

NHIA v. Alex Azar

Frequently Asked Questions

Why is NHIA suing the federal government?

For the past three years, NHIA has been fighting to assure that home infusion professional services are reimbursed under the Medicare program. We thought we had cleared this hurdle when Congress enacted the 21st Century Cures Act in 2016, which created the home infusion professional services payment, and when it passed the Bipartisan Budget Act in 2018, which created the transitional payment. Unfortunately, CMS has interpreted those laws very narrowly, and only wants to reimburse home infusion professional services on a day when a professional is present in the patient's home. This narrow interpretation would result in insignificant reimbursement for home infusion providers, and could significantly inhibit patient access to home infusion services.

NHIA did not undertake this decision lightly. Since the rule was initially released, NHIA has fought tirelessly to convince CMS that their interpretation was contrary to Congress' intent, which was to provide reimbursement for each day a patient received an infusion drug. We made legal, policy, and political arguments imploring CMS to recognize and reimburse pharmacy services that are provided remotely, in addition to the nursing services covered under the existing rule. Unfortunately, CMS' refusal to recognize those services has left NHIA with little other choice than to pursue legal action.

Will CMS Punish us for Doing This?

While filing litigation is certainly a significant and important move, it is not necessarily uncommon. Many trade associations take legal action on behalf of their members. The professionals at CMS are accustomed to these types of disagreements and will simply proceed under their current interpretation until the case is resolved.

Further, while NHIA is willing to fight for our members in court, at the same time, we are working to build relationships with CMS so that we can continue to educate them on the value and importance of home infusion. We can disagree without being disagreeable.

What are NHIA's Legal Arguments?

NHIA is challenging the agency's interpretation of "infusion drug administration calendar day," which limits payment to only those days in which a "skilled professional is in the patient's home." We believe that the agency action is contrary to the law, an unreasonable construction of the statute, arbitrary and capricious and a violation of the Administrative Procedures Act. More specifically, we argue that:

- The law requires reimbursement for *all* professional services, including (but not limited to) nursing
- Congress directed that reimbursement occur on each "infusion drug administration calendar day"— *i.e.*, each day an infusion drug was administered to a beneficiary
- The law does not require professional services to be furnished "in the home"

What are CMS' Legal Arguments?

CMS will likely argue that the wording of the law is ambiguous, and that the court should defer to the agency for its interpretation. Further, CMS might point to the following statutory provisions as evidence of their case:

- CURES defines “home infusion therapy” to mean “the items and services...furnished by a qualified home infusion therapy supplier... which are furnished in the individual’s home”
- BBA defines infusion drug administration calendar day as “the date on which professional services...were furnished to administer such drugs to such individuals”
- Pharmacy services associated with the preparation and dispensing of home infusion therapy are covered under the DME benefit

What are the potential outcomes?

NHIA believes we have a strong case and that our legal counsel is well equipped to persuade the court to rule in our favor. We are also hopeful that taking legal action will allow CMS to engage in a negotiation that will allow us to reach a mutually agreeable settlement.

How quickly will we know how this works out?

NHIA is working with legal counsel to negotiate an expedited briefing schedule to get the merits before the Court quickly. Our hope is that the case will be litigated and a judgement rendered by early-mid Summer.

How will this affect our legislative strategy?

NHIA will continue to pursue legislative relief that assures appropriate reimbursement for home infusion professional services. That includes transitional payment relief, but we will likely also seek additional reforms to the permanent payment. We also plan to pursue professional services reimbursement for Part D covered infusion medications. While legal action might resolve the transitional payment issue, it may not be sufficient to address our concerns about the permanent payment and will have no impact on Part D. We will continue to maintain a robust presence on Capitol Hill.

How can my company help?

NHIA is currently the sole claimant in the litigation. However, the claim can be amended to add any supplier members who would like to be a party to the suit. [do we need any more help with claims?]

Further, to assure that NHIA has the financial resources needed to see this matter through, we have also created a “Major Donors” initiative as part of the PITCH In Campaign. Major donors are companies that contribute either \$10,000 or 50% of their NHIA dues (whichever is greater) to support the legal effort. If you would like to become a major donor, please contact Sharon Pearce at Sharon.pearce@nhia.org.