publication/2018/mar/investing-social-services-core-strategy-healthcare> [<https://perma.cc/6F4X-LWQA>]; We acknowledge that coverage integration introduces new challenges, familiar to traditional health care interventions. For example, health insurance “churn” or the frequency with which individuals move in and out of different insurance plans remains an ongoing challenge for patient access, specifically in the context of maternity care. For example, pregnant people in non-Medicaid expansion states typically lose guaranteed Medicaid coverage just sixty days after the birth. As a result, their access to post-partum services, such as those offered through the Strong Start, is limited. *See generally* Kathy Gifford et al., *Medicaid Coverage*

C. Phase Three: Full Integration as a Covered Benefit

Some innovative interventions have transitioned into the third phase, which is full health care integration. For example, the Diabetes Prevention Program (DPP),⁵¹ non-emergency medical transportation (NEMT) services, and doula services have become covered health care benefits under several traditional insurance programs.⁵² For example, after several states successfully piloted Medicaid coverage for doula services, CMS provided technical assistance, including SPA templates, to encourage more states to add these services to their programs.⁵³ Now, several states cover doula services under various benefit categories, most commonly under the “preventive services” category.⁵⁴

To achieve success, innovators typically first demonstrate improved outcomes and cost savings during the grant-funding and pilot phases. Then, they show that their services are compatible with existing legal and administrative frameworks (e.g., for delivery, billing, and oversight). Finally, programs can be formally adopted as mandated or optional covered benefits through federal or state programs—or both. Once integrated, such services can become accessible

of Pregnancy and Perinatal Benefits: Results from a State Survey, KAISER FAMILY FOUND. 5–6 (2017), <https://www.kff.org/report-section/medicaid-coverage-of-pregnancy-and-perinatal-benefits-introduction/> [https://perma.cc/6XAV-MLNE]. Policy changes that expand and encourage continued coverage have the potential to reduce these effects. *Id.* at 6.; see also Sachs, *supra* note 13, at 71.

51. The Diabetes Prevention Program is a value-based intervention program that works to prevent the progression of type 2 diabetes through a lifestyle change program. See generally *About Prediabetes and Type 2 Diabetes*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/diabetes-prevention/about-prediabetes-type-2/index.html>. [https://perma.cc/AG6L-WBJU] (last visited Apr. 6, 2026).

52. See, e.g., 42 C.F.R. § 410.79 (DPP coverage under Medicare Part B); Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 209, 134 Stat. 1182, 2986–89 (2020) (adding NEMT as a Medicaid requirement); *Commercial Coverage Landscape: Payer List*, NAT’L DPP COVERAGE TOOLKIT, <https://coveragetoolkit.org/commercial-coverage-landscape/> [https://perma.cc/HT3S-4SH3] (last updated July 30, 2025) (listing commercial health plans that cover DPP’s lifestyle change program); Anoosha Hasan, *State Medicaid Approaches to Doula Service Benefits*, NAT’L ACAD. FOR STATE HEALTH POL’Y (Mar. 31, 2026), <https://nashp.org/state-tracker/state-medicare-approaches-to-doula-service-benefits/> [https://perma.cc/59FM-CA4K] (showing doula coverage under state Medicaid programs); see also U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 21 (describing NEMT benefits); NAT’L HEALTH L. PROGRAM, *supra* note 27 (describing doula benefits).

53. U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., SHO# 21-007 RE: IMPROVING MATERNAL HEALTH AND EXTENDING POSTPARTUM COVERAGE IN MEDICAID AND THE CHILDREN’S HEALTH INSURANCE PROGRAM (CHIP) 9–10, 22 (2021), <https://www.medicare.gov/federal-policy-guidance/downloads/sho21007.pdf> [https://perma.cc/W9QU-JH8K].

54. See Priti Khanal et al., *Covering Doula Services Under Medicaid: Design and Implementation Considerations for Promoting Access and Health Equity*, CTR. FOR HEALTH CARE STRATEGIES 12 (Dec. 2022), https://www.chcs.org/media/Covering-Doula-Services-Under-Medicaid-Brief_120822.pdf [https://perma.cc/KYT4-FUT9]; Hasan, *supra* note 52 (showing doula coverage under state Medicaid programs and listing coverage under “Preventive,” “Other Diagnostic, Screening, Preventive, and Rehabilitative Services,” and “Freestanding Birth Centers” benefit categories); see also 42 C.F.R. § 440.130.

to qualifying beneficiaries through standard reimbursement mechanisms, enabling sustainable support for scale and impact. Although processes and pathways vary across services and insurer types, in all cases, long-term coverage requires demonstration of both efficacy and legal fit.

III. UNDERSTANDING THE STRUCTURAL GAP: EXAMINING SERVICE MODELS AND LEGAL FRAMEWORKS TO ADDRESS BARRIERS TO HEALTH CARE INTEGRATION

On the path from community-based intervention to health care benefit, many services struggle to achieve sustainable integration into traditional insurance coverage. These difficulties often stem not from clinical inefficacy but from mismatches between how innovative services operate and how health care is structured.

Understanding this gap is essential to navigating the transition from innovation to integration. This section begins by comparing traditional and non-traditional service models to illustrate where and why misalignment occurs. These structural differences help explain why, despite demonstrated health and cost benefits, many services struggle to move beyond short-term funding and achieve long-term integration into health care. This section goes on to examine how these challenges emerge and how alignment with one or more of the country's three major health care coverage frameworks—Medicaid, Medicare, and the ACA—can serve as tools to design coverage-compatible models. As innovative services gain traction under value-based care, understanding structural and legal barriers and how programs have navigated them is essential to maximizing benefits, expanding access, and minimizing costs and waste.

A. Differences Between Traditional and Innovative Service Provision and Coverage

To contextualize the obstacles that arise during the transition from pilot to covered benefit, it is helpful to highlight some core differences between how traditional and innovative services are provided, covered, and reimbursed. A comparison between a routine service, such as a measles vaccination, and a non-traditional intervention, like doula care, helps illustrate the underlying structural differences.

When a patient seeks a measles vaccination, they will likely go to their local doctor's office. The provider administering the vaccine has likely attended and graduated from a professional school, such as medical school, been licensed by their state's medical board, and credentialed by the relevant specialty board. After the appointment, the doctor's office will submit a claim for the service to the appropriate insurer, private or governmental, using a set billing code for the vaccination. Then, the insurer will reimburse the provider at a predetermined rate or through a set pathway, such as a Medicaid managed care arrangement.

Service delivery, coverage, and reimbursement for innovative services can vary significantly from this familiar process. Take, for example, a patient seeking access to a doula for pregnancy support. Doulas are “non-medical professionals who provide emotional, physical, and informational support and guidance” before, during, and after labor and birth.⁵⁵ Patients are less likely to go to a doctor’s office to receive doula care, as doulas often make prenatal and postpartum home visits.⁵⁶ The doula is not a medical provider and is unlikely to have attended a professional school for their doula training or been licensed by a state medical board.⁵⁷ While the doula has likely undergone a formal training program, that training is not necessarily required or standardized.⁵⁸ After the appointment, the doula may be paid through out-of-pocket payments, grant- or pilot-funded organizations, or health care insurance reimbursement.⁵⁹ However, the reimbursement amount is unlikely to cover the entire cost of providing care, including time spent traveling, researching and gathering client resources, and completing administrative tasks.⁶⁰

In addition to differences between traditional and non-traditional services, innovative services often vary significantly among themselves, even within the same category. The disaggregated nature of funding and development leads to many providers and organizations operating without coordination or shared standards, despite delivering similar services. For example, Organization A may offer doula training, certification, and facilitate reimbursement under one model, while Organization B provides the same services using an entirely different approach.⁶¹ This fragmentation results in duplicative efforts, inconsistent implementation strategies, and divergent outcomes, all contributing to common integration pitfalls and undermining efforts to achieve integrated, sustainable coverage.⁶²

These inefficiencies compound at the system level. Organizations operating outside of a coverage scheme are more likely to work independently, requiring

55. NAT’L HEALTH L. PROGRAM, *supra* note 27.

56. See Amy Chen, Alexis Robles-Fradet, & Helen Arega, *Building A Successful Program for Medi-Cal Coverage for Doula Care: Findings from a Survey of Doulas in California*, NAT’L HEALTH L. PROGRAM 7–8 (May 2020), <https://healthlaw.org/resource/doulareport/> [<https://perma.cc/4DAQ-6L39>].

57. See Amy Chen, *Routes to Success for Medicaid Coverage of Doula Care*, NAT’L HEALTH L. PROGRAM 6 (Dec. 14, 2018), <https://healthlaw.org/resource/routes-to-success-for-medicaid-coverage-of-doula-care/> [<https://perma.cc/LZ22-5PBP>].

58. Chen, Robles-Fradet, & Arega, *supra* note 56 at 13; Chen, *supra* note 57.

59. See *supra* note 28 and accompanying text.

60. See, e.g., HILL ET AL., *supra* note 42, at 143; Alicia Camaliche et al., *Charting the Course for Community Health Workers*, FAMILIESUSA.ORG 8 (Sep. 2024), <https://familiesusa.org/wp-content/uploads/2024/10/CHW-Listening-Sessions-9-27-24.pdf> [<https://perma.cc/2VKN-L2SR>]; see generally Peters & Robles-Fradet, *supra* note 16.

61. See, e.g., Khanal et al., *supra* note 54 (comparing six states’ approaches to adopting the doula services Medicaid benefit across seven domains, including training, certification, and reimbursement).

62. See, e.g., *id.* at 6–8 (demonstrating, in the context of coverage for doula services, fragmented approaches and their resulting challenges).

each to resolve similar legal issues in isolation. For example, many community-based organizations—especially smaller ones—face challenges navigating the complexities of HIPAA, which is often a requirement for delivering services within health care systems.⁶³ This fragmentation increases inefficiency and diverts resources away from service delivery, undermining the goals of coordinated, value-based systems.

Comparisons across delivery, coverage, and infrastructure expose the structural gap between innovative services and existing insurance frameworks. The following section builds on this analysis by identifying the key legal and administrative challenges that arise from this misalignment.

B. Barriers to Sustainable Integration into Health Care Coverage

The structural gap between innovative services and the legal frameworks that govern them creates various barriers to smooth integration into health care reimbursement models. Innovators do not bear these challenges alone; regulators, payers, and health care systems must also grapple with how generally applicable principles interact with these non-traditional services. Stakeholders face challenges in defining the scope of services, credentialing providers, and creating appropriate systems for reimbursement. These barriers can limit scalability, undermine attempts to build longevity for these programs, decrease provider participation, and perpetuate disparities. However, aligning providers that deliver similar services with the same governing legal standards can promote stability and consistency. Moreover, as explained above, compatibility with existing coverage frameworks is essential for scaling access and securing sustainable reimbursement.

This section examines three core categories of barriers that stem from the structural gap: (1) limitations in benefit design; (2) rigid or unclear licensing and credentialing requirements; and (3) billing and reimbursement challenges.

1. Benefit Design

Benefit design—or the rules that structure insurance plans and determine which services will be covered, under what conditions, and by which providers—can derail successful health care integration of innovative services from the start. Each coverage program’s legal framework addresses benefit

63. See Rachel Landauer, Katie Garfield & Carmel Shachar, *Network Contracting to Address Health-Related Social Needs: Considerations for HIPAA Compliance*, HEALTH L. LAB & CTR. FOR HEALTH L. & POL’Y INNOVATION (Nov. 2023), <https://www.healthlawlab.org/wp-content/uploads/2023/11/Network-Contracting-to-Address-Health-Related-Social-Needs-HIPAA-2023.pdf> [<https://perma.cc/7UF3-QXZT>]; see, e.g., Letter from Ctr. for Health L. & Policy Innovation of Harvard L. Sch. et al., to Chiquita Brooks-LaSure, Administrator, U.S. Ctrs. For Medicare & Medicaid Servs., U.S. Dep’t of Health & Hum. Servs. 3 (Apr. 24, 2024), <https://www.healthlawlab.org/wp-content/uploads/2023/04/Letter-to-CMS-re-1115-Waiver-Survey-2023.pdf> [<https://perma.cc/M3TE-R4KL>].

design differently.⁶⁴

a. Medicaid benefit design rules

Although every state establishes and administers its own Medicaid program, the federal government sets broad rules and baseline standards that all state programs must follow.⁶⁵ All covered services must fit within one of the mandatory or optional benefit categories specified in § 1905(a) of the Social Security Act.⁶⁶ Each state lays out the details of its program, including services covered, in its “state plan,” which is an agreement between the state and the federal government that outlines how that state will administer its Medicaid program.⁶⁷ States can make changes to their programs by submitting state plan amendments (SPAs) and getting approval from CMS.⁶⁸ Through the state plan process, states have flexibility to define the type, amount, duration, and scope of each service so long as those interpretations are sufficient to “reasonably

64. *Health IT Playbook Glossary*, OFF. OF THE NAT’L COORDINATOR FOR HEALTH INFO. TECH., <https://playbook.healthit.gov/playbook/glossary/#b> [<https://perma.cc/V67T-G9AE>] (last updated Feb. 28, 2018) (defining “benefit design”); *see, e.g.*, 42 U.S.C. 1396d(a) (Medicaid covered benefits); 42 C.F.R. §§ 440.10–185 (Medicaid service definitions); 42 U.S.C. § 1395(k) (Medicare Part B scope of benefits); 42 C.F.R. §§ 410.10–175 (Medicare Part B service definitions); 42 U.S.C. § 18022 (ACA Essential Health Benefits); 45 C.F.R. § 156.100 (ACA benchmark plan process and scope of benefits).

65. *See* 42 U.S.C. § 1396a(a); 42 C.F.R. §§ 430.10–430.25 (requiring that state Medicaid programs meet federal standards to receive federal funding); *see also* *What’s the difference between Medicare and Medicaid?*, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-difference-between-medicare-medicaid/index.html> [<https://perma.cc/2SK5-M2MJ>] (last visited Apr. 8, 2026).

66. § 1905(a) of the Social Security Act, 42 U.S.C. § 1396d(a). Federal law requires states to provide certain “mandatory benefits,” such as inpatient hospital services, laboratory and X-ray services, and transportation to medical care. *Id.*; *see* 42 C.F.R. §§ 440.210–440.220. Additionally, states may choose to provide “optional benefits,” such as prescription drugs, preventive services, and rehabilitative services. 42 C.F.R. § 440.225; *see* 42 C.F.R. §§ 440.10–440.185 (service definitions); *see also* *Mandatory & Optional Medicaid Benefits*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.medicaid.gov/medicaid/benefits/mandatory-optional-medicaid-benefits/index.html> [<https://perma.cc/FV63-Y56N>] (last visited Apr. 8, 2026).

67. *See* 42 U.S.C. § 1396a; 42 C.F.R. §§ 430.10–430.25; *Medicaid State Plan Amendments*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments> [<https://perma.cc/HB5J-8T3J>] (last visited Apr. 8, 2026); *see also* *State Plan*, MEDICAID & CHIP PAYMENT & ACCESS COMM’N (Aug. 14, 2019), <https://www.macpac.gov/subtopic/state-plan/> [<https://perma.cc/6QYT-4L4P>] (“The state plan: provides assurances that a state will abide by federal rules in order to claim federal matching funds; indicates which optional groups, services, or programs the state has chosen to cover or implement; and describes the state-specific standards to determine eligibility, methodologies for providers to be reimbursed, and processes to administer the program.”).

68. 42 C.F.R. § 430.12(c); *see* MEDICAID & CHIP PAYMENT & ACCESS COMM’N, *supra* note 67. For example, states can continue or discontinue coverage of an optional service or change a provider payment methodology by submitting a SPA. *Id.*

achieve [the service’s] purpose.”⁶⁹ States may also impose “appropriate” limits on covered services, which are often grounded in “medical necessity,” the requirement that services meet accepted clinical standards and be suitable for diagnosing or treating an individual’s condition.⁷⁰

Innovators seeking to gain Medicaid coverage of new services must first determine whether their service falls within an existing benefit category. Many innovative services likely fall within one or more existing categories; for example, community health workers (CHWs) have been included in several Medicaid SPAs under the preventive services, primary care case management, and dental categories.⁷¹ Innovators must also ensure that their services meet the state’s criteria, as defined by the relevant state’s definition, of medical necessity.⁷²

69. 42 C.F.R. § 440.230(a)–(b); see *Medicaid Benefits*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.medicaid.gov/medicaid/benefits> [<https://perma.cc/R5QX-52TD>] (last visited Apr. 8, 2026). For example, one state could deem a ridesharing service to fit within the “transportation to medical care” mandatory benefit category or the “case management” optional benefit category, while another state might not cover a ridesharing service at all.

70. States cannot arbitrarily deny coverage solely because of the diagnosis, type of illness, or condition. 42 C.F.R. § 440.230(c). For example, a state cannot deny Medicaid coverage of X-rays for individuals presenting with chronic pain solely because of their diagnosis but may require that X-rays be ordered by a licensed provider in accordance with established criteria. See 42 C.F.R. § 440.230(d). Notably, the Medicaid Act does not define the term “medical necessity.” See 42 U.S.C. 1396d; 42 C.F.R. § 400.203; see also Melissa McCall, *Medical Necessity and the Law*, FINDLAW, <https://www.findlaw.com/healthcare/patient-rights/medical-necessity-and-the-law.html> [<https://perma.cc/B3ES-LNXW>] (last updated Jan. 23, 2025); see, e.g., *State Definitions of Medical Necessity under the Medicaid EPSDT Benefit*, NAT’L ACAD. FOR STATE HEALTH POL’Y (Apr. 23, 2021), <https://nashp.org/state-tracker/state-definitions-of-medical-necessity-under-the-medicaid-epsdt-benefit/> [<https://perma.cc/U8GA-RR66>] (collecting definitions of “medical necessity” for the EPSDT Medicaid benefit).

71. See, e.g., Colorado State Plan Amendment (SPA) 24-0025, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS. (Sep. 17, 2024), <https://www.medicaid.gov/medicaid/spa/downloads/CO-24-0025.pdf> [<https://perma.cc/2PT3-92UW>] (authorizing reimbursement for CHW services as preventive health services); Maine State Plan Amendment (SPA) 24-0022, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS. (Sep. 24, 2024), <https://www.medicaid.gov/medicaid/spa/downloads/ME-24-0022.pdf> [<https://perma.cc/3UXU-SDTA>] (authorizing reimbursement for CHW services as primary care services); California State Plan Amendment (SPA) 24-0016, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS. (July 25, 2024), <https://www.dhcs.ca.gov/SPA/Documents/SPA-24-0016-Approval.pdf> [<https://perma.cc/2MCR-ZTUQ>] (authorizing reimbursement for CHW services in the dental setting); see generally NAT’L ACAD. FOR STATE HEALTH POL’Y, *supra* note 19.

72. CMS guidance may also help programs structure their services to align with medical necessity requirements. For example, CMS has emphasized that services be “evidence-based” and provided to Medicaid beneficiaries based on a documented need, rather than applied through a one-size-fits-all approach. See, e.g., ADDRESSING HEALTH-RELATED SOCIAL NEEDS IN SECTION 1115 DEMONSTRATIONS, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS. 18–19 (Dec. 6, 2022), <https://www.medicaid.gov/medicaid/downloads/addrss-hlth-soc-needs-1115-demo-all-st-call-12062022.pdf> [<https://perma.cc/9CVG-ZNYK>].

b. Medicare benefit design rules

Unlike Medicaid, Medicare is a purely federal program administered by CMS with little involvement from the states.⁷³ Medicare beneficiaries can receive coverage through two options: “Original Medicare” or “Medicare Advantage.”⁷⁴ Original Medicare encompasses Parts A and B, which include hospital insurance and medical insurance, respectively.⁷⁵ CMS identifies three criteria for Original Medicare coverage: a service must (1) fall within at least one defined benefit category established in § 1861 of the Social Security Act; (2) not be specifically excluded by the Act; and (3) be “reasonable and necessary.”⁷⁶

Original Medicare is a defined benefit program, meaning that a service must fall within one of the enumerated benefit categories to be considered for coverage.⁷⁷ If a service does not fall within one of the categories, Congress must amend the Social Security Act to add a new category that encompasses the service.⁷⁸ Certain services are explicitly excluded from Medicare coverage, such as routine dental care, cosmetic surgery, and custodial long-term care.⁷⁹ Moreover, statutory provisions forbid payment for services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”⁸⁰ A “reasonable and necessary” service that falls within a Medicare benefit category may be eligible for Original Medicare coverage, subject to an extensive, evidence-based determination process at the national, local, or claim level.⁸¹

73. U.S. DEP’T OF HEALTH & HUM. SERVS., *supra* note 65.

74. *Parts of Medicare*, MEDICARE.GOV, <https://www.medicare.gov/basics/get-started-with-medicare/medicare-basics/parts-of-medicare> [<https://perma.cc/JK9R-4RZL>] (last visited June 9, 2026); 42 U.S. Code §§ 1395c–1395i-5 (Medicare Part A); 42 U.S.C. §§ 1395j–1395w-6 (Medicare Part B); 42 U.S.C. §§ 1395w-21–1395w-29 (Medicare Part C or Medicare Advantage).

75. MEDICARE.GOV, *supra* note 74; 42 U.S. Code §§ 1395c–1395i-5 (Medicare Part A); 42 U.S.C. §§ 1395j–1395w-6 (Medicare Part B); 42 U.S.C. §§ 1395w-21–1395w-29 (Medicare Part C or Medicare Advantage).

76. *See* 42 U.S.C. § 1395x (defining benefit categories); 42 U.S.C. § 1395y(a)(1)(A) (excluding services not “reasonable and necessary”); 42 C.F.R. § 411.15(k) (excluding particular services from coverage); *see generally Medicare Coverage of Items and Services*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/coverage/medicare-coverage-items-and-services> [<https://perma.cc/XH6G-VPSN>] (last updated Mar. 10, 2026, 8:33 PM).

77. *See* 42 U.S.C. 1395x. For example, covered categories include hospital services, certified nurse-midwife services, and diabetes screening tests. *Id.*

78. For example, Congress added medical nutrition therapy (MNT) services as a benefit category in 2000. *See* 42 U.S.C. 1395x(vv)(1) (2000).

79. *See generally* 42 U.S.C. 1395y(a). If a service falls within one of these exclusions, it cannot be covered absent a specific exception or a statutory amendment to remove or narrow the exclusion.

80. 42 U.S.C. 1395y(a)(1)(A).

81. There are three main coverage pathways under Original Medicare: national coverage determinations (NCDs), local coverage determinations (LCDs), and claim-by-claim review. *See*

As an alternative to Original Medicare, beneficiaries can opt into “Medicare Advantage,” or Part C, which is a Medicare-approved plan from a private company that bundles Parts A, B, and may include Part D (prescription drugs).⁸² While Medicare Advantage plans are still subject to regulation by CMS, they have greater flexibility in benefit design.⁸³ In addition to covering all Original Medicare benefits, Medicare Advantage plans may also offer “supplemental benefits,” which fall into three categories.⁸⁴ First are traditional, health-related benefits, such as vision, fitness, hearing, and dental, which have the primary purpose of preventing, curing, or diminishing an illness or injury.⁸⁵ Second, Expanded Primarily Health-Related Supplemental (EPHR) benefits are services that “ameliorate the effect of health conditions or reduce avoidable emergency and health care utilization.”⁸⁶ Examples of EPHRs include in-home support services and support for caregivers of enrollees.⁸⁷ Third, Special Supplemental Benefits for the Chronically Ill (SSBCI) can cover non-health-related services so long as they “have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.”⁸⁸ This third pathway offers a promising avenue for coverage of innovative, non-traditional services that may not otherwise be able to meet the legal requirements of other insurance programs.⁸⁹

42 U.S.C. § 1395y (listing NCDs); 42 C.F.R. § 405.1060(a) (describing NCDs); 42 U.S.C. § 1395fff(f)(2) (describing LCDs); 42 U.S.C. § 1395y(a)(1)(A) (enabling case-by-case determinations where no NCD or LCD exists); *see generally* U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 72.

82. *See* 42 U.S.C. § 1395w-21(a)(1) (permitting enrollment in Original Medicare or “Medicare+Choice” (Medicare Advantage)); 42 U.S.C. § 1395w-22(a) (enumerating basic benefits); 42 C.F.R. § 422.2 (defining Medicare Advantage programs and their required coverage); *see also* SOC. SEC. ADMIN., MEDICARE 11 (Jan. 2025), <https://www.ssa.gov/pubs/EN-05-10043.pdf> [<https://perma.cc/5TYT-CGCG>].

83. *See generally* 42 U.S.C. § 1395w-22(a)(3) (allowing Medicare Advantage plans to provide enrollees with approved supplemental benefits, subject to limitations and requirements).

84. 42 U.S.C. § 1395w-22(a)(3). Medicare Advantage plans are required to cover all benefits and services that are covered under Original Medicare. 42 U.S.C. § 1395w-22(a)(1)(A). However, for some services, plans may use their own coverage criteria to determine medical necessity. *See* 42 C.F.R. § 422.101.

85. *Id.*; GAO, *Medicare Advantage: Plans Generally Offered Some Supplemental Benefits, but CMS Has Limited Data on Utilization*, U.S. GOV’T ACCOUNTABILITY OFF. 6 (Jan. 2023),

<https://www.gao.gov/assets/d23/105527.pdf> [<https://perma.cc/N4X8-DXZU>]; *see* U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *Reinterpretation of “Primarily Health Related” for Supplemental Benefits* 1 (Apr. 27, 2018), <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/CMS/hpms-memo-primarily-health-related-4-27-18.pdf>

[<https://perma.cc/2CW9-TATN>] (expanding definition to include additional benefits). These types of benefits have historically been defined as an item or service (1) not covered by Original Medicare, (2) that is primarily health related, and (3) for which the plan must incur a non-zero direct medical cost, *id.*

86. GAO, *supra* note 85; 42 U.S.C. § 1395w-22(a)(3)(A).

87. GAO, *supra* note 85.

88. 42 U.S.C. § 1395w-22(a)(3)(D); *see also* 42 C.F.R. § 422.102(f).

89. For example, nutrition support, subsidies for rent or utilities, and transportation for non-medical needs have all been covered under this type of benefit, *see* GAO, *supra* note 85, at 7.

c. Affordable Care Act benefit design rules

The ACA governs a significant portion of the private insurance market.⁹⁰ One of the ACA's key regulatory mechanisms is the requirement that non-grandfathered plans offered in the individual and small-group markets cover a standardized set of "essential health benefits" (EHBs).⁹¹ The statute enumerates ten categories of benefits, including "preventive and wellness services and chronic disease management" and "rehabilitative and habilitative services."⁹² The Act delegates the authority to further define these EHBs—within certain parameters⁹³—to the Secretary of the U.S. Department of Health and Human Services (HHS).⁹⁴ HHS has since delegated that responsibility to the states.⁹⁵

Through a "benchmarking" process, each state selects a model plan that serves as the state standard for EHBs and defines the specific items and services included in each EHB category.⁹⁶ Each state's process is different, but states often consider costs, clinical effectiveness, administrative feasibility, and public

90. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); *see also* OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, HEALTH COVERAGE UNDER THE AFFORDABLE CARE ACT: CURRENT ENROLLMENT TRENDS AND STATE ESTIMATES, 1–2 (Mar. 22, 2024), available at <https://aspe.hhs.gov/sites/default/files/documents/8e81cf90c721dbbf58694c98e85804d3/health-coverage-under-aca.pdf>. [<https://perma.cc/5HR2-RHKB>].

91. 42 U.S.C. §§ 18021–18022; *see generally* *Information on Essential Health Benefits (EHB) Benchmark Plans*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/marketplace/resources/data/essential-health-benefits> [<https://www.cms.gov/marketplace/resources/data/essential-health-benefits>] (last updated Mar. 13, 2026, 5:50 PM). A limited number of plans which were in existence before the ACA's enactment date and have not had major changes to their provisions are "grandfathered" into the law and are exempt from many ACA requirements, including the obligation to cover EHBs. *See* 45 C.F.R. § 147.140; 42 U.S.C. § 18011.

92. 42 U.S.C. § 18022(b).

93. 42 U.S.C. § 18022(b)(2)(A). For example, the scope of the EHBs must be "equal to the scope of benefits provided under a typical employer plan." *Id.* Additionally, EHBs must "reflect an appropriate balance among the categories . . . so that benefits are not unduly weighted toward any category." 42 U.S.C. § 18022(b)(4)(A). And benefits cannot be designed "in ways that discriminate against individuals because of their age, disability, or expected length of life." *See* 42 U.S.C. § 18022(b)(4)(B).

94. 42 U.S.C. § 18022(b)(1); *see generally* Héctor Hernández-Delgado & Wayne Turner, *Explainer: Proposed Changes to the Essential Health Benefits Standard in the 2025 Notice of Benefits and Payment Parameters*, NAT'L HEALTH L. PROGRAM, (Dec. 1, 2023), <https://healthlaw.org/wp-content/uploads/2023/12/EHB.-NBPP-Explainer-vAP.pdf> [<https://perma.cc/K99H-TB8V>]. HHS must also periodically review and update the EHBs "to address any gaps in access to coverage or changes in the evidence base." *See* 42 U.S.C. §§ 18022(b)(4)(G)–(H).

95. *See* 45 C.F.R. § 156.100, et seq.; *see generally* Stacey Pogue et al., *Enhancing Essential Health Benefits: How States Are Updating Benchmark Plans to Improve Coverage*, THE COMMONWEALTH FUND (Nov. 14, 2024), <https://www.commonwealthfund.org/publications/issue-briefs/2024/nov/enhancing-essential-health-benefits-states-updating-benchmark-plans> [<https://perma.cc/73VM-BX27>].

96. *See* 45 C.F.R. §§ 156.100, 156.111.

comments.⁹⁷ All Qualified Health Plans (QHPs) offered through the ACA's Health Insurance Marketplace must, at minimum, cover the services in their state's selected benchmark.⁹⁸ States can change their EHB benchmark plans subject to federal rules.⁹⁹ Because the ten EHB categories are broadly defined, the scope of covered services varies significantly from state to state.¹⁰⁰ However, plans offered on the ACA Marketplace must not discriminate in their benefit design based on age, expected length of life, disability, degree of medical dependency, quality of life, or other health conditions.¹⁰¹

Coverage of an innovative service will depend on whether that service is already included in a benchmark plan or whether it can be interpreted to fall within a category, like doula services as “maternity and newborn care” or produce prescriptions as “preventive and wellness services and chronic disease management.” Because states may update EHB benchmark plans and must consider public input when doing so, innovators have the opportunity to advocate for their service's inclusion.¹⁰²

d. Challenges and lessons learned in innovative service benefit design

While the legal frameworks above define benefit categories and eligibility rules, regulators, payers, and providers have faced challenges in applying these rules to many innovative services.¹⁰³ Often, these challenges stem from the

97. See, e.g., Madeline McBride et al., *State Flexibility to Add Adult Dental Care to Essential Health Benefits: An Update on State Action*, CTR. ON HEALTH INS. REFORMS (Apr. 8, 2025), <https://chirblog.org/state-flexibility-to-add-adult-dental-care-to-essential-health-benefits-an-update-on-state-action/> [<https://perma.cc/FGQ3-XY4T>] (citing several states' considerations of cost, public comments, administrative efficiency, and overall health when considering adding adult dental services as an EHB); see *EHB Benchmark Plan*, ME. BUREAU OF INS. (Nov. 7, 2024), <https://www.maine.gov/pfr/insurance/sites/maine.gov.pfr.insurance/files/inline-files/EHB%20Benchmark%20Plan%20Initiative%20%28110724%29.pdf> [<https://perma.cc/SGE7-A88S>] (ensuring Maine's Benchmark plan offers comprehensive coverage that is affordable and in alignment with public comments).

98. See 45 C.F.R. § 156.115. Qualified Health Plans are insurance plans that are certified by the Health Insurance Marketplace. See 42 U.S.C. § 18021(a)(1); 45 C.F.R. § 155.20. QHPs must provide EHBs, follow established limits on cost sharing, and meet other outlined requirements. See 42 U.S.C. § 18021(a)(1); 45 C.F.R. § 156.200.

99. See 45 C.F.R. § 156.111.

100. 42 U.S.C. § 18022(b).

101. See 45 C.F.R. § 156.125(a).

102. See 45 C.F.R. § 156.111(c); see, e.g. ME. BUREAU OF INS., *supra* note 97; see generally Hayley Penan, *Step Guide to Updating Your State's Essential Health Benefits Benchmark Plan*, NAT'L HEALTH L. PROGRAM (May 9, 2018), <https://healthlaw.org/wp-content/uploads/2018/05/EHB-Step-Guide-BBP-5.9.182.pdf> [<https://perma.cc/FW3U-K4EZ>] (providing advocates with guide to effective EHB advocacy).

103. Cf. Erika Hanson et al., *Applying Legal and Clinical Quality Standards to 'Food Is Medicine'*, HEALTH AFFAIRS (Nov. 27, 2024), <https://www.healthaffairs.org/content/forefront/applying-legal-and-clinical-quality-standards-food-medicine> [<https://perma.cc/PZ4F-V7TL>]. For example, in the context of produce prescriptions, stakeholders must determine what groups of

innovative and non-traditional nature of the interventions, as insurers are uncertain about how to structure coverage and hesitant to provide the services at all.¹⁰⁴ Even when insurers cover these services, there is wide variation in the scope of coverage, leading to fragmented benefit definitions across insurance programs.¹⁰⁵

Poorly-defined benefit design can complicate efforts to ensure quality and accountability. For example, the Food is Medicine (FIM) movement has recently faced criticism due to uncertainty regarding coverage requirements.¹⁰⁶ While FIM programs are meant to provide “access to nutritious food through the health care system for patients with specific health conditions,”¹⁰⁷ some companies receiving health care reimbursement “fall far short” of providing interventions that meet generally accepted quality principles.¹⁰⁸ Due to the lack of universal standards as to what constitutes a high-quality, reimbursable FIM intervention, bad actors threaten to derail progress and distract from successful program development by receiving reimbursement for foods, such as Jimmy

people should be eligible for enrollment, available delivery methods (e.g. produce box, voucher for grocery store or farmers market), and the length of coverage. *Id.*

104. See, e.g., NORC MCO Learning Hub, *Key Findings from the Medicaid MCO Learning Hub Group Discussion Series and Roundtable – Focus on Social Determinants of Health*, UNIV. OF CHI. 5–6 (Oct. 2020), https://www.norc.org/content/dam/norc-org/pdfs/MCOLearningHub_KeyFindings_SDOHGroupRoundtableDiscussion_Formatted.pdf [<https://perma.cc/K4HS-XN3L>]; HILL ET AL., *supra* note 42 (explaining Strong Start program’s difficulty of contracting with Medicaid MCOs).

105. See, e.g., *Medicaid Coverage of Community Health Worker Services*, MEDICAID AND CHIP PAYMENT AND ACCESS COMM’N 8 (Apr. 2022), <https://www.macpac.gov/wp-content/uploads/2022/04/Medicaid-coverage-of-community-health-worker-services-1.pdf> [<https://perma.cc/VQY6-ZJZT>] (discussing variation in state coverage of CHW services); Megan D’Alessandro et al., *Updates and FAQs: Developing and Implementing a Medicaid State Plan Amendment to Authorize Community Health Worker Reimbursement*, NAT’L ACAD. FOR STATE HEALTH POL’Y (Aug. 5, 2024), <https://nashp.org/updates-and-faqs-developing-and-implementing-a-medicaid-state-plan-amendment-to-authorize-community-health-worker-reimbursement/> [<https://perma.cc/K6UE-VGP7>] (compiling state definitions and scope of coverage for CHWs); *Doulas in Medicaid: Case Study Findings*, MEDICAID AND CHIP PAYMENT AND ACCESS COMM’N 1, 2 (Nov. 2023), <https://www.macpac.gov/wp-content/uploads/2023/11/Doulas-in-Medicaid-Case-Study-Findings.pdf> [<https://perma.cc/GD7J-D5BZ>] (highlighting that while “[s]tates vary in the doula benefit design,” a standard scope of services has emerged to include “prenatal, labor and delivery, and postpartum services.”).

106. See, e.g., Nicholas Florko, *Medicaid is Paying Millions for Salty, Fat-laden ‘Medically Tailored’ Cheeseburgers and Sandwiches*, STAT (July 11, 2024), <https://www.statnews.com/2024/07/11/medicaid-food-is-medicine-medically-tailored-meals-quality-questioned/> [<https://perma.cc/M9YZ-EGX2>]; see also Letter from Sens. Thom Tillis & Ted Budd to Xavier Becerra, HHS Secretary (June 12, 2024), <https://nsjonline.com/wp-content/uploads/2024/06/Tillis-Budd-Letter-to-HHS-on1115-Renewal-NCCARES360.pdf> [<https://perma.cc/5HQM-JUBN>] (expressing concern regarding shared technology platform used in Medicaid demonstration program that provided select evidence-based, non-medical interventions to high-need Medicaid beneficiaries, including FIM services.).

107. Hanson et al., *supra* note 103.

108. See Florko, *supra* note 106.

Dean sandwiches, that do not meet the “nutritious” objectives of FIM.¹⁰⁹

In response to this scrutiny, leading FIM-focused nonprofits have worked independently and collaboratively with federal regulators to promulgate best practices, voluntary accreditation standards, and quality measurement frameworks.¹¹⁰ Many of these standards intentionally align with existing legal frameworks by, for example, requiring referrals from health care personnel, eligibility and needs assessments, and individualized care plans.¹¹¹ Through these efforts and others, FIM stakeholders are working to ensure that future health care coverage includes only clinically effective food-based interventions to ensure that the benefits received are compatible with existing benefit structures and their parameters for coverage.¹¹²

The Diabetes Prevention Program (DPP) offers valuable insights into how clear benefit design and standardization can facilitate a successful transition from community-based intervention to health insurance benefit. DPP is an evidence-based lifestyle program used to delay or prevent the onset of type 2 diabetes for people with prediabetes while also lowering health care costs over time.¹¹³ Following ongoing collaboration between providers, regulators, and insurers, the DPP established standardized eligibility criteria, a CDC-approved curriculum, and quality assurance protocols that align with traditional benefit definitions and have now become widely accepted as the standard DPP “health

109. See Colin M. Schwartz et al., *What Is ‘Food Is Medicine,’ Really? Policy Considerations on the Road to Health Care Coverage*, 44 HEALTH AFFAIRS 406, 409–10 (2025) (describing that the lack of a standard definition of FIM as a health care intervention makes the transition to coverage difficult); see, e.g., Florko, *supra* note 106 (describing a “a Jimmy Dean frozen sausage breakfast sandwich, biscuits and gravy, a cheeseburger” sold by one company providing Medicaid-funded services).

110. See, e.g., FOOD IS MED. COALITION, MED. TAILORED MEAL INTERVENTION ACCREDITATION CRITERIA AND REQUIREMENTS, Version 1.1 (2023), <https://fimcoalition.org/wp-content/uploads/2024/03/Food-is-Medicine-Coalition-Medically-Tailored-Meal-Intervention-Accreditation-Criteria-and-Requirements.pdf> [<https://perma.cc/5EBM-8MJV>]; OFF. OF DISEASE PREVENTION & HEALTH PROMOTION, *Food is Medicine Analytic Framework*, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://odphp.health.gov/foodismedicine/research-and-measurement/food-medicine-analytic-framework> [<https://perma.cc/BH49-NAYF>] (last updated Sep. 15, 2024); Health Care x Food, *Common Measures for AHA Health Care x Food Funded Studies*, AM. HEART ASS’N (Jan. 3, 2025), https://www.healthcarexfood.org/en/-/media/Files/HCF/Health-Care-x-Food-Funded-Studies-Common-Measures-Version-1-11.pdf?sc_lang=en [<https://perma.cc/YKG6-6FJV>] (offering required, preferred, and optional measure sets for studies into FIM interventions).

111. FOOD IS MED. COAL., *supra* note 110 (detailing standards for the Medically Tailored Meal intervention).

112. See Schwartz et al., *supra* note 109, at 410.

113. See U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 51; National Insts. of Health, *NIH Study Finds Interventions to Prevent Type 2 Diabetes Give Good Return on Investment*, U.S. DEP’T OF HEALTH & HUM. SERVS. (Apr. 18, 2024), <https://web.archive.org/web/20250201192711/https://www.nih.gov/news-events/news-releases/nih-study-finds-interventions-prevent-type-2-diabetes-give-good-return-investment> [<https://perma.cc/5R99-663R>].

care benefit.”¹¹⁴ These features enabled the program—which started as a demonstration project—to be adopted as a national Medicare benefit and by many state Medicaid programs.¹¹⁵ By aligning with existing legal frameworks, DPP’s clearly defined structure facilitated its widespread adoption by public and private insurers, thereby expanding access to this life-saving benefit.¹¹⁶

These examples demonstrate the pivotal role that benefit design plays in scaling innovative interventions. When stakeholders can settle on clearly defined benefits that are grounded in legal frameworks, programs are more likely to achieve sustainable coverage, promote quality, and expand access.¹¹⁷ As the health care system continues to evolve towards value-based care, which encourages coverage for non-traditional services that reduce costs through upstream interventions, purposeful benefit design will remain central to ensuring that innovation translates into long-term coverage and impact.

2. Licensing and Credentialing Providers

A second common barrier to successful health care integration is licensing and credentialing, which are verification processes intended to ensure a provider meets educational, training, and professional standards of conduct.¹¹⁸ Under all three legal frameworks, almost all health care services must be delivered by

114. *Diabetes Prevention Recognition Program: Requirements for CDC-Recognized Organizations*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (May 15, 2024), <https://www.cdc.gov/diabetes-prevention/php/program-provider/program-requirements.html> [https://perma.cc/7L9V-M46V] (defining eligibility criteria, service delivery requirements, and provider standards for DPP).

115. See C.F.R. § 410.79 (noting that the program is covered under Medicare Part B for eligible beneficiaries, enabling nationwide implementation); Nat’l DPP Coverage Toolkit, *Medicaid Coverage Landscape*, NAT’L ASS’N OF CHRONIC DISEASE DIR., <https://coveragetoolkit.org/medicaid-coverage-landscape/> [https://perma.cc/A4VK-EZVD] (last updated July 30, 2025) (state Medicaid coverage table); see also *Medicare Diabetes Prevention Program*, CTRS. FOR MEDICARE AND MEDICAID SERVS., <https://www.medicare.gov/coverage/medicare-diabetes-prevention-program> [https://perma.cc/Y5WU-MNNR] (last visited May 18, 2025).

116. See *id.* It is important to note that DPP has faced criticism for its eligibility requirements, particularly those related to weight loss. See, e.g., Stephanie L. Fitzpatrick et al., *Soc’y for Health Psychol. (APA Div. 38) & Soc’y of Behav. Med. Joint Position Statement on the Medicare Diabetes Prevention Program*, 7 TRANS. BEHAV. MED. 385 (June 2017). Additionally, DPP’s structure and requirements, such as its capitated payment structure, have sometimes made it difficult for health systems and community-based providers to implement the program. See Inga Gruß et al., *Challenges with Implementing the Diabetes Prevention Program for Medicare Beneficiaries in an Integrated Health System*, 27 AM. J. MANAGED CARE 1 (Nov. 2021).

117. As the FIM program demonstrates, stakeholders can include, among other parties, regulators, payers, community-based organizations, and service providers.

118. See *Provider Credentialing in Healthcare*, ANDROS, <https://andros.co/insights/guide-to-provider-credentialing/> [https://perma.cc/EDH2-6ZXD] (last visited May 18, 2025); 42 C.F.R. § 422.204 (outlining credentialing requirements for Medicare Advantage providers and suppliers).

appropriately licensed or credentialed providers to qualify for reimbursement.¹¹⁹ While these requirements aim to promote patient safety and quality of care,¹²⁰ they also pose significant barriers to achieving widespread coverage of innovative services.¹²¹

In practice, many non-traditional providers lack clear, accessible pathways to licensure or certification.¹²² For instance, the Doula Medicaid Project reports that “there are currently no mandatory licensure, certification, or credentialing requirements for doulas to practice in the United States.”¹²³ Even when credentialing pathways exist, they are often designed for traditional clinical roles and are not readily transferable to contexts in which providers have varied training backgrounds, serve multiple functions, and operate in unique service settings.¹²⁴ Credentialing aside, many providers, such as doulas and CHWs, are non-medical professionals who are likely unfamiliar with the complexities of

119. See, e.g., 42 C.F.R. § 422.204 (outlining credentialing requirements for Medicare Advantage providers and suppliers); 42 C.F.R. § 424.516 (outlining provider and supplier licensure, certification, and regulatory compliance requirements in Original Medicare); 42 C.F.R. § 455.410 (requiring “all ordering or referring physicians or other professionals providing services under the [Medicaid] State plan or under a waiver of the plan to be enrolled as participating providers”); 45 C.F.R. § 155.1045(a)(1)(vi) (requiring accreditation of QHP issuer). Notably, for benefits provided under Medicare Advantage EPHR and SSBCI benefits, plans have flexibility in determining provider qualifications. See U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., Pub. 100-16, MEDICARE MANAGED CARE MANUAL, ch. 4 (Benefits and Beneficiary Protections), § 30.1 (2016) (“Supplemental benefits need not be provided through Medicare providers nor at Medicare certified facilities.”); 42 C.F.R. § 422.204(b)(3) (requiring only “basic benefits” be furnished by providers who meet qualification requirements).

120. Ellis M. “Mac” Knight, *Credentialing — The Foundation for Quality and Safety*, 10 PHYSICIAN LEADERSHIP J. 22, 22–23 (2023); see also Medicare and Medicaid Programs; Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities; Medicare Providers’ and Suppliers’ Disclosure of Private Equity Companies and Real Estate Investment Trusts, 88 Fed. Reg. 80,141, 80,143 (Nov. 17, 2023) (describing the provider enrollment process as a “gatekeeper” intended to exclude unqualified providers and protect program beneficiaries from harm).

121. See, e.g., NILUFER ISVAN ET AL., U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF THE ASSISTANT SEC’Y FOR PLAN. & EVALUATION, CREDENTIALING, LICENSING, AND REIMBURSEMENT OF THE SUD WORKFORCE: A REVIEW OF POLICIES AND PRACTICES ACROSS THE NATION, 17–21, 39–40 (Nov. 2019), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/193271/CLRSUDWorkforce.pdf [<https://perma.cc/GUX7-RSN4>] (explaining how the lack of uniform credentials and use of non-standard requirements for practice bars entrance to the field of “Substance Use Disorder” counseling).

122. See, e.g., Amy Chen & Kate Rohde, *Doula Medicaid Training and Certification Requirements: Summary of Current State Approaches and Recommendations for Improvement*, NAT’L HEALTH L. PROGRAM (Mar. 16, 2023), <https://healthlaw.org/doula-medicaid-training-and-certification-requirements-summary-of-current-state-approaches-and-recommendations-for-improvement/> [<https://perma.cc/EUA4-CT5K>]; see *Medicaid Coverage of Community Health Worker Services*, *supra* note 105, at 9–10 (explaining the lack of consensus on CHW certification and training requirements).

123. Chen & Rohde, *supra* note 122.

124. *Id.* (explaining how “states must balance protecting quality of care with ensuring fair access for doulas who want to serve, or who are already serving,” considering that “doulas as a profession have not historically sought licensing by state medical boards.”).

pursuing provider reimbursement.

These gaps in policy and infrastructure place heavy burdens on providers. First, those unable to navigate costly or administratively complex licensing or credentialing processes may be excluded from reimbursement altogether.¹²⁵ Absent reimbursement, providers may resort to offering their services for free or charging fees on a sliding scale, undermining the financial viability of their work and limiting patient access to care.¹²⁶ Second, even if providers are willing and able to meet licensure standards, unsettled and disparate licensing requirements across reimbursement types create confusion and administrative inefficiencies.¹²⁷ Some providers report that the heavy burden of complying with varying health plan requirements deters them from enrolling in any plan at all.¹²⁸

Thus, the barriers providers face are two-fold. On one hand, overly rigid, traditional licensing and credentialing models risk excluding essential providers and undermining the foundations of the services themselves. On the other, unclear rules and shifting expectations across jurisdictions and payers force providers to confront a fragmented, often unfamiliar, landscape without the promise of transferability from payer to payer. To understand how these challenges manifest in practice, it is helpful to examine how licensing and credentialing are structured across the major health coverage frameworks. Together, these regulatory schemes create a patchwork of overlapping and sometimes conflicting requirements that non-traditional providers must navigate to deliver care.

a. Licensing and credentialing across coverage frameworks

To be eligible for Medicaid reimbursement, providers must be officially enrolled in the Medicaid program.¹²⁹ State Medicaid agencies enroll providers and ensure they pass screening and license verification to protect patient safety and ensure quality care.¹³⁰ Although licensure is generally required, services provided by non-licensed individuals can sometimes be covered if

125. See, e.g., Chen, Robles-Fradet, & Arega, *supra* note 56, at 29, 32 (documenting doula's concerns that training and certification costs can be prohibitively expensive); *Medicaid Coverage of Community Health Worker Services*, *supra* note 105, at 10 (noting that "rigid standards for certification and training can be time-consuming or costly, and may exclude potential CHWs"); *Doulas in Medicaid: Case Study Findings*, *supra* note 105, at 7 (documenting doula concern of administrative complexity regarding credentialing may deter doulas from enrolling as Medicaid providers).

126. See, e.g., Peters & Robles-Fradet, *supra* note 16.

127. Chen & Rohde, *supra* note 122.

128. See, e.g., *Doulas in Medicaid: Case Study Findings*, *supra* note 105, at 7.

129. 42 C.F.R. § 455.410 (requiring "all ordering or referring physicians or other professionals providing services under the [Medicaid] State plan or under a waiver of the plan to be enrolled as participating providers").

130. 42 C.F.R. §§ 455.410, 455.412.

“recommended by a physician or other licensed practitioner.”¹³¹ States may establish provider screening methods that are in addition to, or more stringent than, those required by federal regulations.¹³² Providers are subject to monitoring and evaluation by state Medicaid agencies to enforce quality standards and ensure compliance with federal and state requirements.¹³³ Providers that fail to meet requirements face financial, legal, and operational risks, including investigation and prosecution for fraud by federal and state authorities.¹³⁴ State Medicaid agencies can withhold payments and terminate services from the program in cases of fraud.¹³⁵

For Original Medicare, providers and suppliers must enroll in the Medicare program and obtain a National Provider Identifier (NPI) to be eligible for reimbursement.¹³⁶ Enrolled providers must resubmit and revalidate their information every five years.¹³⁷ CMS contracts with Medicare Administrative Contractors (MACs) to screen and enroll providers.¹³⁸ Oversight is governed by

131. *See, e.g.*, 42 C.F.R. § 440.130 (permitting Medicaid coverage of preventive services provided by non-licensed providers); 42 U.S.C. § 1396d(a)(13) (defining Medicaid “rehabilitative services” as “any medical or remedial services . . . recommended by a physician or other licensed practitioner.”). The “recommended by” exception is not a silver bullet; innovative services such as CHWs, for instance, struggle to be meaningfully integrated into multidisciplinary care teams because providers are often unfamiliar with the scope of CHW services and are not financially incentivized to collaborate. As a result, CHWs’ ability to provide care is curtailed. *See* Camaliche et al., *supra* note 60, at 10.

132. 42 C.F.R. § 455.452. States may also rely on the result of screening performed by Medicare contractors or Medicaid agencies of other states. 42 C.F.R. §455.410.

133. *See, e.g.*, 42 C.F.R. § 431.107 (requiring “an agreement between the Medicaid agency and each provider or organization furnishing services” for recordkeeping, fraud control, and other compliance purposes).

134. State-based, jointly funded Medicaid Fraud Control Units (MFCUs) are primarily responsible for detecting, investigating, and prosecuting fraud, waste, and abuse. *See About the Medicaid Fraud Control Units*, NAT’L ASS’N OF ATTNY. GEN., <https://www.naag.org/about-naag/namfcu/about-the-medicaid-fraud-control-units/> [<https://perma.cc/JB82-X79C>] (last visited May 29, 2025). The federal government also retains authority to bring criminal, civil, or administrative legal actions in cases of fraud in both Medicaid and Medicare. 42 U.S.C. § 1320a-7a (discussing civil penalties); 42 U.S.C. § 1320a-7b (discussing criminal penalties for acts involving Federal health care programs); 31 U.S.C. §§ 3729–3733 (False Claims Act); *see also* Off. of Inspector Gen., *Enforcement Actions*, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://oig.hhs.gov/fraud/enforcement/> [<https://perma.cc/RWW6-LH67>] (last visited May 28, 2025).

135. 42 C.F.R. § 455.23. The federal government can also bring enforcement actions for fraud or violations of the False Claims Act. 31 U.S.C. §§ 3729–3733.

136. 42 C.F.R. §§ 424.506 (requiring National Provider Identifier); 424.510 (discussing Medicare enrollment requirements); 424.516 (requiring compliance with state licensure, certification, and regulatory requirements).

137. 42 C.F.R. § 424.515.

138. *See* 42 U.S.C. § 1395kk-1(a). MACs are private insurers that have been awarded a regional geographic jurisdiction to administer claims under Original Medicare. *What’s a MAC*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/whats-mac> [<https://perma.cc/9BVH-YK8B>] (last visited July 20, 2025). CMS also contracts with Unified Program Integrity Contractors (UPICs)

the Medicare Integrity Program, which authorizes CMS to conduct provider education, monitor compliance, and prevent fraud.¹³⁹ If a provider or supplier fails to meet Medicare requirements, CMS may revoke their enrollment or limit their billing privileges.¹⁴⁰

These enrollment requirements, and the high stakes of noncompliance under Medicaid and Original Medicare, jeopardize the scalability of many promising interventions. For example, while douglas and CHWs may be well-established in their communities, the administrative complexity of maintaining Medicaid enrollment or obtaining an NPI can overwhelm providers who may lack the infrastructure to manage these processes.¹⁴¹ Without institutional support or administrative capacity, even highly effective service providers risk being excluded from formal health care reimbursement systems.

In Medicare Advantage (MA), providers are subject to similar requirements. Enforcement of the provider requirements, however, is typically carried out by the plans themselves, pursuant to applicable federal and state regulations. For example, 42 C.F.R. § 422.204 requires MA organizations to implement “a documented process” for the selection and evaluation of providers, including verification of licensure, credentialing, and accreditation.¹⁴² Plans must also re-credential at least every three years and consider provider performance indicators related to quality improvement, utilization management, and patient satisfaction.¹⁴³ Because MA plans have more flexibility in credentialing criteria, they may be more amenable to credentialing and contracting with non-traditional providers, so long as those providers comply with applicable state licensure requirements.¹⁴⁴

ACA QHPs must implement a provider credentialing process, but unlike in the federal health insurance programs, ACA plans are not required to formally “enroll” providers. Federal regulations require “QHP issuers”¹⁴⁵ to verify the credentials of participating providers, but they do not prescribe specific

to investigate potential fraud and abuse. *See* 42 U.S.C. § 1395ddd (authorizing contracts); U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PROGRAM INTEGRITY MANUAL (CH. 6), <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c06.pdf> [<https://perma.cc/VG4D-C3UY>]; *see generally* *Unified Program Integrity Contractor (UPIC)*, NORIDIAN HEALTHCARE SOLUTIONS, <https://med.noridianmedicare.com/web/jddme/cert-reviews/upic> [<https://perma.cc/P5G8-YRZW>] (last updated Aug. 22, 2025).

139. *See* 42 U.S.C. § 1395ddd.

140. *See* 42 C.F.R. § 424.535.

141. *See supra* note 125 and accompanying text.

142. *See* 42 C.F.R. § 422.204.

143. *See* 42 C.F.R. § 422.204(b)(2)(ii).

144. Because provider licensing is conducted at the state level, plans and providers are subject to applicable state regulations in that context. *See id.* § 422.204(b)(1)(i).

145. QHP issuers are health insurance issuers that offer QHPs in a state in accordance with a certification from an Exchange. 45 C.F.R. § 155.20. Issuers are required to be licensed to engage in the business of insurance in the state and are subject to state law that regulates insurance. *See* 45 C.F.R. § 144.103.

licensing or credentialing standards.¹⁴⁶ Instead, QHPs generally rely on standards set by recognized accrediting entities.¹⁴⁷ These organizations, such as the National Committee for Quality Assurance (NCQA) and URAC, require health plans to “establish the qualifications of their licensed medical professionals by assessing their background and legitimacy to provide care.”¹⁴⁸ Because QHPs typically focus on traditional medical professionals, providers may still be excluded from participation due to unclear or mismatched credentialing standards.

The fragmented structure across Medicaid, Medicare, and the ACA not only creates inefficiencies—it contributes directly to the uncertainty and exclusion that prevent promising care models from scaling. Fortunately, several state and federal initiatives demonstrate how flexible design can expand access without compromising health and safety.

b. Structuring credentialing pathways to support non-traditional providers

Stakeholders can develop appropriate yet accessible provider qualification standards that align with quality and safety goals while avoiding overburdening longstanding community providers who may struggle to meet rigid, overly prescriptive requirements. For example, some states have utilized alternative vetting processes and flexible licensing options that still meet federal requirements.¹⁴⁹ To develop these alternative models, regulators should collaborate with providers—who bring essential institutional knowledge—to ensure credentialing systems reflect best practices and preserve the core principles of the services themselves.¹⁵⁰ This approach supports broader

146. See 42 U.S.C. § 18031(c)(1)(D); 45 C.F.R. § 156.275 (requiring QHPs to be accredited on the basis of, *inter alia*, provider credentialing). QHPs must also maintain accurate provider directories. 45 C.F.R. § 156.230(b).

147. See 45 C.F.R. § 155.1045 (permitting state exchanges to use accreditation by recognized entities in certifying QHPs).

148. See *Credentialing Accreditation & Certification Programs*, NCQA, <https://www.ncqa.org/programs/health-plans/credentialing/> [<https://perma.cc/DYR3-BLYA>] (last visited May 29, 2025); see also *Credentials Verification Organization Accreditation*, URAC, <https://www.urac.org/accreditation-cert/credentials-verification-organization-accreditation/> [<https://perma.cc/7L7G-J4QT>] (last visited May 29, 2025).

149. See, e.g., Hasan, *supra* note 52.

150. See, e.g., *Expanding Doula Support Services in Massachusetts: Consideration for Successful Implementation*, BETSY LEHMAN CTR. 14 (Jan. 2022), https://betsylehmancenterma.gov/assets/uploads/DoulaSupportMA_Report.pdf [<https://perma.cc/7J7H-BX7Q>] (documenting concern that primarily recognizing westernized, white-dominant training programs can overshadow training programs run by Black and brown doulas); *Doulas in Medicaid: Case Study Findings*, *supra* note 105, at 7 (citing doula concerns that if training and certification organizations are not community-based, they may not sufficiently train doulas to meet the needs of their patients); see also Leticia Boughton Price et al., *Illinois Community Health Worker Roundtables*, CHWA & CTR. FOR HEALTH L. & POL’Y INNOVATION OF HARVARD L. SCH. 4, 8 (July 2022), <https://chlp.org/wp-content/uploads/2022/07/Illinois-Community-Health-Worker->

provider participation, enhances access to culturally competent care, and promotes more sustainable, equitable systems.

Growing state Medicaid coverage of doula services demonstrates how provider credentialing and licensing can be adapted to accommodate innovative service models while advancing value-based care objectives. Doula care has been shown to improve health outcomes, reduce costs, and mitigate the effects of racism and racial bias in health care settings.¹⁵¹ In Medicaid, in particular, pregnant people who received doula support during labor and delivery exhibited lower preterm birth rates and required fewer cesarean sections, decreasing the risk of costly and dangerous complications.¹⁵² According to the Doula Medicaid Project, states have adopted a range of certification approaches for doulas, with many relying on independent training organizations and/or offering multiple pathways to credentialing, including recognition of demonstrated field experience.¹⁵³ Leading advocates and policy experts argue that this flexibility is essential for reducing barriers to entry.¹⁵⁴

Like doulas, community health workers (CHWs) offer a compelling example of how stakeholders can adapt credentialing frameworks to support non-traditional providers. As introduced earlier, CHWs serve as culturally competent intermediaries between health systems and communities.¹⁵⁵ CHW interventions have consistently demonstrated positive outcomes, particularly in

Roundtables.pdf [https://perma.cc/2RXZ-KFKS] (advocating for CHW leadership in training programs and flexibility in training formats to credit highly qualified CHWs for their prior professional experience).

151. See Alexandria Sobczak et al., *The Effect of Doulas on Maternal and Birth Outcomes: A Scoping Review*, 15(5) CUREUS 1, 11 (May 24, 2023) (“... doulas have been found to reduce cesarean section frequency, low birth weight, and premature labor” and increase well-being and satisfaction rates); see Meghan A. Bohren et al., *Continuous Support for Women During Childbirth*, COCHRANE DATABASE OF SYS. REV. 1 (2017) (meta-analysis of 26 studies finding continuous, one-to-one intrapartum support may improve outcomes for women and infants compared with usual care); see also *Doulas and Midwives Are Key Partners in Improving Maternal and Infant Health Outcomes*, NAT’L ACAD. FOR STATE HEALTH POL’Y (Dec. 23, 2022), https://nashp.org/doulas-and-midwives-are-key-partners-in-improving-maternal-and-infant-health-outcomes/ [https://perma.cc/UP4E-X4WT].

152. Kathleen Knocke, *Doula Care and Maternal Health: An Evidence Review*, ASPE OFF. OF HEALTH POL’Y 5 (Dec. 13, 2022), https://aspe.hhs.gov/sites/default/files/documents/dfcd768f1caf6fabf3d281f762e8d068/ASPE-Doula-Issue-Brief-12-13-22.pdf [https://perma.cc/LH62-RB4S].

153. Chen & Rohde, *supra* note 122; see, e.g., *Doula Application Information*, CAL. DEP’T OF HEALTH CARE SERVS., https://www.dhcs.ca.gov/provgovpart/Pages/Doula.aspx [https://perma.cc/EME4-AB77] (last visited May 19, 2025) (requiring doulas to either complete minimum hours of training or have at least five years of recent experience in doula care, supported by letters of recommendation). For more information about the Doula Medicaid Project, see *About the Doula Medicaid Project*, NAT’L HEALTH LAW PROG., https://healthlaw.org/doulamedicaidproject/ [https://perma.cc/97SJ-8J2T] (last visited May 19, 2025).

154. Chen, *supra* note 30.

155. See AM. PUB. HEALTH ASS’N, *supra* note 19; see also *Medicaid Coverage of Community Health Worker Services*, *supra* note 105, at 1 (“CHW services may include health promotion and education, patient outreach and follow-up, assistance in navigating the health care system, translation and interpretation services, and care coordination and case management.”).

increasing access to and adherence to care, enhancing patient satisfaction, and reducing racial disparities.¹⁵⁶ Many states certify CHWs after they complete specific training programs or a certain number of supervised practice hours.¹⁵⁷ States have also made efforts to avoid unnecessary credentialing barriers by, for instance, exempting CHWs with prior experience from such requirements or by recognizing licenses and certifications from other states.¹⁵⁸ This balance—setting clear, navigable guidelines that legacy providers can follow while maintaining the flexibility to accommodate diverse backgrounds and models of care—is essential to equitably expanding access and increasing provider enrollment.¹⁵⁹

While doula and CHW services illustrate how states can flexibly structure credentialing to support emerging services, non-emergency medical transportation (NEMT) demonstrates a different approach via federally mandated coverage that can ensure baseline standards while still preserving state flexibility. NEMT ensures that Medicaid beneficiaries can access medically necessary health care services by providing transportation to and from those services.¹⁶⁰ When Congress added NEMT as a mandatory Medicaid benefit through Section 209 of the Consolidated Appropriations Act in 2020, it

156. *Medicaid Coverage of Community Health Worker Services*, *supra* note 105, at 2–3 (collecting research); Emmett Ruff et al., *Advancing Health Equity through Community Health Workers and Peer Providers: Mounting Evidence and Policy Recommendations*, FAMILIES USA 19 (Nov. 2019), https://familiesusa.org/wp-content/uploads/2019/11/HEV_PCORI-CHW-Report_11-04-19.pdf [<https://perma.cc/DE73-4Q58>].

157. *See Medicaid Coverage of Community Health Worker Services*, *supra* note 105, at 9.

158. *See id.* (including an example from Oregon allowing documentation and experience certification requirements); *cf.* CALIFORNIA DEP'T OF HEALTH CARE SERVS., *MEDI-CAL COMMUNITY SUPPORTS, OR IN LIEU OF SERVICES (ILOS) POLICY GUIDE 55* (July 2023), <https://www.dhcs.ca.gov/Documents/MCQMD/DHCS-Community-Supports-Policy-Guide.pdf> (explaining how California FIM programs provide alternative vetting process for community-based providers); *see, e.g.*, Mass. Exec. Off. of Health & Hum. Servs., *Order Maximizing Available Health Care Providers* (Apr. 2020), <https://www.mass.gov/doc/order-maximizing-available-healthcare-providers-april-2020/download> [<https://perma.cc/8Z35-Q3KD>] (issuing Massachusetts licenses to health care providers “who are licensed in another State who present to the corresponding Massachusetts licensing authority verification that such license is in good standing in that other State” during the COVID-19 state of emergency).

159. *See* Ctr. for Health L. & Pol'y Innovation of Harvard L. Sch., Nat'l Council of La Raza & Am. Acad. of Family Physicians Found., *Recommended Model Guidelines for Credentialing Community Health Worker Programs and Community Health Workers* (2013), <https://chlp.org/wp-content/uploads/2013/12/PATHS-Credentialing-Guidelines-Final-070815.pdf> [<https://perma.cc/EUB7-UWJ5>]; *see, e.g.*, Emmett Ruff & Eliot Fishman, *Building Capacity for Community Health Worker Integration: Three Key Steps State Policymakers Should Take during the COVID-19 Crisis and Beyond*, FAMILIES USA 2–3 (July 2020), https://familiesusa.org/wp-content/uploads/2020/07/HE-267_Integrating-CHWs_Report_7-21-20.pdf [<https://perma.cc/D2PQ-2KMT>] (explaining how standardized certifications can create the infrastructure for Medicaid reimbursement and also lay out the scope of practice for CHWs, facilitating recruitment and contracting).

160. *See* 42 C.F.R. § 440.170(a); U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 21.

imposed minimum federal standards on NEMT providers and drivers.¹⁶¹ These requirements include that drivers hold valid licenses, that providers have procedures to address violations of state drug laws, and that driver histories be disclosed to state agencies.¹⁶² Although these requirements may seem simple, they provide greater legal clarity and opportunities for long-term system alignment while preserving state flexibility above a consistent floor.¹⁶³ In addition to improving access and consistency, federal provider qualification and enrollment standards have supported oversight efforts by reducing administrative confusion and reinforcing broader goals of program integrity and quality of care.¹⁶⁴

These case studies demonstrate that several approaches can help pull non-traditional providers out of regulatory gray areas and certification limbo, and into clear, navigable pathways that support access while advancing quality and safety goals.

3. *Billing and Reimbursement*

A final common barrier to sustainable health care integration involves billing and reimbursement, where limited administrative capacity and inadequate payment rates pose significant obstacles to incorporating innovative interventions into mainstream coverage frameworks.

161. Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 209, 134 Stat. 1182, 1456 (2020).

162. *Id.* at 2988.

163. See 42 U.S.C. § 1396a(a)(87) (allowing states to impose more rigid requirements). A majority of states have amended their state plans to implement the new requirements, demonstrating the statute's effectiveness of promoting regulatory alignment. See *29 States Have CMS-Approved State Plan Amendments (SPAs) to Implement the New Non-Emergency Medical Transportation (NEMT) Requirements*, SIMON & CO. (Mar. 31, 2022), <https://mjsimonandcompany.com/non-emergency-medical-transport/mandatory-medicare-benefit-campaign/half-of-states-have-cms-approved-state-plan-amendments-spas-to-implement-the-new-non-emergency-medical-transportation-nemt-requirements> [<https://perma.cc/UU4D-8PY2>].

164. See Sharon Silow-Carroll et al., *Medicaid's Non-Emergency Medical Transportation Benefit: Stakeholder Perspectives on Trends, Challenges, and Innovations*, HEALTH MGMT. ASSOCS. 21 (Aug. 2021), https://www.healthmanagement.com/wp-content/uploads/HMA_NEMT_Report_MACPAC_Aug-21.pdf [<https://perma.cc/LF7J-WEMS>] (discussing how regulation and oversight can reduce fraud and abuse). Additional federal guidance further crystallizes expectations regarding state oversight responsibility, see U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUM. SERVS., STATE MEDICAID DIR. LETTER NO. 23-006, 26 (Sep. 28, 2023), <https://www.medicare.gov/federal-policy-guidance/downloads/smd23006.pdf> [<https://perma.cc/8MMJ-H5FX>], and provider expectations, see generally *Medicaid Non-Emergency Medical Transportation Booklet for Providers*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 2016), <https://www.cms.gov/medicare-medicare-coordination/fraud-prevention/medicaid-integrity-education/downloads/nemt-booklet.pdf> [<https://perma.cc/JX9R-G6YT>].

a. Medicaid rate setting and reimbursement structure

Under Medicaid, services are reimbursed according to policies and methodologies that each state outlines in its state plan (subject to CMS approval).¹⁶⁵ Because there are no federal minimums, states have considerable flexibility to establish Medicaid provider payment rates for most provider types.¹⁶⁶ That flexibility, however, is bounded by several federal requirements designed to ensure adequate access and value.

For instance, § 1902(a)(30)(A) of the Social Security Act requires that payments for services be consistent with “efficiency, economy, and quality of care” while “safeguard[ing] against unnecessary utilization” of care and services.¹⁶⁷ This section also requires that rates be “sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area.”¹⁶⁸ If a state wants to reduce or restructure rates, it must consider stakeholder input—including from providers and beneficiaries—and the impact that the proposed change will have on access to the service.¹⁶⁹ While Medicaid MCOs are not subject to these exact payment provisions, state payments for MCO services must be actuarially sound, meaning that the rates are projected to provide “for all reasonable, appropriate, and attainable costs” required under the contract.¹⁷⁰ When determining those rates, states must consider utilization and cost data, trends, and demographic factors.¹⁷¹ Together, these structural safeguards are intended to promote access and payment adequacy.

b. Medicare rate setting and reimbursement structure

As with other barriers, reimbursement differs between Original Medicare and Medicare Advantage. In Original Medicare, CMS centrally administers payment and directly reimburses providers. CMS sets national Medicare payments through prospective payment systems for Part A (hospital insurance)

165. See 42 C.F.R. § 447.201.

166. See *Medicaid Qualified Practitioner Services – Methodologies for Enhanced Payment Made to Physicians and Practitioners Associated with Academic Medical Centers and Safety Net Hospitals and Upper Payment Calculation*, CTRS. FOR MEDICARE AND MEDICAID SERVS. 1, <https://www.medicaid.gov/medicaid/downloads/upl-instructions-qualified-practitioner-services-replacement-new.pdf> [<https://perma.cc/CBU2-C8KN>] (last visited Apr. 10, 2026); *Upper Payment Limit Supplemental Payments*, MEDICAID AND CHIP PAYMENT AND ACCESS COMM’N 1 (Nov. 2021), <https://www.macpac.gov/wp-content/uploads/2021/11/Upper-Payment-Limit-Supplemental-Payments.pdf> [<https://perma.cc/2QPW-YDJE>].

167. Codified at 42 U.S.C. § 1396a(a)(30)(A).

168. 42 U.S.C. § 1396a(a)(30)(A).

169. 42 C.F.R. § 447.204.

170. 42 U.S.C. § 1396b(m)(2)(A); 42 C.F.R. § 438.4.

171. 42 C.F.R. § 438.5.

and fee schedules for Part B (medical insurance).¹⁷² Providers are generally reimbursed on a fee-for-service basis, meaning they are paid a set amount based on the diagnosis, treatment, or service rendered.¹⁷³

By contrast, in Medicare Advantage, CMS pays plans a capitated, risk-adjusted monthly amount per beneficiary, not per service.¹⁷⁴ MA plans then negotiate rates and payment models directly with contracted providers.¹⁷⁵ Importantly, CMS does not regulate provider payment amounts offered by MA plans, but it does require that “benefits [be] available and accessible” to enrollees with “reasonable promptness” and “continuity.”¹⁷⁶

c. Affordable Care Act rate setting and reimbursement structure

Although federal law requires that all QHPs cover services included in the state’s EHB benchmark plan, the ACA does not establish a centralized federal reimbursement system.¹⁷⁷ Instead, QHP issuers negotiate payment rates directly with providers and can implement their preferred payment models, including those that forward value-based principles.¹⁷⁸ While there are no federal minimums or caps on these rates, plans must meet federal network adequacy standards, which may indirectly influence payment rates.¹⁷⁹

d. Challenges arising from billing and reimbursement

Problems with billing codes and processes create structural barriers to the

172. 42 U.S.C. § 1395ww(d) (establishing Inpatient Prospective Payment Systems (IPSS) methodology for Medicare Part A); 42 C.F.R. pt. 412 (detailing regulations for IPPS); 42 U.S.C. § 1395w-4 (requiring the HHS Secretary to establish Medicare Part B fee schedules based on several factors); 42 C.F.R. pt. 414 (implementing regulations for payment of Part B services).

173. *See supra* notes 169–70 and accompanying text.

174. *See* 42 U.S.C. § 1395w-23(a); *see also* 42 C.F.R. § 422.250–422.266. MA’s capitated payment model furthers the goals of value-based care by incentivizing providers to keep patients healthy within the fixed budget. *See generally* Margaret Lindquist, *Understanding Value-Based Care Models*, ORACLE HEALTH (Apr. 16, 2025), <https://www.oracle.com/health/value-based-care-models/> [<https://perma.cc/9MV2-ZE3Q>].

175. *See* 42 U.S.C. § 1395w-22(d); 42 C.F.R. § 422.112(a)(1).

176. *See* 42 U.S.C. § 1395w-22(d).

177. *See* 45 C.F.R. § 165.115 (requiring provision of benefits that are “substantially equal to the EHB-benchmark plan”); Letter from Ctr. for Consumer Info. & Ins. Oversight, U.S. Ctrs. For Medicare & Medicaid Servs. on 2024 Final Letter to Issuers in the Federally-facilitated Exchanges (May 1, 2023), <https://www.cms.gov/files/document/2024-final-letter-issuers-508.pdf> [<https://perma.cc/STN4-7WTK>] (clarifying that “states are the primary regulators of health insurers” in federally-funded exchanges and are responsible for reviewing rates for reasonableness and compliance with federal laws and regulations).

178. *See, e.g., Rate Justification for QHP Plans*, EMPIRE HEALTHCHOICE ASSURANCE, INC., 1 (Jan. 2023), https://www.anthembluecross.com/content/dam/anthem/us/global/pdf/2023_NY_G1921_SG_RateJustification.pdf [<https://perma.cc/8U3E-UV22>] (QHP issuer explaining how, despite a rate increase, it “continue[s] to negotiate the best possible rates for covered services” and to collaborate with providers through value-based payment models).

179. *See* 45 C.F.R. § 156.230.

scalability and sustainability of innovative services. Medical Nutrition Therapy (MNT), a “nutrition-based treatment provided by a registered dietitian”¹⁸⁰ that uses education and behavioral counseling to prevent or manage a medical condition, illustrates these challenges to integrating into the reimbursement systems.¹⁸¹ Although Medicare Part B and other insurers cover MNT for certain conditions,¹⁸² billing procedures often remain unclear, particularly in non-traditional settings. The lack of guidance has led to service caps, staffing shortages, and access limitations.¹⁸³ These problems, in turn, limit beneficiary access and exacerbate the underutilization of services.¹⁸⁴ Similar challenges have been reported in other innovative services, such as those involving CHWs; as researchers have noted, “when regulatory language lacks clarity, organizations struggle to translate regulations into [effectuating] service delivery, submitting claims, and successfully receiving payment.”¹⁸⁵

Beyond regulatory ambiguity, non-traditional providers and community-based organizations (CBOs) often lack the necessary infrastructure and expertise to manage the complexities of health care coding, billing, and payment systems.¹⁸⁶ Some CHWs have noted that navigating the billing process can be

180. See *Medical Nutrition Therapy*, U.S. CTRS. FOR DISEASE CTRL. & PREVENTION (May 15, 2024), <https://www.cdc.gov/diabetes-toolkit/php/reimbursement/medical-nutrition-therapy.html> [https://perma.cc/E4RP-XJHG]; see also 42 U.S.C. 1395x(vv)(1) (defining MNT services as “nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional”).

181. *Medical Nutrition Therapy*, U.S. CTRS. FOR DISEASE CTRL. & PREVENTION (May 15, 2024), <https://www.cdc.gov/diabetes-toolkit/php/reimbursement/medical-nutrition-therapy.html> [https://perma.cc/E4RP-XJHG]; see also 42 U.S.C. 1395x(vv)(1) (defining MNT services as “nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional”); *Medical Nutrition Therapy*, CLEVELAND CLINIC, <https://my.clevelandclinic.org/health/treatments/medical-nutrition-therapy-mnt> [https://perma.cc/6EBB-CPW2] (last updated Feb. 29, 2024).

182. 42 C.F.R. § 410.132; see also *Medical Nutrition Therapy Services*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.medicare.gov/coverage/medical-nutrition-therapy-services> [https://perma.cc/VY87-QKAU] (last visited Apr. 10, 2026); Eat Right Pro, *Places of Service and Specific Healthcare Services*, ACAD. OF NUTRITION & DIETETICS, <https://www.eatrightpro.org/career/payment/coding-and-billing/places-of-service-and-specific-health-care-services> [https://perma.cc/R9AG-B94W] (last visited Apr. 10, 2026).

183. Eat Right Pro, *Academy Advocates for Sustainable Billing Practices for Medical Nutrition Therapy*, ACAD. OF NUTRITION & DIETETICS (Mar. 28, 2024), <https://www.eatrightpro.org/news-center/public-policy-news/academy-advocates-for-sustainable-billing-practices-for-mnt> [https://perma.cc/8P39-QXZA].

184. See, e.g., Letter from Jeanne Blankenship & Carly Leon, Acad. of Nutrition & Dietetics to Gift Tee, Director, Division of Practitioner Services, U.S. Ctrs. For Medicare & Medicaid Svcs., U.S. Dep’t of Health & Hum. Svcs. 2 (Mar. 22, 2024), https://www.eatrightpro.org/-/media/files/eatrightpro/about-us/about-us-regulatory-comments/3-28-24-academy-comments-to-cms-hopd_march-2024.pdf?rev=316fa3c4d7a54599afa33cf26165a547&hash=816F29BC6BEA3C9297212E98E97B7272 [https://perma.cc/WUZ7-YM6W].

185. Kathryn E. Gunter et al., *Barriers and Strategies to Operationalize Medicaid Reimbursement for CHW Services in the State of Minnesota: A Case Study*, 38 J. GEN. INT’L MED. S70, S71 (Mar. 2, 2023).

186. See, e.g., Camaliche et al., *supra* note 60, at 6–7.

“the equivalent of learning a whole new language from scratch.”¹⁸⁷ Thus, even when insurers technically cover services, many organizations struggle to operationalize and access reimbursement.¹⁸⁸ For instance, registered dietitian nutritionists (RDNs) delivering MNT report low reimbursement levels, primarily due to a limited understanding of the coding and billing processes.¹⁸⁹ The Academy of Nutrition and Dietetics has warned that RDNs providing clinical services “may be at risk for losing income and/or jobs to other, more business-savvy health care providers” who are better able to navigate payment systems.¹⁹⁰ However, technical assistance and training can meaningfully reduce these administrative barriers.¹⁹¹ For example, to facilitate Medicaid coverage of doula services in Oregon, liaisons were deployed to assist doulas with submitting Medicaid claims and billing.¹⁹²

Even when reimbursement is available and accessible, low payment rates for non-traditional services often fail to reflect the full scope of work required to deliver effective care.¹⁹³ A primary reason for this insufficiency is the

187. Camaliche et al., *supra* note 60, at 6–7.

188. See, e.g., Kathryn E. Gunter et al., *supra* note 185; CTR. FOR HEALTH L. & POL’Y INNOVATION OF HARV. L. SCH. & FOOD IS MED. COAL., *supra* note 20, at 33 (explaining that complicated billing and reimbursement processes in Medicaid nutrition programs “threaten the timely delivery of services and payments”).

189. See Bonnie T. Jortberg et al., *Trends in Registered Dietitian Nutritionists’ Knowledge and Patterns of Coding, Billing, and Payment*, 120 J. OF THE ACAD. OF NUTRITION & DIETETICS 134, 144 (July 2019). Underutilization of insurance can have broader negative impacts. Failure to log services can skew data needed to assess important metrics such as cost, volume, and utilization, making services “invisible” to rate-setting parties. Cf. KPMG, *Investing in Social Services as a Core Strategy for Healthcare Organizations: Developing the Business Case*, THE COMMONWEALTH FUND 9 (Mar. 2018), <https://www.commonwealthfund.org/publications/other-publication/2018/mar/investing-social-services-core-strategy-healthcare> [<https://perma.cc/C9TR-UFF3>] (describing how failing to log services due to a lack of payment codes makes expenses “invisible” to rate-setting parties). For instance, if registered dietitians are not billing for the MNT services they provide, then systems cannot evaluate their efficacy or credit the value that is being delivered. See Jortberg et al., *supra* note 189, at 144.

190. Jortberg et al., *supra* note 189, at 144.

191. See, e.g., Anna Mudumala et al., *Challenges and Strategies in Expanding Non-Traditional Pregnancy-Related Services: Findings from a Survey of State Medicaid Programs*, KFF (May 3, 2024), <https://www.kff.org/medicaid/challenges-and-strategies-in-expanding-non-traditional-pregnancy-related-services-findings-from-a-survey-of-state-medicaid-programs/> [<https://perma.cc/4VUY-VLMA>] (explaining how states such as New Mexico and Virginia have provided technical assistance and resources to help MCOs and providers navigate billing).

192. Cara B. Safon et al., *Access to Perinatal Doula Services in Medicaid: A Case Analysis of 2 States*, 2(3) HEALTH AFF. SCHOLAR 1, 7 (Mar. 4, 2024); see also A. J. Admon et al., *Assessing and Improving Data Quality from Community Health Workers: A Successful Intervention in Neno, Malawi*, 3(1) PUB. HEALTH ACTION 56, 58 (Mar. 2013) (shifting data collection and aggregation responsibilities away from community health workers, resulting in rapid improvements in data quality).

193. See *Doulas in Medicaid: Case Study Findings*, *supra* note 105, at 8; see also HILL ET AL., *supra* note 42. Low reimbursement is particularly prevalent in Medicaid, see *Evaluating the Effects of Medicaid Payment Changes on Access to Physician Services*, MEDICAID AND CHIP

continued reliance on the fee-for-service payment model, which is built around discrete, quantifiable services typically performed by licensed medical professionals.¹⁹⁴ By contrast, many non-traditional interventions—such as those supplied by CBOs and non-medical providers—do not conform to this structure.¹⁹⁵ As a result, billing codes often undervalue the frequency, duration, cost, and/or complexity of these services, leading to low provider participation, workforce turnover, and diminished quality of care.¹⁹⁶ For instance, CBOs delivering DPP services report that “covering their full, ongoing costs is a primary challenge,” with many relying on supplemental funding sources such as grants to sustain operations.¹⁹⁷

e. Alternative payment models present new opportunities

While this Article focuses primarily on the legal and structural barriers inhibiting widespread adoption of innovative services, there remain additional factors, such as payer reluctance to expand coverage for preventive services, which constrain integration. As some researchers have noted, financial incentives do not always align to encourage insurers to cover preventive services.¹⁹⁸ The frequency with which patients rotate on and off different insurance plans, especially Medicaid, may disincentivize insurers from covering preventive treatments that increase short-term costs when a future insurer may reap the full benefits down the line.¹⁹⁹ However, the shift from volume-based to

PAYMENT AND ACCESS COMM’N 1–2 (Jan. 2025), <https://www.macpac.gov/wp-content/uploads/2025/01/Evaluating-the-Effects-of-Medicaid-Payment-Changes-on-Access-to-Physician-Services.pdf> [<https://perma.cc/Z92A-P8E4>]. Making matters worse, in 2015, the Supreme Court held that providers cannot sue State Medicaid Agencies to enforce federal reimbursement rate standards. *Armstrong v. Exceptional Child Center, Inc.*, 575 U.S. 320, 328–29 (2015).

194. Camaliche et al., *supra* note 60, at 8.

195. Several factors contribute to this misalignment, including the prevalence of non-medical providers (e.g., doulas), team-based models of care (e.g., CHWs), multi-touch engagements, and the time-intensive nature of the intervention.

196. Joseph Humphry & Jasmin Kiernan, *Insights in Public Health: Community Health Workers Are the Future of Health Care: How Can We Fund These Positions?*, 78 HAW. J. HEALTH & SOC. WELFARE 371, 371 (Dec. 2019); *see, e.g., Doulas in Medicaid: Case Study Findings*, *supra* note 105, at 8; *see also* HILL ET AL., *supra* note 42; Mudumala, *supra* note 191; Camaliche et al., *supra* note 60, at 8.

197. Nat’l Disease Prevention Program Coverage Toolkit, *Nat’l DPP Lifestyle Change Program Delivery Options*, NAT’L ASS’N OF CHRONIC DISEASE DIR. (Mar. 12, 2025), <https://coveragetoolkit.org/medicaid-agencies-delivery/program-delivery-options/> [<https://perma.cc/CN49-7F2Q>].

198. *See, e.g.,* Katherine Pryor & Kevin Volpp, *Deployment of Preventive Interventions — Time for a Paradigm Shift*, 378 NEW ENG. J. MED. 1761, 1761 (2018).

199. *See* Pryor & Volpp, *supra* note 198, at 1762; Sachs, *supra* note 13, at 76; *cf.* Musumeci et al., *supra* note 199 (discussing the same disincentives in the context of high-cost disease treatment). Medicaid enrollment “churn” is particularly high, “the typical enrollee is covered for less than 10 months, and 10 percent of enrollees lose and regain Medicaid within 12 months.”

value-based care offers promise to counteract this narrow cost-avoidance framing.

Alternative value-based payment models, which widen the scope of optimization to include long-term outcomes and system-wide efficiency, offer a critical opportunity to redesign reimbursement structures to better support the sustainability and scalability of innovative, community-based services. By tying payment to quality metrics and cost savings rather than to service volume, they allow for more flexible and comprehensive reimbursement.²⁰⁰ CMS is increasingly integrating value-based care models into both Original Medicare and Medicare Advantage.²⁰¹ Under Original Medicare's Shared Savings Program, Accountable Care Organizations (ACOs) can share in the savings they generate for the Medicare program by delivering high-quality, cost-effective care.²⁰² MA organizations, similarly, often incorporate value-based arrangements into their provider contracts to share financial risks and encourage efficient use of resources.²⁰³

As CMS continues its shift to value-based care across both systems, innovative services will have greater opportunities to access reimbursement, particularly where they improve quality and reduce costs through upstream interventions.²⁰⁴ Medicare's Accountable Care Organization Realizing Equity,

MaryBeth Musumeci et al., *Reducing Medicaid Churn: Policies to Promote Stable Health Coverage and Access to Care*, COMMONWEALTH FUND (June 11, 2025). These high rates are due, in part, to the income-based nature of Medicaid eligibility and the heightened barriers to renew enrollment. *Id.*

200. See, e.g., Camaliche et al., *supra* note 60, at 8.

201. See, e.g., Abe Sutton, CMS Innovation Center Strategy to Make America Healthy Again, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/priorities/innovation/about/cms-innovation-center-strategy-make-america-healthy-again> [https://perma.cc/T6JS-GUDX] (last updated May 13, 2025) ("Medicare Advantage models will be designed to increase high-value coverage options and to help beneficiaries select plans that best meet their health needs."); *Strategic Direction*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/priorities/innovation/about/strategic-direction> [https://perma.cc/SF6K-8B56] (last updated Mar. 16, 2026) (discussing strategy of increasing provider participation in and improving administration of value-based payment programs).

202. See 42 U.S.C. § 1395jjj (directing HHS Secretary to establish a shared savings program for ACOs under Original Medicare); 42 C.F.R. pt. 425. ACOs are "groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to the Medicare patients they serve." See generally *Accountable Care Organizations (ACOs): General Information*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/priorities/innovation/innovation-models/aco> (last visited May 30, 2025); see also 42 C.F.R. § 425.20.

203. See *Value-based contracts: Evaluating Medicare Advantage*, AM. MED. ASS'N 3 (2025), <https://www.ama-assn.org/system/files/2019-04/medicare-advantage-value-based-contracts.pdf> [https://perma.cc/NJ2E-55TT] ("Because MA plans are at risk for the full cost of Medicare-covered health expenses [under the capitated payment model], they have incentives to 'push down' or delegate this risk to providers.")

204. Not all value-based models have been successful. For example, CMS terminated Medicare Advantage's Value-Based Insurance Design (VBID) Model early due to its "substantial and unmitigable costs." See *Medicare Advantage Value-Based Insurance Design (VBID) Model*

Access, and Community Health (ACO REACH) model provides for team-based care and bundled payments for sets of services, which better supports the delivery of innovative interventions.²⁰⁵ While the ACO REACH model is currently slated to sunset at the end of 2026, CMS has continued to refine the model, suggesting an intention to renew it. Similarly, Medicaid MCO contracts can be designed to operationalize the inclusion of non-traditional providers via specially designed payment methodologies.²⁰⁶

While these alternative payment models provide a necessary component, ensuring inclusion of innovative services in these existing structures still requires system-wide alignment with legal infrastructure. The examples of successful integration discussed above demonstrate that alignment with coverage frameworks is possible, particularly when stakeholders collaborate to adapt benefit definitions, credentialing pathways, and payment models to support scalability while preserving program integrity.

IV. CONCLUSION

The transition from community-based intervention to complete health care coverage often overwhelms longstanding providers and community-based organizations that may be unprepared or insufficiently resourced to meet newly imposed legal requirements. Late-stage barriers can delay implementation, incur unnecessary expenses, and push out legacy providers who have long served marginalized populations. Given that most CBOs “have very little experience with many of the processes used in the health care industry,”²⁰⁷ stakeholders must ensure that these organizations are brought into compliance, not left behind.

While short-term funding mechanisms, such as pilot programs and demonstration projects, offer valuable early support, innovators should treat them as bridges to full coverage opportunities, rather than as long-term financing solutions. Reliance on time-limited financing can inhibit the scaling and sustainability of many promising interventions and prohibit these programs from achieving “cruising altitude.” Instead, these programs should be optimized from the outset to align with public and private coverage frameworks, laying the groundwork for long-term integration.

On the road to this long-term integration, many innovative services

to End After Calendar Year 2025, CMS.GOV BLOG (May 15, 2024), <https://www.cms.gov/newsroom/blog/medicare-advantage-value-based-insurance-design-vbid-model-end-after-calendar-year-2025-excess-costs> [<https://perma.cc/U95S-467C>].

205. *ACO Reach*, U.S. CNTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/priorities/innovation/innovation-models/aco-reach> (May 1, 2025) (this model is authorized under Medicare’s Shared Savings Program, see 42 C.F.R. § 425.10 et seq.); see Humphry & Kiernan, *supra* note 196, at 372 (describing benefits of team-based care and bundled payment models for inclusion of CHWs in clinical payment structures).

206. See Ruff & Fishman, *supra* note 159, at 8.

207. See, e.g., NAT’L ASS’N OF CHRONIC DISEASE DIR., *supra* note 197.

encounter recurring obstacles that stem from mismatches between service design and legal requirements. Understanding the main requirements of the three major insurance coverage opportunities in the United States is a crucial first step to ensuring the legal compatibility necessary for integration. If innovators and providers do not understand the legal frameworks that apply to their services from the outset, they may struggle to incorporate legal requirements into their program design and delivery down the road. If payers and regulators lack insight into how innovative services operate, they may miss opportunities to collaborate with providers and legacy organizations in adapting legal and regulatory frameworks to support coverage in ways that maintain safety, promote quality, and expand access.

Stakeholders have the opportunity—and responsibility—to proactively guard against the sudden onslaught of legal requirements. By familiarizing themselves with these requirements early on, implementers will be better positioned to navigate the recurring challenges and achieve sustainable, scalable integration. Moreover, these frameworks can guide stakeholders in aligning best practices, developing workable guidelines, and building the infrastructure necessary for and compatible with sustainable coverage. With thoughtful planning and collaboration, stakeholders can ensure that integration is not only achievable but also preserves best practices that support program integrity, quality of care, and other value-based goals.