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Informational Hearing

Hospital at Home: Considerations for Future Implementation
Tuesday, May 2, 2023 – 1:30 to 3:30 p.m.
1021 O Street, Room 1100

INTRODUCTION

On March 30, 2020, the Centers for Medicare and Medicaid Services (CMS) through its blanket 1135 waiver authority implemented a "Hospital without Walls" policy to allow hospitals to provide and bill for hospital services in other healthcare facilities and sites, such as ambulatory surgery centers. The waiver was intended to ensure that local hospitals and health systems had the capacity to handle the surge of COVID-19 patients through the duration of the Public Health Emergency (PHE).

When the President declares a disaster or emergency under the Stafford Act or National Emergencies Act and the federal Health and Human Services Secretary declares a PHE under Section 319 of the Public Health Service Act, the Secretary is authorized to take certain actions in addition to their regular authorities, including the authority to waive certain CMS "conditions of participation." These waivers, under section 1135 of the Social Security Act, typically end no later than the termination of the emergency period, or 60 days from the date the waiver, or modification is first published, unless the Secretary of the Department of Health and Human Services (DHHS) extends the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period. Examples of these 1135 waivers or modifications include:

1) Conditions of participation or other certification requirements;
2) Program participation and similar requirements;
3) Preapproval requirements; and,
4) Requirements that physicians and other health care professionals be licensed in the State in which they are providing services, so long as they have equivalent licensing in another State (this waiver is for purposes of Medicare, Medicaid, and the Children's Health Insurance Program reimbursement only; state law governs whether a non-Federal provider is authorized to provide services in the state without state licensure).

The Acute Hospital Care at Home (AHCaH) program is an expansion of the CMS Hospital without Walls initiative and permits Medicare-certified hospitals to provide inpatient-level care at their patients' homes. The CMS waiver aimed to incentivize implementation of Hospital-at-Home (HaH) care. HaH provides hospital-level acute care in patients' homes as a substitute for care traditionally provided in the hospital.

The concept of HaH programs originated in 1995 when Dr. John Burton of Johns Hopkins School of Medicine and Dr. Donna Regenstreif of the John A. Hartford Foundation conceived of a program to provide hospital-level care at home. A geriatric study team conducted a 17-patient pilot trial that showed that the program was feasible and cost effective. In the early 2000's other HaH programs were tested in three Medicare managed care organizations and one Veterans Affairs medical center. Subsequently in 2011, the company Clinically Home was formed to develop and commercialize the telemedicine-based care model.

According to an October 2022 study published in the *Journal of the American Geriatrics Society,* HaH was developed to reduce complications associated with traditional hospital care and honor patients' preferences to recover at home, particularly older adults with medically complex conditions such as congestive heart failure and chronic obstructive pulmonary disorder (COPD) exacerbations. Given the higher risk of serious complications and death from COVID-19 among older adults, HaH also maintained access to care while keeping older patients out of medical and congregate settings where they may have been at higher risk for exposure and associated morbidity and mortality.

This is the first time CMS has permitted payment for at-home, inpatient-level care for Medicare fee-for-service and non-managed care Medicaid beneficiaries. The waiver took into consideration several factors, including the experience of the institution, patient safety, nursing oversight, physician and advanced practice provider care, and electronic medical records practices. Hospitals that meet the waiver criteria are still required to meet applicable state regulations.

This hearing will provide an overview of HaH programs, present information on the current requirements of the AHCaH program, implementation challenges with the current program, and issues for policy makers to consider moving forward. On Thursday, December 29, 2022, President Biden signed into law H.R. 2716, the Consolidated Appropriations Act for Fiscal Year 2023. Among other things, this legislation extended the AHCaH individual waiver, to December 31, 2024.

BACKGROUND

AHCaH. The CMS program created additional flexibility that allows for certain health care services to be provided outside of a traditional hospital setting and within a patient's home. There are several requirements that a hospital must meet in order to participate in the program. These include:

1) Having appropriate screening protocols in place before care at home begins to assess both medical and non-medical factors;

2) Having a physician or advanced practice provider evaluate each patient daily either in-person or remotely;

3) Having a registered nurse (RN) evaluate each patient once daily either in-person or remotely;

4) Having two in-person visits daily by either registered nurses (RNs) or mobile integrated health paramedics based on the patient's nursing plan and hospital policies;

5) Having the capability of immediate, on-demand remote audio connection with an AHCaH team member who can immediately connect either an RN or medical doctor (MD) to the patient;

6) Having the ability to respond to a decompensating patient within 30 minutes;

7) Tracking several patient safety metrics with weekly or monthly reporting, depending on the hospital's prior experience level;

8) Establishing a local safety committee to review patient safety data;

9) Using an accepted patient leveling process to ensure that only patients requiring an acute level of care are treated; and,

10) Providing or contracting for other services required during an inpatient hospitalization.

The program waives the CMS Conditions of Participation that nursing services be provided on premises 24/7 and covers 60 acute conditions such as asthma, congestive heart failure, and COPD. Beneficiaries can only be admitted to a home hospitalization from emergency departments or an inpatient bed, and an in-person physician evaluation is required prior to starting services at home. In instances where the patient is admitted to a home hospitalization from an inpatient bed, it is to be considered an intra-facility transfer and does not impact payment.

Additionally, there must be immediate connection 24/7 to a physician or a nurse and the capability for an emergency response within 30 minutes. As part of the waiver application process, hospitals have to demonstrate how they will provide services to meet the following needs: pharmacy, infusion, respiratory care including oxygen delivery, diagnostics (labs, radiology), monitoring/vitals, transportation, food services, durable medical equipment, physical therapy, occupational therapy, speech-language therapy, and social work and care coordination (including safe and seamless patient discharges). There are separate waiver applications for hospitals with experience (treated more than 25 patients in a HaH program) with the HaH model and those without.

Program flexibility. Division 5 of Title 22 of the California Code of Regulations (CCR) contains the regulations that govern the different types of health facilities, home health agencies, and clinics. However, the California Department of Public Health (DPH) has the ability to grant written approval for the use of alternate concepts, methods, procedures, techniques, equipment, personnel qualifications, bulk purchasing of pharmaceuticals, or conducting of pilot projects, as long as statutory requirements are met. DPH has a form on its website for facilities to request program flexibility, which asks what section of Title 22 is being requested for program

flexibility, and what is the proposed alternate method for meeting the intent of the regulations. This is the process DPH uses to administer the AHCaH program in California.

California nurse staffing ratios. In 2004, regulations implementing nurse-to-patient ratios in California hospitals pursuant to AB 394 (Kuehl), Chapter 945, Statutes of 1999, went into effect. However, long before California had specific nurse-to-patient ratios, hospitals were required by regulation to establish a patient classification system. This patient classification system is a method by which hospitals establish staffing requirements by unit, patient, and shift, and includes a method by which the amount of nursing care needed for each category of patient is validated for each unit.

The regulations implementing the AB 394 nurse-to-patient ratios law set the minimum ratio of nurses to patient by unit, including 1:1 in operating rooms, 1:2 in intensive care units or other "critical care units," 1:3 in a step down unit, 1:4 in a telemetry unit, and 1:5 in general medical-surgical units.

These regulations also incorporated the patient classification system requirement. In essence, the specific nurse-to-patient ratios establish the minimum number of nurses by unit, while the patient classification system determines whether there needs to be a higher level of staffing beyond the minimum ratio after taking into consideration factors such as the severity of the illness, the need for specialized equipment and technology, and the complexity of clinical judgment needed to evaluate the patient care plan, among other factors. The nurse-to-patient ratio regulations require that the minimum ratios be met at all times.

Based on the criteria for eligibility for the AHCaH, patients would most likely be on the medical-surgical unit if admitted to the brick and mortar hospital, with the required minimum ratio of one nurse for every five patients. However, as noted above, the AHCaH program waives the requirement for 24/7 nursing services. Although the CMS requirements limit the program to one nurse for every five patients, there is no 24 hour in-person nursing care, rather the program must have the capability of immediate, on-demand remote audio connection with an AHCaH team member who can then "immediately" connect either an RN or MD to the patient.

Adventist Health (AH) AHCaH pilot program. AH is the only hospital system to be approved by DPH to operate an AHCaH pilot in California. AH had five hospitals with an approved hospital program flex**.** AH began AHCaH services in May 2020 in accordance with the 1135 waiver and by contract between AH and DPH, executed on May 14, 2020. AH was granted approval to provide AHCaH services by applying for program flex for the following CCR, Title 22 requirements, as summarized below:

1) **Planning and Implementing Patient Care**. The AH Command Center is staffed with RNs 24/7/365 days. The RN is assigned a maximum of five AHCaH patients, consistent with medical-surgical staffing ratios. The RN must follow AH nursing policies and procedures including initial and ongoing assessment, planning, supervision, implementation and evaluation of the nursing plan of care, monitoring of vital signs, medications, and response to care, development of the education plan, and discharge teaching in accordance with the medical plan of care. AHCaH patients receive at least four virtual visits by an RN and two in-person visits by AHCaH practitioner (nurse

practitioner or RN) each day for assessment, monitoring, medication management/administration, patient education, care/family support, and coordination of care. All findings are documented in the patient's electronic medical record.

2) **Pharmaceutical Service General Requirements**. The field nurse carries a supply kit with medications that can be used while the nurse is in the home setting. The patient is located within approximately 25 miles from the physical hospital to accommodate unscheduled visits to the home setting in a timely manner (expected 30 to 60 minutes). If the command center recognizes or the patient experiences a medical emergency 911 is called or immediate response. Upon transfer to AHCaH, patients and families are provided education related to medical emergencies and calling 911 or the command center. All intravenous medications are administered in the home setting by a licensed RN and documented in the medical record. The patient/family is instructed on admission that all medications while in the home setting must be given by a nurse in the home or witnessed by a command center nurse on video.

3) **Dietetic Service General Requirements**. Patients will have meals delivered in accordance with the dietary order placed by the AHCaH MD in the electronic medical record. Meals delivered by the vendor service require refrigeration and reheating. The nurse will assess the food preparation area, storage and reheating appliances to ensure cleanliness and appropriate, functioning appliances. If the patient lacks appropriate food provisions, preparations, or appliances, steps will be taken to find alternatives or return the patient to the hospital setting for the remainder of their inpatient admission.

4) **Fire Safety**. The patient's home environment is assessed upon admission for general safety by the admitting clinical team. If the clinical team identifies safety concerns, the patient will be returned to the physical hospital to resume care. Patients are provided safety information for steps to take in the event of a change in the physical environment (i.e., power outage, wildfire, etc.). Home assessments are conducted by the field RN using the Federal Emergency Management Agency Home Safety Assessment Tool. Any issues identified will be addressed by the clinical team. If issues cannot be resolved to achieve a safe environment, the patient will be returned to the physical hospital.

5) **Patient Accommodations**. Patients are admitted to a virtual unit within the electronic medical record to allow for documentation, management, and billing purposes. The number of beds in the virtual setting is limited only by staffing and available equipment. If staffing or equipment is unavailable, the patient will not be admitted to the AHCaH. If staff is unavailable or equipment fails and cannot be replaced, the patient will be returned to the physical hospital to resume care.

6) **Patient Room Furnishings**. The patient's home setting will be evaluated on admission to ensure the patient has necessary tools and equipment to support the plan of care in the home setting. If any tools or equipment are needed, they will be ordered by the AHCaH MD and delivered to the home by a contracted medical equipment vendor. If tools and equipment are not available and alternatives cannot be located, the patient will be returned to the physical hospital to resume care.

7) **Laundry Service**. No laundry service will be provided for patients in the home setting, cleaning guidelines are provided to the patient/family as described in the alternative concept for Housekeeping below.

8) **Housekeeping**. Personal Protective Equipment is used by nursing staff and provided for patient/family members in accordance with the AH AHCaH policy on Infection Control. The nurses in the home setting wipes surfaces used for patient care items during in-person visits using disinfectant wipes approved by AH Infection Prevention. The home is assessed for environmental cleanliness by the nurse upon admission and ongoing throughout the course of care. Family/caregivers are engaged and provided education to support the patient in the home setting to ensure cleaning standards can be achieved. If the patient/family does not have the necessary resources, alternative cleaning options will be provided by the AHCaH team.

9) **Air Filters**. Air filters and air system maintenance is the responsibility of the patient/family. The home environment is assessed for safety, cleanliness, and fire safety upon admission and ongoing by the nursing team. This assessment includes ensuring the patient has proper utilities.

10) **Solid Waste Containers**. Waste containers are the responsibility of the patient/family with the exception of medication/biohazard waste containers.

11) **Lighting**. Lighting and lighting maintenance are the responsibility of the patient/family. The home environment is assessed for safety, cleanliness, and fire safety upon admission and ongoing by the nursing team. This assessment includes ensuring the patient has proper utilities.

12) **Water Supply and Plumbing**. Water supply and plumbing are the responsibility of the patient/family.

13) **Ice**. Patients requiring ice in connection with food and drink are the responsibility of the patient/family.

According to AH, their AHCaH program provided over 6,000 days of AHCaH to more than 1,100 patients throughout California. Seventy percent of patients in the program were covered by Medi-Cal or Medicare, and 17% had commercial coverage. Forty percent of the individuals receiving acute hospital care at home identified as Hispanic and 40% were 60 years of age or older. AH data also show that the program reduced re-admission rates (43% lower than in a traditional hospital setting) and had high positive patient satisfaction rates. No patients had a fall with injury, a hospital acquired pressure injury, C-diff (infection of the large intestine), MRSA (infections caused by specific bacteria that are resistant to commonly used antibiotics), or SSI (surgical site infection). AH was granted several extensions of this waiver**,** however, AH closed its last remaining pilot site at Adventist Health Rideout Hospital in Marysville in March of 2022.

Effectiveness of AHCaH programs. According to a 2015 study published in the *American Journal of Managed Care,* "Scalable hospital at home with virtual physician visits: pilot study," patients in HaH programs that had substantial contact with the HaH physician, as well as in-person visits with nurse practitioners and other care providers were more satisfied with their care and met illness-specific quality standards at similar rates to hospital comparison patients. The study outcomes were notable for a trend toward improvements in activities of daily living among HaH patients. Compared with hospital patients at 90 days after discharge, HaH patients were less likely to experience a hospital readmission.

According to a Commonwealth Fund article, HaH programs that enable patients to receive hospital-level care in the comfort of their homes have flourished in countries with single-payer health systems, but their use in the U.S. has been limited. Such programs are well established in England, Canada, Israel, and other countries where payment policies encourage, or at least do not discourage, the provision of health care services in less costly venues. In Victoria, Australia, for example, every metropolitan and regional hospital has a HaH program, and roughly 6% of all hospital bed-days are provided that way. For specific conditions, the use of at-home care is significantly greater: nearly 60% of all patients with deep venous thrombosis were treated at home in 2008, as were 25% of all hospital patients admitted for acute cellulitis.

The Commonwealth Fund article notes that instituting this type of care in the U.S. could produce dramatic savings for the Medicare program and private payers, by eliminating the fixed costs associated with operating a brick-and-mortar hospital, and that some pilots of the model have already achieved savings of 30% and more per admission, while delivering equivalent outcomes and fewer complications than traditional hospital care.

Access and Equity. A 2022 study published in the *Journal of the American Geriatric Society*, Health equity in Hospital at Home: Outcomes for economically disadvantaged and non-disadvantaged patients (Siu, A.L., Zhao, D., Bollens-Lund, E., et al.) states that their study data suggest that HaH is feasible for economically disadvantaged patients and that these patients may even receive greater benefits from HaH. The authors hypothesized that better outcomes for low socioeconomic status (SES) patients may result from the ability of HaH providers to directly observe and provide care to patients in their homes, where they can address social determinants of health (e.g., food insecurity, medical equipment needs, and management of chronic diseases in real-world situations).

It should be noted that study limitations included the use of retrospective data and proxy indicators of SES status, and a limited ability to adjust for potential confounders due to cell size constraints (a total of 477 hospital episodes across 443 unique subjects were included in this analysis). A "proxy indicator" is sometimes used when something is being studied that cannot be directly measured, for example, the possession of household assets such as a television or computer, can be good proxy indicators for household income, rather than earnings from a job. The authors also noted that more research on HaH and healthcare equity needs to be performed, including routine measurement of multiple dimensions of SES, to better understand how HaH supports these populations.

CONCLUSION

According to the American Hospital Association, as of September 2022, 114 health systems and a total of 253 hospitals have been approved to provide HaH services to patients in the U.S. The HaH is a novel concept aimed at reducing complications associated with hospital care and honoring patients' preferences to recover at home. Their approval to assist in handling capacity during the surge of COVID-19 patients through the duration of the PHE was certainly necessary given hospital capacity challenges. However, a broader expansion of this program needs thorough vetting to ensure a balanced approach is taken to ensure patient safety, quality and equity of care, and cost containment.