NATIONAL ACADEMY OF MEDICINE

EXPERT PANEL OVERVIEW OF POST-PANDEMIC PATHWAYS FOR HOSPITAL-AT-HOME MODELS

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Overview

Hospital-at-Home (HaH) is a care delivery model in which the entirety of an inpatient acute episode is substituted for hospital-level, at-home treatment. During the pandemic, the Centers for Medicare & Medicaid Services (CMS) created the Acute Hospital Care at Home (AHCaH) program to provide hospitals across the country with regulatory flexibility to establish HaH programs to increase acute capacity for COVID-19 patients. Beyond the exigency of the public health emergency, HaH also represents an opportunity to transform acute care in America, with evidence generated from pre-pandemic programs illustrating the model's potential to improve outcomes and reduce costs. However, realizing the benefits of HaH at scale will require consideration and mitigation of potential issues including equity, payment, quality, and safety.

The National Academy of Medicine (NAM) has organized a number of multi-stakeholder convenings throughout the pandemic to identify opportunities for enhancing health system resiliency in response to the public health emergency. In this vein, the NAM in March 2022 convened an Expert Meeting to support post-pandemic planning for HaH, with a specific focus on issues related to model design, payment reform, and legal and regulatory risk. Based on the discussion, which is summarized in the accompanying report, meeting attendees offered the following policy priorities for CMS's consideration:

1. Model Design: CMS should use alternative payment models and total cost of care models as the chassis upon which health systems build and operate HaH programs.
2. Payment Reform: CMS should take a multi-payer approach to designing HaH reimbursement and explore policies such as social risk adjustment or upfront payments to advance equity for acute care.
3. Legal and Regulatory Risk: CMS should request that the Office of General Counsel issue guidance on key legal and regulatory issues for HaH, including around liability, data security, workforce, and anti-kickback proceedings.

CMS's forward-looking leadership throughout the public health emergency has supported the development of several policies and programs with the potential to advance health system transformation beyond COVID-19. HaH may prove to be one such area, and the incorporation of multi-stakeholder perspectives will be crucial to support further development of the model. As post-pandemic policy planning begins, the NAM looks forward to supporting the agency's work to advance health and equity for all.

Meeting Context

Hospital-at-Home is a framework for acute care delivery in which a portion or the entirety of an inpatient acute care episode is substituted for hospital-level, at-home treatment. Increased demand for acute care from aging populations coupled with regulatory tailwinds from the COVID-19 pandemic have heightened interest in HaH models. Converting the home environment into a site of care represents an opportunity to improve the patient experience and outcomes and reduce health care expenditures. However, migrating the locus of acute care delivery from the hospital to the home is not without operational complexity and challenges due to mitigating risks associated with care quality, safety, and liability. The Centers for Medicare & Medicaid Services acknowledged these challenges when designing its COVID-19 waiver for HaH, and sought to collaborate with stakeholders across the health system to address key concerns for program design. Coalitions such as the Hospital-at-Home Users Group have also formed to share resources and best practices for HaH, highlighting the value of multi-stakeholder convenings to inform policy and practice for health system transformation.

The NAM, which is charted by Congress to serve as an independent, evidence-based scientific advisor committed to catalyzing action and achieving impact, has convened a number of multi-stakeholder meetings throughout the public health emergency to support policymakers in post-pandemic planning for health system reform. These activities include the Leadership Consortium's discussion paper series on *Emerging Stronger After COVID-19: Priorities for Health System Transformation* and the Expert Panel on *Priorities in Advancing High Quality Value-Based Health & Health Care* for the CMS Innovation Center. In July 2021, the NAM organized a virtual planning meeting to highlight key issues relevant to HaH program dissemination from the vantage point of patients, care delivery organizations, caregivers, technology vendors, health equity, care quality, legal concerns, and payment frameworks. The NAM also published an article in *NEJM Catalyst* to highlight key regulatory questions for HaH, particularly around data, payment, and equity.

As regulators begin planning for the end of the public health emergency, stakeholders have requested guidance from CMS about the future of HaH beyond COVID-19. Recent publications have also highlighted the challenges associated with HaH implementation during COVID-19, with issues ranging from securing provider buy-in to clinicians' concerns around liability. To support CMS with post-pandemic planning for HaH, the NAM in March 2022 convened an Expert Meeting to evaluate potential policy pathways for AHCaH, with a specific focus on model design, payment reform, and legal considerations. This document seeks to summarize the key points from the meeting and offer a series of policy prescriptions for CMS from leading experts.

Delivery Reform Context for Hospital-at-Home

Evidence for HaH dates back nearly fifty years to pilot programs in the United Kingdom. To date, HaH programs have been implemented at scale by international health systems and piloted by leading American hospitals, including those that were part of a CMS Innovation Center grant. Research suggests that acute care delivered under HaH models is associated with comparable or improved care quality and equivalent or reduced health care spending and readmission rates.

Nevertheless, the diffusion of HaH models in the United States (U.S.) was limited prior to 2020 due to regulatory barriers and reimbursement gaps.

However, several intersecting trends have renewed interest among stakeholders across the health system in HaH. First, America's population is rapidly aging as the baby boomer generation approaches 65 years of age. The expanding elderly population and the increasing complexity of the chronic disease burden among older adults is anticipated to substantially increase demand for acute care. Indeed, older adults account for a substantial portion of inpatient days in U.S. hospitals. However, the number of hospital beds available to provide such care is steadily declining, creating a potential mismatch between supply and demand for acute care services, and generating interest in substitute but effective sites of care .

Second, with the COVID-19 pandemic imposing significant stress on America's hospitals, policymakers launched the "Hospital Without Walls" program to provide health systems with regulatory flexibility to generate additional acute care capacity. A notable expansion of this initiative was the November 2020 Acute Hospital Care at Home (AHCaH) waiver, through which Medicare reimbursed certified health systems for providing patients with hospital-level care at home. Over 200 hospitals representing nearly 100 health systems across more than 30 states have been approved under the AHCaH program as of spring 2022.

Third, these regulatory tailwinds have spurred follow-on interest and investments in HaH for post-pandemic applications. Several prominent health systems and national payers have signaled a long-term commitment to HaH, and HaH-focused start-up companies have raised substantial private capital to scale these care models. While programs operating under AHCaH waivers are limited to the duration of the public health emergency, a bipartisan group of lawmakers in March 2022 introduced the Hospital Inpatient Services Modernization Act to extend the program beyond the pandemic.

These policy and programmatic developments for HaH come amidst a significant shift in the government's approach to health care organization and financing. Over the past decade, CMS has leveraged authorities granted under the Affordable Care Act to implement a number of payment and delivery reforms to rein in rising national health expenditures. While some demonstration models have successfully been certified by the CMS Actuary for permanent expansion, the majority have not generated savings. Furthermore, the proliferation of demonstration models with substantial variation in design created operational challenges for providers delivering care under potentially conflicting incentive structures and for regulators seeking to evaluate the effectiveness of payment reforms relative to each other and traditional fee-for-service (FFS). Consequently, in 2021, the CMS Strategic Innovation Center announced a strategic refresh, with key provisions including an effort to consolidate models and a goal of transitioning all Medicare and most Medicaid beneficiaries to accountable care arrangements by 2030. This pivot in turn has implications for the future of HaH, which under the AHCaH waiver is currently reimbursed under Medicare FFS, but may need to be incorporated into broader value-based payment initiatives to align with the agency's strategic goals and become a sustainable service line for health systems.

Given these ongoing developments for HaH and payment and delivery reforms broadly in the U.S., the Expert Meeting considered (1) how to approach model design for HaH, (2) what an appropriate

financing structure for HaH could be, and (3) what the key legal considerations are for operating and regulating HaH programs.

Model Design Considerations for HaH

The key question facing policymakers and health system leaders is how to transition current HaH programs operating under the AHCaH waiver into a plan for future payment, care delivery, regulation, and evaluation. Although a route exists for Medicare Advantage (MA), Medicaid, and commercial payers, no mechanism currently exists for traditional Medicare beyond the waiver. Consequently, HaH services would be unavailable to the millions of beneficiaries enrolled in traditional Medicare. Furthermore, because Medicare's policies serve as a bellwether for health plans across the country, the absence of a national approach could impede uptake of HaH efforts by other payers.

An initial option would be to revive a 2017 proposal to the Physician Focused Payment Model Technical Advisory Committee (PTAC) to establish a Medicare demonstration model for HaH. However, a standalone demonstration for HaH may no longer be ideal given the agency's stated goal of developing a portfolio of models and avoiding conflicting interactions between different alternative payment models (APMs). This is especially salient with regards to HaH, as prevailing value-based payment models such as Accountable Care Organizations (ACOs) also have financial incentives for managing acute care delivery. Notably, although a Medicare Fee-For-Service (FFS)-focused plan for payment is needed , a stand-alone Medicare FFS program would not be best suited to organizing activities for a delivery model with multi-payer implications.

Given these challenges, an alternative approach would be for CMS to execute a phased transition from the AHCaH waiver—which is currently reimbursed under Medicare FFS—into existing APMs and total cost of care (TCOC) models. These models may include, but are not limited to, ACO tracks within the Medicare Shared Savings Program, global capitation, and direct contracting via CMS's new ACO REACH model. It is critical that Medicare's strategy provide flexibility with regards to APM design as health systems develop HaH programs, as there is a need for sufficient critical mass across the Medicare and Medicaid programs, to justify the infrastructure investments necessary to sustain safe and efficient programs. To support programs that are currently operating under the AHCaH, regulators could consider allowing for some form of transitional FFS payment while plans are developed for converting payments into APMs or TCOC models.

An APM-first approach to HaH model design would offer several benefits. First, it would align with CMS's proposed strategy of migrating all Medicare beneficiaries into accountable care relationships. Second, this approach would have the added benefit of establishing HaH as a standard model of care available to all beneficiaries, as clinically appropriate, within those payment arrangements. Third, care delivery organizations would have greater flexibility with regards to the design and operations of HaH (e.g., triggers, required number of visits, and encompassed services) and be better positioned to approach acute care delivery from a population health perspective. Fourth, APMs and TCOC models can be used as a chassis for supporting more comprehensive home-based care models, from home-based primary care (e.g., CMS's Independence at Home demonstration) to rehabilitation at home (in lieu of skilled nursing facility care), which was recently piloted in a randomized controlled trial.

Future expansion of HaH via APMs does require several key considerations. First, although the services rendered under HaH are still hospital-level treatment, the shift in site-of-care begs the question of whether payments for HaH should be classified under Part A or Part B, given that this care is no longer delivered within the inpatient setting. This decision has significant weight for the Medicare program given looming insolvency forecasts for the Hospital Trust Fund. How payments are categorized also has implications for APMs such as ACOs, as benchmarking for these models is inclusive of total costs for beneficiaries incurred under Parts A and B.

Second, the incorporation of HaH into APMs should leave room for flexibility given variation in the capabilities of different providers according to the geographies in which they operate and the types of patients which they serve. Regulators could consider applying the "tracks" used within previous APM models such as the Medicare Shared Savings Program to accommodate the varying speeds at which health systems may develop HaH capabilities and build up patient volumes. These tracks or graduated approach could also be leveraged as a framework for identifying and addressing the specific needs of participating health systems.

Third, a multi-payer approach to APM design for HaH is needed to ensure the long-term sustainability of the delivery model and to encourage parallel uptake among commercial payers. Reimbursement under traditional Medicare FFS may not be sufficient to sustain volume growth for HaH, particularly given that the majority of elderly Americans are expected to be enrolled in MA by 2030. Consequently, regulators will need to ensure model design for HaH is aligned across payers.

Fourth, a quality measurement system that reflects care processes (e.g., caregiver training) and structural requirements (e.g., home safety assessments, data infrastructure), in addition to outcome measures, will be imperative for optimizing patient care and experience. Consequently, payers and providers will need to first and foremost establish standard guardrails for HaH quality and safety. During the public health emergency, payers and providers have benefited from CMS guidance and safety requirements under the AHCaH waiver and technical resources developed by the HaH Users Group to define the different use cases for HaH. As policymakers look beyond the pandemic, continuing to promote alignment with the CMS Hospital Conditions of Participation and codify best practices for HaH (e.g., around patient eligibility, on safety protocols) will be critical.

Expert Meeting Policy Priority: CMS should use alternative payment models and total cost of care models as the chassis upon which health systems build and operate HaH programs.

Payment Considerations for HaH

The current landscape of acute care is characterized by the same inequities which afflict the American health care system writ large, with worse access, quality, and outcomes for people of color and of low socioeconomic status. Consequently, as part of its multi-payer approach to HaH reimbursement, CMS will need to consider how payment can be a lever for advancing health equity and improving care quality.

With regards to equity, HaH offers both significant opportunities to increase access and improve outcomes as well as risks for exacerbating existing gaps in care delivery. Optimizing the model requires prospectively defining its limitations, including situations when an inpatient admission would be preferable to HaH (e.g., for patients with substance use disorder or unstable housing). Additionally, all HaH models are by definition geographically constrained, as they must operate in close enough proximity to brick-and-mortar hospitals to ensure a timely response in the event that escalation of care is required. This in turn can limit the pool of patients within a community who are eligible for enrollment in HaH. Lastly, providers and payers will need to ensure patient trust in the model's safety and effectiveness, and always preserve patients' choice with respect to the care model that aligns with their preferences and values.

Moving forward, payers can help to advance the equity imperative for HaH through the design of reimbursement policies. For one, deploying HaH through APMs would align incentives across all stages of the patient's care journey. Rather than treating the acute care episode in isolation, a population-based payment model would incentivize clinicians take a holistic approach to patient care at home and provide care teams with the flexibility to devote resources towards health-related social needs. However, different patients may require different degrees of support, and it is imperative that reimbursement within APMs appropriately accounts for both clinical and social risk. This is especially key in the context of HaH, as converting a patient's home into a care setting may require different levels of health system investment depending on the specific environment. For example, as HaH models become increasingly tech-enabled, model vendors and operators will need to consider relative costs for key elements (e.g., broadband, utilities) and work with payers to determine appropriate reimbursement. Incorporating methodologies for social risk adjustment, such as those outlined in the NAM's report on *Accounting for Social Risk in Medicare Payment*, will be a key pillar for equity in HaH. In addition to patient-facing considerations, the equity impacts of payment reform also carry provider-facing considerations. The ability of HaH to reach underserved populations will depend in part on whether providers accountable for these patients have the resources and capabilities to operate HaH models, especially considering the high start-up costs and the low patient volumes during the initial ramp-up period. Payers could consider policies to defray the costs of upfront investment to ensure that HaH becomes a feasible acute care option for the highest risk patients. A key area for investment will likely be workforce development, from non-physician providers such as paramedics, to personnel such as community health workers that are dedicated to outreach and support.

Lastly, as noted in the previous section on model design considerations, it is imperative that payment policies for HaH are developed using a multi-payer lens, and incorporate nuances related to different populations. For example, Medicaid—which in several states such as Massachusetts has provided coverage for HaH during the public health emergency—may present unique opportunities to develop wraparound models that integrate home care and social services. Likewise, the supplemental benefits offer by MA plans may represent avenues for providers and payers to help contextualize the home delivery of acute care services to patient needs. A multi-payer strategy to payment reform will therefore help to improve the model's accessibility and create new opportunities for health system transformation.

Expert Meeting Policy Priority: CMS should take a multi-payer approach to designing HaH reimbursement and explore policies such as social risk adjustment or upfront payments to advance equity for acute care.

Legal and Regulatory Considerations for HaH

Hospital medicine in the U.S. is highly regulated with regards to issues ranging from standard of care, professional liability, and data security and patient privacy. As a delivery model focused on hospital-level care and adherent to the core quality and safety requirements of CMS's Hospital Conditions of Participation, HaH programs will also need to address legal risks related to these issues. To date, HaH models have not reported any significant legal concerns or issues related to malpractice. However, as models disseminate and patient volumes increase, precautionary governance and proactive mitigation of traditional and potentially novel legal risks—which have been voiced by clinicians and outlined in the academic literature—will be critical to avoiding unforeseen consequences.

First, hospitals will need to consider how provider liability may differ when hospital-level care is provided outside of a traditional hospital. HaH introduces nuances for both standard (e.g., distribution of liability across vendors) and new (e.g., extreme weather events interfering with care at home) questions in health law. Second, HaH raises questions about legal considerations for caregiver responsibilities, from whether the caregiver has any contractual obligations related to services rendered in the home, to questions about how data collected about caregivers as part of a home assessment should be stored and handled. Third, caring for patients within their home may alert providers to other issues unrelated to the patient's care, raising questions about the scope of provider obligations to report or act in response to these situations (e.g., awareness of elder abuse or infant neglect). Fourth, actions taken by HaH providers to convert the home into a care environment (e.g., from physical changes to the built environment to the short-term provision of services such as data plans or meals) could be considered inducements for patients to participate in HaH in lieu of an inpatient admission. Given that beneficiary inducements are prohibited under federal law, health systems and vendors may benefit from clarification from the Office of the Inspector General as to how service provision under HaH would be considered under the federal anti-kickback statute.

To date, health systems have sought to address legal risks for HaH through proactive identification of issues and mitigation via program design. It is also worth noting that many of these questions may be applicable to existing home health programs without eliciting substantial concerns in the status quo. Nevertheless, a clear legal framework would be beneficial to support new programs as HaH continues to disseminate in health systems across the country. Efforts to promote national consistency—especially with regards to workforce regulation and provider liability—would be especially helpful for payers and clinicians, as the set-up of HaH programs may currently vary due to differences in state regulations. For example, in New York state, providers must be certified as home health agencies in order to receive reimbursement for providing home health services. However, not all hospitals may necessarily have this certification, requiring systems to either use third-party vendors or procure an additional certification from the state, which represents added regulatory and financial costs. Likewise, many HaH programs are increasingly using allied health professionals such as paramedics and pharmacists and as part of their workforce model. However,

scope of practice for these health care workers varies on a state-by-state basis, imposing constraints on health systems or vendors operating in multiple regions. These issues point to the value of legal guidance from federal regulators and collaboration with quality stewards and convening organizations (e.g., the National Governors Association) to promote regulatory consistency for HaH models.

Expert Meeting Policy Priority: CMS should request that the Office of General Counsel issue guidance on key legal and regulatory issues for HaH, including around liability, data security, workforce, and anti-kickback proceedings.

Conclusion

The expansion of HaH models during the public health emergency both helped to fill an immediate need for hospital capacity under COVID-19 and created a new opportunity for transforming acute care delivery in the U.S. Realizing the promise of HaH will require a coordinated policy strategy informed by multi-stakeholder perspectives. This synthesis from an expert meeting of the NAM aims to support CMS's ongoing work related to HaH and highlights key considerations for the agency with regards to model design, payment reform, and legal and regulatory risk. By promoting synergies between HaH and the value-based care movement, policymakers can use the current moment to create a foundation future health system transformation.

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