A Pathway for High-Value Home Hospital Care in the United States

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Statutory, Reimbursement, and Cybersecurity Strategies in the Age of Hybrid Care

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I INTRODUCTION

Prior to the emergence of modern health insurance programs after World War I, house calls were standard practice for physicians in the United States.¹ The end of the twentieth century saw a resurgence of interest in health care at home, partly fueled by the expansion of home health services by Medicare.² By the 1990s, pilot hospital-at-home (H@H) programs demonstrated the potential to provide similar levels of inpatient care at home while decreasing costs.³

Although before 2020 most payers offered plans covering home health services for older adults, a population that experiences a disproportionate share of hospitalizations, only a handful of hospitals around the country offered H@H programs.⁴ Among those were world-renowned health systems, like Brigham and Women's Hospital and the Johns Hopkins Hospital, capable of securing pilot study funding to demonstrate the safety and effectiveness of their individual H@H models. In turn, these studies allowed the programs to receive reimbursement for H@H services from the Centers for Medicare & Medicaid Services (CMS), the federal entity responsible for setting health care service costs and coverage under the nation's

¹ Bruce Leff & John R. Burton, The Future History of Home Care and Physician House Calls in the United States, 56 J. Gerontology: Series A M603–08 (2001).

² Nelda McCall et al., Utilization of Home Health Services Before and After the Balanced Budget Act of 1997: What Were the Initial Effects?, 38 Health Serv. Rsch. 85–106 (2003).

³ Sasha Shepperd et al., Avoiding Hospital Admission Through Provision of Hospital Care at Home: A Systematic Review and Meta-analysis of Individual Patient Data, 180 Can. Med. Ass'n J. 175–82 (2009).

⁴ Alexander L. Janus & John Ermisch, Who Pays for Home Care? A Study of Nationally Representative Data on Disabled Older Americans, 15 BMC Health Servs. Rsch. (2015); Maureen Anthony, Hospitalat-Home, 39 Home Healthcare Now 127 (2021).

insurance program for adults ages 65 and older.⁵ Since 2005, the majority of H@H programs have demonstrated noninferior or superior outcomes to in-hospital care;⁶ however, the widescale implementation of H@H by community and regional hospitals remained elusive, chiefly due to a lack of coverage and guaranteed reimbursement under the Medicare fee-for-service (FFS) program.⁷ It is estimated that only a few thousand patients had received care through the limited number of H@H programs in the USA before 2020.⁸

According to the CMS's Conditions of Participation, Medicare-certified hospitals must staff nurses 24/7 and on-site to be eligible for the reimbursement of services provided to hospitalized patients. During the COVID-19 Public Health Emergency (PHE), the CMS solicited applications from hospitals to deliver inpatient-level care at home under its temporary Acute Hospital Care at Home (AHCaH) waiver, which lifts the on-premises requirement for nurses providing acute care.⁹ From its launch in November 2020 through October 2021, the waiver enabled H@H programs to care for 1,878 patients in thirty-three states.¹⁰ As of March 2023, the program has expanded to thirty-seven states at 123 health systems and 277 hospitals.¹¹ This waiver allowed hospitals to partner with software platforms and vendors to develop care pathways that blended in-person, telehealth, and remote patient monitoring (RPM) services and were adjusted to reflect the local and geographic constraints associated with a hospital's location.

Today, hospitals are negotiating with private payers to develop H@H models beyond the scope of the CMS's H@H definition, which exclusively focuses on acute care.¹² However, there are many concerns about the future viability of H@H

- ⁵ Alisa L. Niksch, Hospital at Home: Transformation of an Old Model with Digital Technology, in Leveraging Technology as a Response to the COVID-19 Pandemic, 1, 18 (Harry Pappasv and Paul Frisch eds., 2022).
- ⁶ Man Qing Leong et al., Comparison of Hospital-at-Home Models: A Systematic Review of Reviews, 11 BMJ Open (2021).
- ⁷ Linda V. DeCherrie et al., Hospital at Home services: An Inventory of Fee-for-service Payments to Inform Medicare Reimbursement, 69 J. Am. Geriatrics Soc'y 1982–92 (2021); Shikha Garg et al., Hospitalization Rates and Characteristics of Patients Hospitalized with Laboratory-Confirmed Coronavirus Disease 2019 – COVID-NET, 14 States, March 1–30, 2020, 69 MMWR Morbidity and Mortality Weekly Report, 458–64 (2020); Marilyn Moon, What Medicare Has Meantto Older Americans, 18 Health Care Financing Rev. 49–59 (1996); Sarah Klein et al., The Hospital at Home Model: Bringing Hospital-Level Care to the Patient, *Commonwealth Fund* (August 22, 2016), www.commonwealthfund .org/publications/case-study/2016/aug/hospital-home-model-bringing-hospital-level-care-patient.
- ⁸ Am. Hosp. Ass'n, Hospital at Home (2023), www.aha.org/hospitalathome.
- ⁹ Ctr. to Advance Palliative Care, Acute Hospital Care at Home Frequently Asked Questions, www.capc .org/documents/download/882/.
- ¹⁰ Douglas V. Clarke et al., Acute Hospital Care at Home: The CMS Waiver Experience, NEJM Catalyst Innovations in Care Delivery (December 7, 2021), https://catalyst.nejm.org/doi/full/10.1056/ CAT.21.0338.
- ¹¹ Eli Adashi et al., Hospital at Home Receives a New Lease on Life: A Promising if Uncertain Future, 136 Am. J. Med. 958–59 (2023).
- ¹² Pamela Pelizzari et al., Hospital At Home Is Not Just For Hospitals, Health Affs. Forefront (May 24, 2022), doi:10.1377/forefront.20220520.712735.

programs. Notably, the effectiveness of these models and their patient eligibility criteria are tied to the technology-enabled services they deliver, including telehealth and RPM.¹³ While numerous federal flexibilities for telehealth remain temporarily waived and all fifty states have expanded access to telehealth services, it is unclear which services will secure permanent reimbursement in the future. Though patient satisfaction with H@H and telehealth services remains uniquely high, questions about the long-term effectiveness of these pandemic-era initiatives in the context of value-based care, defined as care that improves patient health outcomes, remain.¹⁴

Based on our experiences at Mayo Clinic, we recommend that H@H care be integrated into the continuum of care, rather than delivered as a separate instance of care, after which patients are traditionally discharged to primary care. Beyond the AHCaH waiver, a flexible telehealth policy framework that allows providers to tailor care plans balancing patient need and convenience is vital to ensuring H@H programs yield high-value outcomes. This approach allows at-home patients recovering from an acute episode to receive post-acute care linked to improved patient outcomes, including rehabilitation, medication management, and patient education, via telehealth. Facilitating a gradual transition to primary care, the H@H model with subsequent hybrid services allows clinicians to monitor and intervene with timelier services during the post-acute period, thereby preventing adverse events and avoidable readmissions.

II HOW THE AHCAH WAIVER AND RELATED FLEXIBILITIES FACILITATED THE CONTINUUM OF CARE

Although the delivery of care at home had grown increasingly popular in the years before the pandemic, reimbursement uncertainty and low patient and provider willingness to use such services limited their adoption.¹⁵ Restrictive regulations, such as the CMS's explicit categorization of telephones as a non-eligible tool for telehealth, also limited patient options.¹⁶ Furthermore, while numerous studies found that RPM of real-time vital signs and symptoms could reduce costs and improve outcomes, its implementation was limited and complicated by the need to integrate device data with electronic health records.¹⁷ Recognizing the technical difficulties associated

¹³ Bruce Leff et al., A Research Agenda for Hospital at Home, 70 J. Am. Geriatric Soc'y 1060–69 (2022).

¹⁴ NEJM Catalyst, What Is Value-based Healthcare?, NEJM Catalyst: Innovations in Care Delivery (January 1, 2017), https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0558.

¹⁵ Asim Kichloo et al., Telemedicine, the Current COVID-19 Pandemic and the Future: A Narrative Review and Perspectives Moving Forward in the USA, 8 Fam. Med. & Cmty. Health, 3 (2020).

¹⁶ Ross D'Emanuele, Medicare Payment Rules Changed to Allow Broad Use of Remote Communications Technology, *JDSupra* (April 8, 2020), www.jdsupra.com/legalnews/medicare-payment-ruleschanged-to-allow-93032/.

¹⁷ Catherine Dinh-Le et al., Wearable Health Technology and Electronic Health Record Integration: Scoping Review and Future Directions, 7 JMIR Mhealth Uhealth 9 (2019), https://mhealth.jmir .org/2019/9/e12861.

Common acute phase conditions treated in H@H programs (Levine et al., 2020)	
Chronic kidney disease with volume overflow	Atrial fibrillation with rapid ventricular response
Urinary tract infection	Hypertension urgency
Pneumonia	Anticoagulation needs
Heart failure	Diabetes complications
Asthma	Gout flare
COPD	Cellulitis

TABLE 12.1 Frequent H@H program condition inclusion criteria

with delivering care remotely, the Secretary of Health and Human Services (HHS) temporarily waived Health Insurance Portability and Accountability Act (HIPAA) sanctions and penalties for the PHE, allowing providers to use any software available to offer telehealth services, including those delivered in H@H.¹⁸

With the 2020 establishment of the AHCaH waiver, a hospital could launch an H@H program with guaranteed reimbursement equal to traditional in-hospital payment for acute care services delivered at a patient's home, provided that 24/7 monitoring by nurses was completed using telehealth and RPM.¹⁹ To be eligible for enrolment in a hospital's H@H program under this waiver, patients first need to be admitted to a hospital and assessed by an on-site physician. The inclusion criteria for admission consider a range of chronic conditions presenting in an acute episode, that is, one that qualifies for inpatient-level care, to ensure a patient's status is sufficiently stable for at-home care (Table 12.1).²⁰

Additional personal mobility, environmental, and social screening measures are implemented on a site-by-site basis. After a carefully evaluated patient enrols in H@H, hospitals must provide twice daily in-person visits from a registered nurse or paramedic at the patient's home and deliver daily telehealth evaluations by a clinician.²¹ With the AHCaH waiver, all Medicaid and Medicare patients, as well as dually eligible beneficiaries, qualified for consideration of H@H care during the PHE.²²

¹⁹ Andis Robeznieks, Tech that Provides High-acuity Home Care Gets High-profile Boost, Am. Med. Ass'n (June 23, 2021), www.ama-assn.org/practice-management/digital/tech-provides-highacuity-home-care-gets-high-profile-boost.

- ²¹ Press Release, CMS, CMS Announces Comprehensive Strategy to Enhance Hospital Capacity Amid COVID-19 Surge (November 25, 2020), www.cms.gov/newsroom/press-releases/cms-announcescomprehensive-strategy-enhance-hospital-capacity-amid-covid-19-surge.
- ²² Clarke et al., supra note 10.

¹⁸ HHS Office for Civil Rights (OCR), Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency, US Dep't of Health and Hum. Servs. (2021), www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/ notification-enforcement-discretion-telehealth/index.html.

²⁰ David M. Levine et al., Hospital-Level Care at Home for Acutely Ill Adults: A Randomized Controlled Trial, 172 Annals Internal Med. 77–85 (2018).

Patients in the prehospitalized, restorative (postacute) or ambulatory phases of care are not eligible for H@H care reimbursed under the AHCaH waiver; however, H@H models negotiated for reimbursement with private payers, like Presbyterian Health's program under Medicare Advantage, are not restricted to acute care.²³ Likewise, some individual hospitals using the AHCaH waiver to cover H@H acute services have designed postacute models of care that combine hybrid services, like at-home rehabilitation therapy and telehealth medication management visits, for different insurance populations, subject to state regulations governing home health and telehealth services.²⁴

Before the pandemic, multiple regulatory barriers restricted access to telehealth services for Medicare beneficiaries at home. Among these were CMS requirements that patients reside in rural areas and be physically present at a designated site to receive telehealth services eligible for reimbursement. For the PHE, the CMS waived these requirements, allowed payment parity for telehealth, and expanded its list of services eligible for telehealth.²⁵ Policies regulating telehealth and H@H programs also vary by state, insurance coverage, and program. In some states, policies apply to both public and private payers delivering care to patients in-state, while in other states there are separate regulatory frameworks for telehealth delivered to public versus private beneficiaries.²⁶ During the pandemic, all fifty states and the District of Columbia introduced reforms to expand access to telehealth at home.²⁷ For instance, states introduced statutory flexibilities to incorporate a broader range of devices eligible for telehealth (Table 12.2). The nation's leading private payer plans also expanded telehealth access by offering payment parity or cost-sharing waivers.²⁸

Combined with the AHCaH waiver, these telehealth flexibilities freed clinical care teams to identify optimal software and monitoring devices to integrate into care pathways for H@H patients in the acute as well as postacute phases. The design of hybrid care models that deliver H@H as a part of the continuum of care, providing services beyond the scope of acute care, was guided by relevant state and federal telehealth and RPM flexibilities (Table 12.3).

²³ Klein et al., supra note 7.

²⁴ Nels Paulson et al., Why US Patients Declined Hospital-at-Home during the COVID-19 Public Health Emergency: An Exploratory Mixed Methods Study, 10 J. Patient Exp. 23743735231189354 (2023).

²⁵ Press Release, CMS, Trump Administration Makes Sweeping Regulatory Changes to Help US Healthcare System Address COVID-19 Patient Surge (March 30, 2020), www.cms.gov/newsroom/pressreleases/trump-administration-makes-sweeping-regulatory-changes-help-us-healthcare-systemaddress-covid-19.

²⁶ Ctr. for Connected Health Pol'y, An Analysis of Private Payer Telehealth Coverage During the COVID-19 Pandemic (2021), www.cchpca.org/2021/04/Private-Payer-Telehealth-Coverage-Reportfinal.pdf.

²⁷ US States and Territories Modifying Requirements for Telehealth in Response to COVID-19, Fed'n of State Med. Bds. (2022), www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirementsfor-telehealth-in-response-to-covid-19.pdf.

²⁸ Ctr. for Connected Health Pol'y, supra note 26.

Telehealth modality	Technology example
Asynchronous/Store-and-forward	Sharing patient images via a HIPAA-secure patient portal
Synchronous	Videoconference with provider and patient
Remote patient monitoring (RPM)	Wireless ECG streams patient data to provider
Autonomous	Smartphone app AI chatbot classifies patient symptoms for triage

 TABLE 12.2
 Example telehealth use cases

AI, artificial intelligence; ECG, electrocardiogram.

AHCaH waiver only (no state or federal telehealth flexibilities)	AHCaH waiver paired with state and federal telehealth flexibilities
Covers acute phase care	Covers acute phase care <u>and can include</u> pre-hospital, post-acute, and ambulatory care
Allows for the use of telehealth and remote monitoring services as necessary for acute phase management only	Allows for the use of telehealth and remote monitoring services before or after an acute episode of care
Daily in-person visits by nurses	Daily in-person visits by nurses
Daily physician evaluation by telehealth	Daily physician evaluation by telehealth
Daily vitals monitoring at multiple timepoints	Daily vitals monitoring at multiple timepoints
Delivery of point-of-care testing, mobile imaging, and IV therapies, as needed	Delivery of point-of-care testing, mobile imaging, and IV therapies, as needed
Skilled nursing services, as needed	Skilled nursing services, as needed

TABLE 12.3 Scope of current H@H models

III CHARACTERISTICS OF HIGH-VALUE H@H PROGRAMS THAT SPAN THE CARE CONTINUUM

The characteristics listed below emerged from evidence generated before and during the pandemic, corroborating our experiences at Mayo Clinic, and can be used to evaluate the design of value-based H@H and other hybrid care models as regulatory and reimbursement frameworks evolve.

A Increased Access to Care

H@H programs allow providers to scale hospital capacity beyond the facility walls and reserve inpatient beds for the most critical patients.²⁹ In areas with inpatient

²⁹ Shereef Elnahal et al., How US Health Systems Can Build Capacity to Handle Demand Surges, Harvard Bus. Rev. (October 4, 2021), https://hbr.org/2021/10/how-u-s-health-systems-can-buildcapacity-to-handle-demand-surges.

capacity shortages, driven particularly by patients waiting to be discharged to restorative care, H@H programs with hybrid postacute services can more efficiently transition patients to postacute services at home, ensuring that they receive timelier rehabilitative care.³⁰ These postacute hybrid services also can expand access to patients residing in rural locations by substituting in-person visits with telehealth and, thereby, reducing travel requirements for follow-up services.³¹ Integrating telehealth into H@H and postacute services also connects patients to specialists they might otherwise be unable to access in their local community hospital.³²

B Enhanced Quality of Care

Patient and family member satisfaction rates are often higher with H@H programs.³³ Moreover, patients in H@H are less sedentary compared to those treated in brickand-mortar hospitals, a finding associated with faster recovery times, and multiple H@H programs have demonstrated lower mortality rates compared to in-hospital care, partially attributed to the increased physical activity that naturally occurs at home.³⁴ Timelier and preventative care is also a potential benefit for H@H, as RPM technology evolves and can alert providers to early signs of patient health deterioration.³⁵

Notably, when H@H programs are offered with hybrid models of postacute or other transitional care, reduced readmission rates and improved patient outcomes are possible.³⁶ While limited data about H@H patient outcomes during the pandemic has been published, a single-site analysis found no difference in readmission rates for H@H or in-hospital patients. Although H@H patients experienced

- ³⁰ Emily Hanson, Why Many Hospitals Are Over Capacity Two Years into the Pandemic, KING5 (July 29, 2022), www.king5.com/article/sponsor-story/hospitals-over-capacity-pandemic-evergreenhealth/281-ad20857e-2017-4cee-b647-a351fd41fdb6; CMS, Medicare Telemedicine Health Care Provider Fact Sheet,(2020), www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-healthcare-provider-fact-sheet.
- ³¹ Bart M. Demaerschalk et al., Quality Frameworks for Virtual Care: Expert Panel Recommendations, 7 Mayo Clin. Proc. Innov. Qual. Outcomes. 31–44 (2022).

- ³³ Sarah Klein, "Hospital at Home" Programs Improve Outcomes, Lower Costs but Face Resistance from Providers and Payers, *Commonwealth Fund* (2019), www.commonwealthfund.org/publications/ newsletter-article/hospital-home-programs-improve-outcomes-lower-costs-face-resistance; Lesley Cryer et al., Costs for "Hospital at Home" Patients Were 19 Percent Lower, With Equal or Better Outcomes Compared to Similar Inpatients, 31 Health Affs. 1237–43 (2012); Klein et al., supra note 7.
- ³⁴ Klein et al., supra note 7; Levine et al., supra note 20.
- ³⁵ Jared Conley et al., Technology-enabled Hospital at Home: Innovation for Acute Care at Home, 3 NEJM Catalyst Innovations in Care Delivery, 3, 2022.
- ³⁶ Cecile Davis et al., Feasibility and Acute Care Utilization Outcomes of a Post-Acute Transitional Telemonitoring Program for Underserved Chronic Disease Patients, 21 Telemedicine and e-Health 705–13 (2015); Stephanie A Hicks & Verena R Cimarolli, The Effects of Telehealth Use for Post-acute Rehabilitation Patient Outcomes, 24 J. Telemedicine & Telecare 179–84 (2018).

³² Nat'l Advisory Comm. on Rural Health & Hum. Servs., *Telehealth in Rural America* (2015), www .hrsa.gov/sites/default/files/hrsa/advisory-committees/rural/publications/2015-telehealth.pdf.

shorter inpatient lengths of stay (LOS), they also experienced longer total LOS, suggesting that H@H care may reduce inpatient-level care costs but require longer recovery times, a percentage of which might be appropriately delivered by post-acute hybrid models focusing on telehealth and monitoring, a strategy employed by Mayo Clinic H@H.

C Reduced Costs

Reducing costs remains of interest as payers and health systems continue to shift from fee-for-service (FFS) to value-based care.³⁷ Evidence supporting H@H's potential to decrease costs without compromising care quality includes a randomized clinical trial that showed H@H patients required fewer laboratory orders and imaging studies.³⁸ Compared to traditional acute care, multiple H@H programs have shown the potential to decrease costs per patient by nineteen or more percent.³⁹ Reduced hospital lengths of stay, fewer readmissions, and decreased skilled nursing facility utilization are also associated with H@H programs.⁴⁰ The chief method of cost containment proffered by H@H with hybrid postacute services is the more comprehensive management of chronic diseases during the transition period from hospital to primary care.⁴¹

D Robust Understanding of Social Determinants of Health (SDoH)

H@H programs afford providers the chance to observe patients in their homes. Although a telehealth visit is limited by the lack of a hands-on physical examination, video telehealth is valuable in assisting with physical exams, especially when augmented by connected devices, such as a stethoscope to assess lung and heart sounds. Pairing in-home and virtual clinicians can help providers gain new insights into a patient's daily life, observing family interactions, domestic environments, and information about food and medication availability.⁴² Such information can help providers design more effective treatment plans tailored to a patient's unique circumstances, such as balancing patient need with convenience by substituting routine follow-up visits with telehealth and RPM for patients who cannot take time off work.⁴³

³⁷ Allison H. Oakes & Thomas R. Radomski, Reducing Low-Value Care and Improving Health Care Value, 325 JAMA 1715–16 (2021).

³⁸ Levine et al., supra note 20.

³⁹ Klein, supra note 33; Cryer et al., supra note 33.

⁴⁰ Alex D. Federman et al., Association of a Bundled Hospital-at-Home and 30-Day Postacute Transitional Care Program With Clinical Outcomes and Patient Experiences, 178 JAMA Internal Med., 1033–40 (2018).

⁴¹ Demaerschalk et al., supra note 31.

⁴² Nicole Warda & Shannon M. Rotolo, Virtual Medication Tours with a Pharmacist as Part of a Cystic Fibrosis Telehealth Visit, 61 J. Am. Pharmacists Ass'n e119–25 (2021).

⁴³ Demaerschalk et al., supra note 31.

IV HOW POLICYMAKERS CAN REMOVE BARRIERS TO HIGH-VALUE H@H PROGRAMS

While the reforms related to H@H, telehealth, and RPM created a regulatory climate that encouraged innovation in hybrid model design, they were implemented temporarily. In May 2023, the federal PHE expired. By June 2023, no state-level PHEs were in effect. While some reforms have been made permanent, the future of H@H, and hybrid care in general, remains uncertain. Yet hundreds of millions of dollars in private capital has been raised to support H@H platforms.⁴⁴ Based on our experiences, we encourage policymakers to remove barriers to developing high-value H@H care by considering the points below.

A Reimbursement and Payment Model Uncertainty

Current reimbursement uncertainty primarily affects publicly insured beneficiaries, many of whom are from marginalized populations, as patients covered by private insurance and managed care programs can receive telehealth, RPM, and H@H services that are negotiated between providers and payers and only subject to state regulations. Regarding the AHCaH waiver, which increases access to care for Medicare and Medicaid beneficiaries, Congress permitted the CMS to extend the waiver, guaranteeing payment parity for inpatient-level care provided at home with 24/7 remote clinical oversight through December 2024.45 Congress also instructed HHS to publish a study on the outcomes and costs associated with AHCaH programs before the waiver's expiration date to evaluate the program's sustainability. While making this waiver permanent would remove one barrier to accessing H@H programs, individual state hospital licensure laws may restrict hospital participation for eligible patients residing in-state.⁴⁶ To determine what role H@H programs should play in terms of care for publicly insured patients, federal and state policymakers should consider the findings of the HHS report to determine appropriate inclusion criteria for H@H programs and patients moving forward.

Equally important to the development of high-value H@H programs, as well as postacute hybrid care models, is the temporary CMS waiver listing a patient's home as an eligible site for telehealth. During the pandemic, patients who transitioned from acute to postacute status during H@H care benefitted from continued access to covered telehealth services when their eligibility for H@H ended. As such, state and federal policymakers should make permanent or expand coverage for telehealth

⁴⁴ Kushal T. Kadakia et al., Omnibus Spending Bill and Hospital-At-Home: A Roadmap to Ensure Enduring Change, *Health Affs. Forefront* (January 25, 2023), doi:10.1377/forefront.20230123.822679.

⁴⁵ Eileen Appelbaum & Rosemary Batt, The New Hospital at Home Movement: Opportunity or Threat for Patient Care?, *Ctr. for Econ. & Pol'y Rsch.* (January 24, 2023), www.cepr.net/wp-content/ uploads/2023/01/new-hospital-at-home-movement.pdf.

⁴⁶ Ctr. to Advance Palliative Care, supra note 9.

services associated with postacute care that have demonstrated improved patient outcomes, enabling clinicians to identify which services are most appropriate for their patient populations. Expanding access to these services can help H@H patients complete routine medication management and therapy, leading to better outcomes and fewer readmissions.

B Access to Digital Health Tools

Recent findings from the pandemic suggest that patients of all ages who are less comfortable with technology prefer using smartphones over personal computers to connect with health providers;⁴⁷ however, 29 percent of US adults aged over 65 do not have a smartphone, and patients with a lower socioeconomic status are also less likely to own a smartphone.⁴⁸ Thus, although Medicare permanently updated its definition of telehealth-eligible devices to include smartphones, barriers to telehealth services delivered as part of H@H and hybrid care models still remain.

No uniform definition for telehealth or RPM exists across states. Some states narrowly define the types of technologies eligible for use in telehealth visits or limit RPM to patients with specific diagnoses. Restricting telehealth to specific device requirements and deploying H@H programs with limited flexibility in terms of device options can potentially exacerbate health disparities for underserved populations. For example, Alaska's Medicaid program only reimburses for self-monitoring RPM services at home, a limitation potentially restricting eligible devices to those that have a patient interface and thereby excluding patients with visual disabilities or limited English proficiency.⁴⁹ These statutory definitions complicate the design of H@H and other hybrid care models by restricting telehealth and RPM offerings covered by different payers to specific devices.

After considering the findings published by the HHS report on the AHCaH waiver, policymakers should ensure their hospital licensure laws and statutory definitions accommodate the 24/7 virtual presence made possible by clinically validated emerging technologies. Since the rate of technological development outpaces the regulatory review and rulemaking process, policymakers should aim to enhance flexibility for patients and providers by taking a technology-neutral approach to defining eligible telehealth devices. Such an approach is inclusive of the digital comfort level and device availability of underserved patients by allowing providers to select software and devices able to be used by their populations, which vary by geographic location and socioeconomic status.

⁴⁷ Jen Lau et al., Staying Connected in The COVID-19 Pandemic: Telehealth at the Largest Safety-Net System in the United States, 39 Health Affs. (Project Hope) 1437–42 (2020).

⁴⁸ Mobile Fact Sheet, Pew Rsch. Ctr. (April 7, 2021), www.pewresearch.org/internet/fact-sheet/mobile/.

⁴⁹ 7 Alaska Admin. Code tit. 7 § 110.625(a)(3).

C Emerging Cybersecurity Issues

While permitting a patient's home to be an eligible site for telehealth is critical to high-value care in the digital age, deploying a H@H or hybrid care program is a resource-intensive endeavor for hospital IT departments. Both IT and clinical personnel require training in new systems and workflows; patients and family caregivers also need orientation to learn their roles in receiving care at home. Hospital IT systems must integrate security and privacy protocols for data aggregated, transmitted, and stored by RPM devices, mobile lab and imaging systems, video telehealth visits, text-based communication, and ancillary services. While HIPAA outlines privacy regulations for provider compliance, individual hospital cybersecurity protocols vary.⁵⁰

As the HIPAA waiver, which expired at the end of the PHE, enabled providers to select platforms to deliver remote care that were not HIPAA-compliant, some providers are now transitioning to HIPAA-compliant software and RPM devices. Simultaneously, the Food and Drug Administration (FDA) offered a temporary expedited review process for digital health apps, software, and RPM devices.⁵¹ Together, these regulatory flexibilities created a perfect storm for the adoption of insecure software products and human error related to mishandling data in remote care delivery.

Cybersecurity for clinical services enabled by RPM and telehealth software is an evolving research and operations area. As institutional cybersecurity policies are confidential, a robust analysis of the set of cybersecurity strategies employed by providers remains elusive. The lack of clarity surrounding telehealth and RPM cybersecurity affects its long-term sustainability. For instance, many patients express a reluctance to participate in remote care due to privacy and security concerns regarding third-party telehealth platforms and RPM devices, rather than about hospitals directly. Patients of low socioeconomic status, like those who lack tech savviness and English fluency, are most at risk from cyber-related exploitation via the most accessible (free or inexpensive) telehealth options. This is because low-barrier applications are the least likely to offer comprehensive data privacy and security policies, disproportionately putting underserved patients most at risk of a data breach.⁵² Moreover, cybersecurity standards specific to telehealth, both in H@H and hybrid care models, are yet to be determined. A 2021 study in the British Medical Journal assessing digital health app privacy policies and risks found that no consistent privacy practices exist in digital health software design. Also, the privacy policies of

⁵⁰ Leff et al., supra note 13.

⁵¹ US Food and Drug Admin., Digital Health Policies and Public Health Solutions for COVID-19 (April 28, 2022), www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/digitalhealth-policies-and-public-health-solutions-covid-19.

⁵² Nicole Martinez-Martin et al., Ethics of Digital Mental Health During COVID-19: Crisis and Opportunities, JMIR Mental Health e23776 (2020).

many leading telehealth platforms, which may be used in home hospital models, are unclear about which associated services access what patient data.⁵³

Current best practices in H@H and hybrid care cybersecurity include infrastructure audit checks and risk assessments during at-home visits. To mitigate emerging cybersecurity issues, institutional policymakers should identify concerns across administrative, physical, and technical domains for their H@H program. The expiration of the HIPAA waiver is critical to advancing a cybersecurity-conscious healthcare data ecosystem. As some reforms are made permanent post PHE, HHS should offer clarity regarding data privacy expectations and gold-standard cybersecurity guidelines for telehealth and hybrid care models like H@H, considering lessons learned during the PHE. Such an approach can assuage patient anxieties and help small-group providers, who face a shortage of skilled IT personnel, transition to HIPAA-compliant hybrid care models.

V CONCLUSION

The CMS's AHCaH waiver, combined with state and federal telehealth and RPM regulatory flexibilities, unleashed innovation in hybrid care models that can improve patient outcomes and decrease costs. To chart a path forward for H@H programs, state and federal policymakers should immediately address statutory and reimbursement issues as top priority issues, developing a framework flexible enough to deliver care during an acute episode at a distance that can help patients transition safely to outpatient status with telehealth and RPM. However, it will also be important for policymakers and those implementing H@H models to ensure a cybersecurity-conscious infrastructure. High-value home hospital programs can increase access to care, reduce costs, and enhance the quality of care, helping clinicians deliver more personalized care through a new understanding of SDoH. To overcome barriers to high-value home hospital care, we encourage government and institutional policymakers to better align statutory and reimbursement policies with updated cybersecurity guidance, facilitating the design of high-value H@H models that span the care continuum.

⁵³ Kirsten Ostherr, Telehealth Overpromises During the Covid-19 Pandemic, STAT (March 19, 2020), www.statnews.com/2020/03/19/telehealth-overpromises-during-the-covid-19-pandemic/.