National Home Infusion Association

Trends in Home Enteral Nutrition—The Impact of Competitive Bidding on Access and Quality

Executive Summary

The goal of this overview is to provide a concise summary of Home Enteral Nutrition (HEN) and how changes to reimbursement under the Medicare program have impacted access to clinical services. The goal is to inform those unfamiliar with the therapy about its complexities and the multidisciplinary health care team required to safely administer formulas and support HEN patients.

Home Enteral Nutrition (HEN), commonly known as tube feeding, is a life-sustaining therapy administered to patients in home settings.[1-5] Despite its vital role in supporting patients with severe and chronic conditions, ranging from dysphagia to neurological disorders and cancer, HEN remains an under-recognized and under-supported patient need.[1,6] An estimated 220,000 individuals in the United States rely on HEN,[7] which demands clinical coordination, specialized equipment, disease-specific nutrition formulas, and a multidisciplinary team to ensure safety, efficacy, and quality of life.[2,3,6]

The current reimbursement model for HEN lacks payment for the post-acute clinical services necessary to support positive patient outcomes on HEN.[8] This void in services impedes patient access and leads to high utilization of the emergency department and limits the number of physicians willing to accept these patients.[9] Additionally, the Medicare Competitive Bidding Program has driven down the reimbursement for pumps, formula, and supplies to unsustainable levels making it impossible to offer robust clinical nutrition support services, which were often available prior to the introduction of the program.[10]

NHIA believes that HEN presents an opportunity for reforming the reimbursement model in a way that supports additional clinical services and the ability of HEN providers to better serve this population. Such reforms would improve outcomes and the quality of life in HEN patients, while lowering the total cost of care.

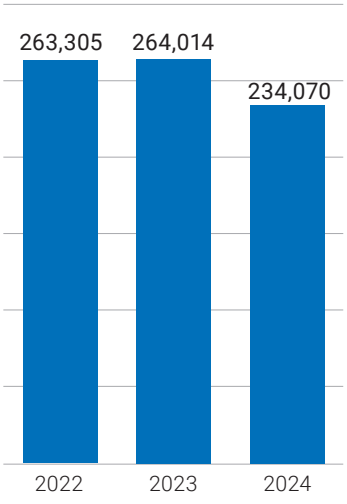
Overview of Home Enteral Nutrition

HEN is a formulated liquid nutrition therapy administered to patients in their homes. It is used by approximately 1,385 patients per million in the United States, and this number is steadily increasing due to the reliance on ambulatory care.[1,2]

In 2006, estimates suggested that more than twice as many patients received enteral nutrition in the community compared to those in hospitals.[11] In 2018, the overall cost for a HEN patient was reported to be between $10,000 and $20,000 per year.[3]

Hundreds of thousands of people rely on HEN for survival. Recent claims data shows that 263,305 individuals in 2022; 264,014 in 2023; and 234,070 in 2024 needed enteral feeding as their primary source of nutrition.[7] [Editor's Note: Electronic claims data for 2024 was likely underrepresented due to a cyber-attack and resulting nationwide outage that necessitated alternative methods of claims filing for most of the year.]

Unique Patients Utilizing HEN Annually, 2022-2024



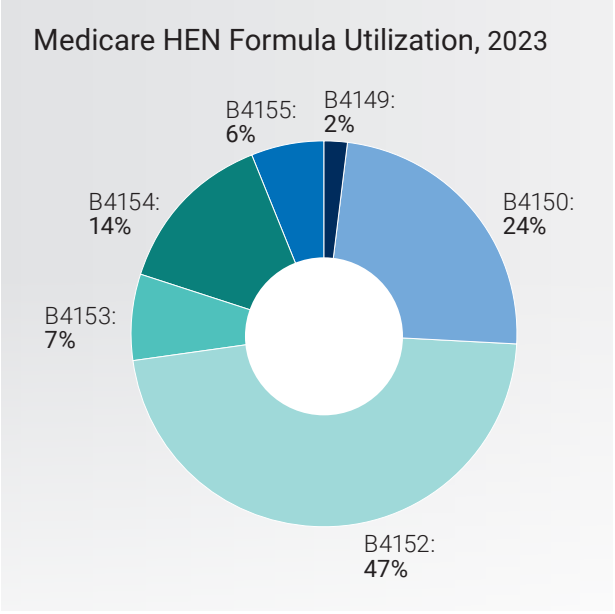
Source: Proprietary claims data

The need for HEN spans all age groups and health conditions, from chronic diseases such as Crohn's disease and cancer to acute conditions that require short-term nutritional support.[1,2,5,6] Many complex diseases require HEN for patient survival. A study published in 2018 reported that a diagnosis of dysphagia accounted for 84.6% of HEN patients, followed by neurological disorders (49.1%) and head and neck cancer (26.5%).[3] The duration of HEN depends on the patient's disease and the physician's recommendation.

HEN Formulation Utilization for Most Common HCPCS, 10-Year Trend

HCPCS	Short Description	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Change 2014-2023
B4149	Ef blenderized foods	280	308	403	554	770	1,050	1,201	1,221	1,199	1,257	**349%**
B4150	Ef complete w/ intact nutrient	36,892	32,812	30,314	26,399	24,602	23,264	21,292	20,211	18,534	20,034	**-46%**
B4152	Ef calorie dense>/=1.5kcal	43,407	43,323	44,014	42,427	42,839	45,083	44,040	42,222	39,438	39,049	**-10%**
B4153	Ef hydrolyzed/ amino acids	4,723	4,470	4,383	4,184	4,435	4,840	5,089	5,436	5,316	5,648	**20%**
B4154	Ef spec metabolic non inherit	21,906	19,782	18,139	16,311	15,570	15,451	14,893	14,024	12,539	11,806	**-46%**
B4155	Ef incomplete/ modular	6,209	5,819	5,056	4,321	4,566	5,056	5,078	5,207	4,879	4,871	**-22%**
B4160	Ef ped caloric dense>/=0.7kc	123	99	97	99	127	140	146	156	159	193	**57%**
B4161	Ef ped hydrolyzed/ amino acid	60	74	82	85	119	157	159	192	215	285	**375%**

Source: Medicare claims data



Source: Medicare claims data

Types of Enteral Nutrition Formulas

Enteral nutrition formulas are designed to provide a balanced intake of macronutrients (carbohydrates, proteins, and fats) and micronutrients (vitamins and minerals). These formulas are categorized into 2 main types: standard and chemically defined.[4,6] Each category includes subtypes, such as disease-specific and specialty formulas, along with a newer class of blenderized EN formulations made from natural whole foods.[4]

Standard formulas are appropriate for most patients and are nutritionally complete regarding macronutrients and micronutrients, meeting dietary reference intakes within a specified volume. However, approximately 40% of all HEN users require disease-specific and specialty formulas formulated for patients with conditions like metabolic disorders, organ dysfunction, or malabsorption issues. Formulas made by commercial manufacturers or diets prepared from whole foods using a blender can be used by patients who prefer natural ingredients or have specific dietary requirements.[4] Medicare claims data shows the change in formula utilization over time.[12]

Routes of Administration

The type of feeding tube depends on the site of feeding tube placement, the patient's medical condition, and the duration of need.[5,6] Short-term enteral nutrition (4-6 weeks) is administered using gastric and post-pyloric feeding tubes, which are inserted through the nose or mouth. Gastrostomy or jejunostomy tubes are used for long-term EN and require endoscopic placement, and in some cases, gastric tubes may need to be placed surgically or radiologically.[2,5,6] These devices allow direct access to the gastrointestinal tract and require diligent monitoring to prevent complications such as site infections and tube dislodgement.[6]

Methods of Administration

Enteral nutrition can be administered in various ways. The choice of method depends on expected tolerance and the feeding site. Bolus feeding is typically preferred in home settings because continuous feeding requires a feeding

pump and the patient to remain connected to it throughout the process. Bolus feeding involves using a syringe to deliver formula intermittently in larger amounts at scheduled times. Pump-assisted feeding is usually reserved for individuals who need a controlled rate of continuous feeding, often for patients requiring precise nutrient delivery.[5,6]

According to claims data, approximately half of all HEN patients receive their formula via electronic pump, with the next largest group using the bolus method.[7]

HEN Methods of Administration in 2024

Enteral Pump Feed (S9342, B4035)	119,721	54.54%
Enteral Syringe/Bolus Feed (S9343, B4034)	74,217	33.81%
Enteral Gravity Feed (S9341, B4036)	20,831	9.49%
Enteral Elastomeric/Non-spec (S9340, B4148)	4,749	2.16%

Source: Proprietary claims data

Equipment and Supplies

HEN requires specialized equipment, including feeding tubes that are placed into the patient, such as nasogastric, gastrostomy (G-tube), or jejunostomy (J-tube).[6] HEN may also require the use of enteral feeding pumps for controlled and continuous feeding. Additional supplies for HEN include syringes and bags necessary for bolus and gravity-assisted feeding methods, as well as the patient's EN formula and accessories like connectors and feeding tube declogging devices.[5,6] HEN products are distributed through home medical equipment (HME) providers, durable medical equipment (DME) suppliers, and home infusion pharmacies. Many providers face reimbursement challenges due to competitive bidding policies, leading to supply shortages and limited patient access to essential equipment and formulas.[5]

Home Infusion Service Component

A multidisciplinary health care team is essential to achieve optimal HEN outcomes. This team should include various medical professionals, such as physicians, dietitians, nurses, and pharmacists.[6] The team supports the complexity of HEN therapy and the need for close patient monitoring.[11] Monitoring may involve checking for serious complications like aspiration pneumonia, dislodged tubes, and gastrointestinal issues.[2] Patient care should be standardized and coordinated by the nutrition support team.[2] For instance, the dietitian evaluates the patient's calorie, protein, and fluid needs, while the pharmacist reviews medications and collaborates with the nurse and physician to coordinate product delivery.[6] Members of the HEN clinical team are available 24/7 to provide ongoing support.

Before hospital discharge or at home, the patient must receive education and demonstrate the ability to administer HEN.[3,6] This step is usually performed by a nurse and is vital because research shows that complications from HEN can be reduced or avoided by providing a thorough education to patients and their caregivers.[13]

Patient and caregiver training is an essential part of providing HEN and should include hand hygiene, HEN administration, how to use supplies, starting and stopping the infusion, programming the pump (if applicable), where to obtain supplies, managing contamination, and who to contact with questions or concerns.[5] In addition to the patient and caregiver receiving training, all health care professionals directly involved in EN patient care should receive education and training relevant to their specific duties.[2]

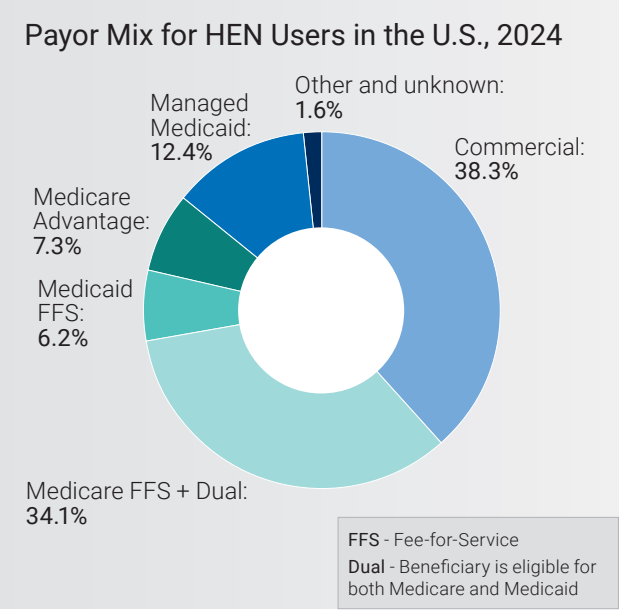
HEN patients need regular monitoring by the health care team, which depends on many factors, including underlying disease, nutritional status on discharge, and whether they are receiving active treatment or palliative care.[2] Although HEN can be lifesaving, it is also associated with complications that can be life threatening. Close monitoring is essential to prevent and identify these issues.[5] Body weight and hydration status should be routinely assessed to ensure adequate nutrition.[2,6] Annually, routine laboratory tests and micronutrient levels should be checked, with more frequent monitoring and supplementation when deficiencies are detected.[14] The nutrition support team and HEN supplier may also monitor ongoing product availability, coordinate logistics for sourcing products, and collaborate with prescribers to identify suitable alternatives and reduce disruptions.[10]

Home Enteral Nutrition Guidelines

HEN administration is complex and requires adherence to medical guidelines. Prior to 2020, no standardized HEN guidelines addressed diagnosing, treating, and preventing adverse events. In 2020, the European Society for Clinical Nutrition and Metabolism (ESPEN) published HEN guidelines based on research and expert consensus.[2] These guidelines cover HEN indications, access devices, recommended products, monitoring protocols, criteria for discontinuation, and structural requirements. The guidelines were developed through interdisciplinary collaboration and underwent a rigorous review process.[2] While widely accepted, adherence to all 61 ESPEN guidelines is challenging for U.S. providers due to a lack of reimbursement for clinical support services.

Enteral Nutrition Services Provided in a U.S. Service Model

Medicare coverage of EN in the home includes the necessary nutrients, supplies for administration, and equipment under the Medicare Part B Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) benefit. Many commercial insurance plans and most Medicaid programs also pay for HEN. According to claims data, Medicare fee-for-service is the primary payor for approximately 34.1% of all HEN patients in the U.S.[7]



Source: Proprietary claims data

Beginning January 1, 2022, the Centers for Medicare and Medicaid Services (CMS) retired the Enteral and Parenteral Nutritional Therapy National Coverage Determination (NCD), as it determined that no NCD was appropriate for the therapies.[15] This left coverage determinations regarding HEN coverage at the local level, with Medicare Administrative Contractors (MACs) being responsible for making Local Coverage Determinations (LCDs) about what is "reasonable and necessary," as required for Medicare coverage. The LCD also lays out documentation requirements for coverage. For example, there must be documentation in the beneficiary's medical record to justify the need for a pump, if one is ordered. The DME MACs jointly reminded stakeholders that final EN LCDs[16] and Policy Articles[8] were in effect for dates of service beginning September 5, 2021.[17] DME MACs may also provide helpful guidance such as clinician and documentation checklists.[18]

For Medicare to cover HEN, a beneficiary must have a permanent:

- Non-function or disease of the structures that typically allow food to reach the small bowel; OR
- Disease that impairs digestion and/or absorption of an oral diet by the small bowel.

The beneficiary also must require feedings through an enteral access device to provide sufficient nutrients to maintain the beneficiary's weight and strength.

Medicare Competitive Bidding and Home Infusion

Prior to 2013, HEN was provided by a supplier that accepted Medicare allowable payment for formula and tube feeding supplies. Under the DMEPOS Competitive Bidding Program, suppliers compete to become Medicare contract suppliers by submitting bids to furnish items in Competitive Bidding Areas (CBAs).[19] The lower payment amounts resulting from the competition, referred to as the single payment amount (SPA), replaced the fee schedule amounts for the bid items. Many of the HEN providers who participated in this program are now defunct, leading to disruption in care for many HEN recipients.

Implementation of the CBP began on January 1, 2011, in what was called the "Round 1 Rebid." In April 2012, CMS announced that the program had saved the Medicare fee-for-service program approximately $202.1 million in its first year. According to the report, the program, implemented across 9 markets, was responsible for a 42% reduction in spending from "lower prices and reduced in appropriate utilization." The report noted that EN and associated equipment and supplies represented $18.8 million in savings. CMS claimed that there were "no negative health care consequences to beneficiaries as a result of competitive bidding."[20]

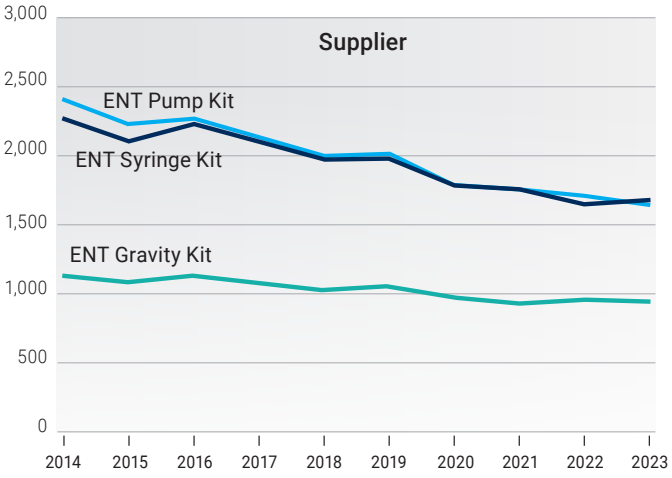
The CBP was expanded to an additional 91 metropolitan areas in July 2013, in "Round 2" of the program.[21] In addition, CMS began phasing in blended rates in non-competitive bidding areas in January 2016. Following this large expansion, Congress and other stakeholders raised concerns about the CBP's impact on beneficiary access. In 2016, CMS reported that the program had saved Medicare more than $580 million through the end of the Round 1 Rebid period, ending December 31, 2013, and a total of $3.6 billion including the first 2 years of Round 2. CMS also stated that the newly adjusted fees "had no negative impact on beneficiary access to quality items and services."[22] In May 2018, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) issued a report,

Medicare HEN User Trend, 2014-2023

Beneficiaries												
HCPCS	Year	Description	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
B4034	2014	ENT Syringe Kit	36,749	35,396	35,533	34,036	33,697	34,712	34,166	33,451	30,970	30,193
B4035	2014	ENT Pump Kit	57,602	53,319	50,361	44,922	43,314	43,760	41,741	39,110	35,921	35,200
B4036	2014	ENT Gravity Kit	7,207	7,150	7,186	7,051	7,017	7,437	7,371	7,171	6,850	6,730
		Total	101,558	95,865	93,080	86,009	84,028	85,909	83,278	79,732	73,741	72,123

Source: Medicare claims data

Medicare HEN Kit Supplier Trend



Source: Medicare claims data

concluding that the vast majority of Medicare beneficiaries continued to have access to enteral nutrition supplies after the beginning of Round 2 of the CBP.[23]

CMS paused the CBP from January 1, 2019 through January 31, 2020.[24] Subsequently, in Round 2021 of the CBP, which ran from January 1, 2021 through December 31, 2023, contracts only were awarded for Off-The-Shelf (OTS) back braces and knee braces.[25] CMS stated that for the remaining categories that previously were awarded CBP contracts, including EN, "payment amounts did not achieve expected savings."[26]

Since January 1, 2024, a temporary "gap period" has been in place for all DMEPOS CBPs. CMS notes that it will reinstitute bidding for the next round of the program after it completes a formal public notice and comment rulemaking process and implements necessary changes to the program.[27] These changes include establishing sustainable prices; saving money for Medicare beneficiaries and taxpayers; reducing Medicare fraud, waste, and abuse; and ensuring beneficiaries have access to quality items and services. In the meantime, CMS continues to adjust the fees in both former CBAs and outside of those areas.

Medicare Utilization Data Indicates a CBP's Negative Impact on HEN Use

Despite reports that competitive bidding has not negatively impacted access to HEN, a review based on publicly available Medicare DME utilization data shows the number of suppliers billing for HEN kits has decreased by 31% over the past decade, while the number of Medicare beneficiaries accessing HEN has declined by 27%.[12] NHIA believes this negative trend would not have occurred without the CBP. HEN utilization would be expected to rise since 2014 based on, (1) the growing number of older adults and (2) higher total Medicare enrollment.

The 65+ population continued to grow rapidly through the 2010s and 2020s, reaching approximately 61.2 million in 2024 (up 3.1% from 2023 to 2024). Aging is tightly linked to conditions that commonly lead to tube feeding (stroke, neurodegenerative disease, cancer treatment sequelae), so a larger older cohort implies higher potential HEN need.[28] Additionally, Medicare enrollment has risen from 55.2 million (2013) to 68.3 million (2022)—a sizable increase that continued into 2024–2025 according to Kaiser Family Foundation dashboards. All else equal, more beneficiaries should result in more DMEPOS users, including enteral nutrition.[29,30]

Since 2021, the DME MACs updated the enteral LCDs (maintaining the "test of permanence" medical-necessity standard) and in 2023 eliminated the DME Information Form (DIF), a change that did not add new barriers and may have modestly reduced administrative friction.[31,32] With a substantially larger Medicare population and a bigger 65+ cohort, the expectation is higher DMEPOS HEN utilization post 2014, even allowing for local variation and Medicare Advantage management practices.[28,29,33] In fact, both beneficiary utilization and supplier participation in the program have significantly declined since 2014.[12] In addition, the average Medicare allowables for enteral formulas and supplies were less in 2023 than they were a decade ago.

State of Enteral Nutrition Care in the U.S.

Hospitals that discharge patients in need of enteral therapy do not have the nutritional support services to continue to manage their needs while on HEN, especially in rural areas.

Reimbursement compression for home HEN has caused many Medicare suppliers to cut back on their nutrition support programs, leaving a void for the ongoing clinical management of HEN.[34]

Competitive bidding may influence other payors' reimbursement rates, which could jeopardize access to EN care in the home. According to reports, 1 in 4 EN providers are considering or planning to discontinue providing EN formulas or supplies due to cost pressures.[10] In a recent report, researchers from large health-systems in the U.S. shared their experience with a lack of systemic support for patients discharged from the hospital to their home on EN. They identified that the lack of support for outpatient care was limited due to financial barriers, coordination of care transitions, and the high complexity of care for home EN patients.[35]

Although access to EN supplies remained steady after competitive bidding, as shown by the OIG data, there is limited evidence directly addressing the impact on clinical support intensity, such as patient and caregiver education, delivery, set-up, and follow-up assessments.[23] CBP rules still require contract suppliers to provide services across entire bidding areas, including delivery and maintenance where needed.[8] However, providers and industry groups have expressed concerns that low bids, especially under lead-item pricing, may reduce reimbursement for vital specialized formulas by 15-40%, potentially making high-acuity, medically complex nutrition less sustainable or accessible.[10,36] This highlights a research gap in studying the factors that affect when EN formulas and supplies are maintained, as well as whether essential steps for safe and effective home EN care, such as hands-on training and tailored formulas, are compromised when contracts are awarded to the lowest bidders. Targeted qualitative research involving patients, clinicians, and suppliers would provide evidence on whether cost-driven contract reductions have led to a decline in care.

Accreditation requirements for EN suppliers have not been relaxed under the CBP. EN remains subject to the DMEPOS Quality Standards, which mandate intake assessments, delivery and setup, patient/caregiver education, and follow-up.[37] To bill Medicare, providers must be accredited by a CMS-approved organization for the specific product lines, including EN, and must maintain active enrollment and licensing.[37] Importantly, recent CMS proposals aim to tighten oversight by moving to annual re-accreditation, increasing data transparency from accrediting bodies, and strengthening enforcement mechanisms rather than lowering minimum standards.[38] Therefore, any observed decline in clinical support for EN patients after competitive bidding likely results from operational or financial pressures, not from changes in accreditation standards.

Directions for Change and Improvement

NHIA believes the HEN service delivery model in the U.S. needs to evolve for access to improve, and to establish clinical service standards, and enhance the beneficiary experience and outcomes. NHIA offers several recommendations for accomplishing these goals. First, improving access to HEN, supplies, and clinical services would benefit from **CMS conducting and reporting the results of a comprehensive study of HEN services, including the quality of services; supplier landscape; patient reported access to services, satisfaction and quality of life; and cost of care.** The results of the research would provide data to support re-evaluating competitive bidding and assess the impact of the program on HEN services.

A similar study from 2018 reported that during the 3 months preceding Round 2, 40,891 beneficiaries used EN supplies in both Round 2 CBAs and non-CBAs. After Round 2 began, 91% of beneficiaries in Round 2 CBAs and 94% in non-CBAs had 1 or more paid claims for EN supplies. Researchers found that the percentage of beneficiaries for whom Medicare payments for EN supplies did not continue was slightly higher in Round 2 CBAs than in non-CBAs.[23] This difference could indicate disruptions in access to EN supplies. The service delivery of HEN should be restructured to support the complex clinical and logistical needs of the patient. Finally, CMS should consider removing EN from competitive bidding to avoid further erosion of the benefit.

Second, there needs to be a path to **develop supplier quality standards that include clinical support expectations and standardized outcomes to improve patient safety and care continuity.** HEN research should conduct demonstration programs that test innovative models that reduce total care costs while maintaining patient access to essential services.

Third, reimbursement models need to **explore adding a service code for clinical activities such as performing nutritional assessments, monitoring nutritional status, making formula changes, troubleshooting problems, and providing nutrition education and support.** Payors should devote resources to discussions that consider implementing an episodic model of payment to capture a broader range of HEN-related clinical services that can reduce the total cost of care.

By implementing these changes, policymakers can improve patient access to HEN, ensure equitable care, and support the sustainability of home enteral nutrition providers.

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