



Federal Court Dismisses NHIA's Lawsuit Over Medicare Home Infusion Therapy Benefit

Alexandria, VA. (June 16, 2021)—On June 15, a U.S. district court dismissed NHIA's case over the implementation of a Medicare home infusion therapy services benefit for a "lack of subject matter jurisdiction." The lawsuit, filed in 2019 against the Department of Health and Human Services (HHS), argued that its final rule implementing a policy enacted by the Bipartisan Budget Act (BBA) of 2018 ignores the intent of Congress. The final rule, which was carried over to the permanent benefit under 21st Century Cures, limited provider payments to days when a "skilled professional was in the patient's home," rather than for each day that a drug is administered to a patient. The Association joined with several member providers whose claims for services were denied under the benefit to file the suit.

Judge Timothy J. Kelly dismissed the case on the grounds that the court's jurisdiction over Medicare is limited and that, in most cases, challengers must complete HHS' 4-step appeal and review process prior to filing with the court. NHIA argued that exhaustion of the multi-year administrative process would have been futile considering the 2-year duration of the benefit, but the Judge disagreed. The court did not reach the merits of NHIA's claims that the Centers for Medicare and Medicaid Services (CMS) has repeatedly misinterpreted the home infusion services statute as enacted by Congress as part of the BBA, and subsequently the 21st Century Cures Act. As Congress had pointed out in [letters](#) to the agency, their interpretation of the statute "contradicts [the] intent in drafting and enacting this legislation and makes the reimbursement required by the bill inadequate."

"It's frustrating and disappointing that this case was dismissed on a technicality and not considered on its merits," said Connie Sullivan, BSPharm, NHIA's President and CEO. "We still believe that CMS' implementation is inconsistent with Congress' intent and over the past 2 years, and we have seen—and documented—how the agency's actions have negatively impacted patient access to home infusion therapy. This ruling reaffirms the need for Congress to enact clarifying legislation."

In a 2021 [white paper](#), NHIA enumerated the effects of Medicare Part B policies, including the transitional benefit in question, on Medicare beneficiary access to home infusion therapy. The report found that in 2019, the first year providers could bill for services, fewer than 700 beneficiaries per month received Part B home infusion (nursing) services. The permanent services benefit created by the 21st Century Cures Act, which began in January 1, 2021 is likely to result in further declines in utilization due to low provider enrollment. As of the time of publication, fewer than 250 individual supplier locations have enrolled.

"Appropriate payment for home-based services has never been more important," said Tim Affeldt, NHIA's Board Chair and Vice President of Specialty/Infusion Operations at Fairview Pharmacy Services in Minneapolis. "Contrary to the goals of our public health system, CMS' rulemaking has increased costs for the Medicare program and put Medicare patients at risk by sending them to other sites of care

during the COVID-19 public health crisis. NHIA continues to pursue this issue and looks to Congress for a legislative solution."

NHIA is a trade association that represents companies that provide infusion therapy to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. Infusion therapy involves patient-specific compounded medications, supplies, and a range of pharmacy, nursing, and other clinical services for delivering care to patients in the home setting. For more information, visit www.nhia.org

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