3 Emerging Legal Risks For Hospital-At-Home Programs

By Devin Cohen and Brett Friedman · Listen to article

https://www.law360.com/articles/1580500/3-emerging-legal-risks-for-hospital-at-home-programs

Law360 (March 1, 2023, 6:40 PM EST) --

Devin Cohen

Brett Friedman

Recent news articles have highlighted the massive proliferation of so-called hospital-at-home models that deliver an inpatient level of care in a patient's home.[1]

While these variations of hospital-like home care programs have existed for some time, the expansion of this care model is directly in response to nationwide shortages and shutdowns amid the emerging stages of COVID-19.

These needs resulted in the Centers for Medicare & Medicaid Services of the U.S. Department of Health and Human Services launching the Acute Hospital Care at Home Program in December, which functioned as a federal waiver program designed to address the realities of ongoing critical care needs for homebound and isolating populations.[2]

CMS' adoption of reimbursement methodologies for over 60 acute conditions treated at home echoed substantial industry adoption of, and investment in, hospital-at-home models, with over 260 hospitals participating in the program as of Jan. 31.[3]

Emphasizing the program's success to date, President Joe Biden signed legislation into law on the last days of 2022 providing more than $1.7 trillion in federal funds to address services initiated during the federal public health emergency.[4]

Given this massive expansion of the model, and the promise that hospital-at-home models might be a fundamental shift in the way that inpatient facilities deliver services to patients needing an acute level of care, this article examines the top three legal risks and considerations for long-term adoption of these programs.

Legal Framework for the Hospital-at-Home Model

The hospital-at-home model relies on an underlying hospital or health systems licensed as an acute hospital, subject to existing Medicare conditions of participation, to accept responsibility for program delivery and on-site hospital escalation as necessary.

At the same time, it embraces flexibilities needed to account for the difference between in-home and institutionalized care, e.g., waiver of the two-midnight rule, flexibility required for place-of-service reporting, etc., in order for care teams to deliver analogous intensity of clinical oversight and intervention as inpatient standards demand.[5]

As hospital reimbursement eligibility is extended to a patient's living room, stakeholders continue to struggle with structuring programs consistent with evolving federal and state regulatory expectations and commercial standards, especially with the rapidly approaching end to the public health emergency.

Successful hospital-at-home operators, investors and partners are focusing, however, on three major emerging regulatory considerations in the space.

Top Three Emerging Legal Risks

1. Do interested hospitals maintain requisite licenses for in-home care?

CMS' hospital-at-home program requires that products or services delivered in the home are billed under a licensed acute care hospital participating in Medicare.

While the extension of, or addition of a new site to, a hospital's license was not itself necessarily groundbreaking — consider, for instance, provider-based services and billing — a hospital-at-home program is subject to overlapping, but not necessarily consistent, state-level requirements.

Some states, such as Arizona,[6] largely track federal licensure requirements, and others are silent all together on what categories of licensed entities may render services in the home — or alternatively, closely regulate categories of in-home paraprofessionals by broadly defined home health agency licensure.[7]

For example, New York state severely limits the types of entities that may deliver skilled nursing services or home care services to those licensed under Article 36 of the Public Health Law, which has resulted in that state requiring hospital-at-home programs to partner with a qualifying and appropriately licensed home care agency.[8]

Prior to participating in or expanding into hospital-at-home models, providers should closely review state-specific licensure requirements to deploy hospital-based nursing, or other skilled or unskilled members of the workforce, into the home to determine what additional licensure, if any, a sponsoring hospital or its clinicians may require as a condition of care delivery.

Additionally, depending on the delivery model required by a particular state, it may necessitate different models of reimbursement consistent with Medicare, Medicare Advantage, Medicaid and commercial billing standards.

Amid these state law considerations, existing hospital-at-home programs reimbursed by CMS are accounting for the planned end of the public health emergency on May 11.[9]

In parallel with advocacy efforts to formally extend CMS waiver policies by the American Hospital Association and other stakeholders,[10] and pursuant to CMS instructions, Medicare-reimbursed hospitals are rapidly developing waiver requests to conditions of participation expressly limiting hospital-at-home reimbursement, including standards requiring nursing services be provided 24/7 and the immediate availability of a registered nurse to any patient.[11]

2. Does the reimbursement model of a hospital-at-home program sufficiently balance traditional diagnosis-related group reimbursement payment with emerging value-based care trends?

Participating hospitals are traditionally reimbursed by diagnosis-related groups under Medicare Part A for inpatient services.

While diagnosis-related group-based reimbursement, e.g., a set fee at discharge, provides predictability and administrative simplification, state and commercial models have relied on value-based care in emerging hospital-at-home programs to better tie the continuum of hospital-based services — including inpatient, pharmacy, rehabilitation and recovery services — to quality and cost levers.[12]

Hospital-at-home models face limitations on billing and claims practices for both diagnosis-related groups and value-based purchasing programs. In particular, it is still to be determined whether claims for care delivery products and services, which became particularly prominent amid the COVID-19 public health emergency due to federal waivers and flexibilities, such as telehealth and remote patient monitoring, will be reimbursable under a hospital-at-home program.

Coverage policies may exclude such products or services from claims processing or, in the value-based purchasing space, from the benchmark against which ultimate costs of in-home hospital care are reconciled.

Despite the planned expiration of the public health emergency and potential limitations on reimbursement, the clinical outcomes and data derived from these emerging technologies indicate potential for expanded coverage in the near future, particularly in the commercial market.[13]

3. What levers can operators rely on to prevent fraud, waste and abuse risks posed by in-home hospital services?

Unlike in the hospital, patients seeing traditionally inpatient, acute care clinicians in the home are welcoming strangers into their most intimate settings and are often at their most vulnerable. In this environment, hospital-at-home programs that are not tailored to in-home fraud and abuse risks may be at risk.

For instance, delaying discharges despite lack of medical necessity, and deploying risk assessment workers or care navigators to focus on increasing the number of hierarchical condition coding numbers listed in a relevant patient chart, raises risk under both the federal Anti-Kickback Statute and False Claims Act.

Relatedly, while transfers of value to beneficiaries are more easily identifiable by colleagues in the hospital setting, more limited safeguards are available on site to ensure Medicare or Medicaid enrollees are not unduly steered to a more costly durable medical equipment product or rehabilitation service, for instance, in violation of the Civil Monetary Penalties Law.

Patient families provide a safeguard against these risks, which may not be present in the hospital. Policies and trainings engaging family members to ensure accurate patient information is relayed to care teams should be revisited for hospital-at-home programs.

Additionally, CMS has provided regulatory avenues to develop provider relationships that pose low risk of fraud and abuse — both through the value-based enterprise safe harbor to the AKS,[14] and the promotes access to care exception to the Civil Monetary Penalties Law[15] — by holding providers accountable for increased costs and facilitating beneficiary transfers of value that may promote reengagement with care planning and eliminate the need for more costly services in the future.

Conclusion

As demonstrated by these legal risks, hospital-at-home programs — while carrying substantial promise in terms of patient experience and value — will require providers and payors to carefully navigate a number of competing state and federal requirements, which were designed for a traditional inpatient hospital admission.

These stakeholders should carefully monitor actions by CMS through the public health emergency unwind to determine whether and how the current flexibilities transition to more permanent authorities, and new or existing programs will likely need to be modified from their current forms to account for these rapidly evolving changes.

That said, there appears to be strong momentum among hospitals, home care agencies, patients, payors and technology companies to make these programs a permanent and sustainable part of the delivery system, which may prove to be a positive legacy of the COVID-19 pandemic.

Devin Cohen and Brett Friedman are partners at Ropes & Gray LLP.

Ropes & Gray law clerk Evelyn Jackson contributed to this article.

[1] Helen Ouyang, Your Next Hospital Bed Might be at Home, N.Y. Times (Jan. 26, 2023).

[2] CMS, Acute Hospital Care at Home, https://qualitynet.cms.gov/acute-hospital-care-at-home (last updated Dec. 29 2022).

[3] CMS, Acute Hospital Care at Home Resources, https://qualitynet.cms.gov/acute-hospital-care-at-home/resources (last updated Jan. 31, 2023).

[4] CMS, Acute Hospital Care at Home, supra.

[5] CMS, Acute Hospital Care at Home Resources, supra.

[6] Ariz. Dep't Health Servs., Licensing (Aug. 20, 2021), https://www.azdhs.gov/documents/licensing/medical-facilities/hospital-at-home-program.pdf?v082021.

[7] See, e.g., D.C. Code § 44-501(a)(7) (defining "home care agency").

[8] See N.Y. Leg. Sec. 3605.

[9] Sharon LaFraniere & Noah Weiland, U.S. Plans to End Public Health Emergency for Covid in May, N.Y. Times (Jan. 30, 2023), https://www.nytimes.com/2023/01/30/us/politics/biden-covid-public-health-emergency.html.

[10] Am. Hosp. Ass'n, AHA Urges Action as HHS Prepares to End the COVID-19 Public

Health Emergency (Feb. 7, 2023), https://www.aha.org/lettercomment/2023-02-07-aha-urges-action-hhs-prepares-end-covid-19-public-health-emergency?utm_source=newsletter&utm_medium=email&utm_campaign=aha-today&mkt_tok=NzEwLVpMTC02NTEAAAGJzQH1RE0euEPYbbr5HnUOYEvWtmi9-LqKu4jAHVo05JX3pKvrCtqfvM84YT7ao9MPlDLvAAKTjrhOLaVqCoqqr5VQqoV4brWPdCT_YFSKeltFpg.

[11] CMS, Acute Hospital Care at Home, supra.

[12] Aditya Achanta & David Velasquez, Hospital at Home: Paying for What It's Worth, Am. J. Managed Care (Sept. 10, 2021), https://www.ajmc.com/view/hospital-at-home-paying-for-what-it-s-worth.

[13] See Peter Pronovost, Melissa Cole, & Robert Hughes, Remote Patient Monitoring During COVID-19: An Unexpected Patient Safety Benefit, 327 JAMA 1125 (2022); see also Elham Hatef et al., Outcomes of In-Peron and Telehealth Ambulatory Encounters During COVID-19 Within a Large Commercially Insured Cohort, 5 JAMA Netw. Open e228954 (2022); Am. Hosp. Ass'n, Studies Find that Remote Monitoring Advanced Care During Pandemic (Sept. 14, 2021), https://www.aha.org/aha-center-health-innovation-market-scan/2021-09-14-studies-find-remote-monitoring-advanced-care.

[14] 42 C.F.R. § 1001.952 (2022).

[15] 42 C.F.R. § 1003.110 (2022).