

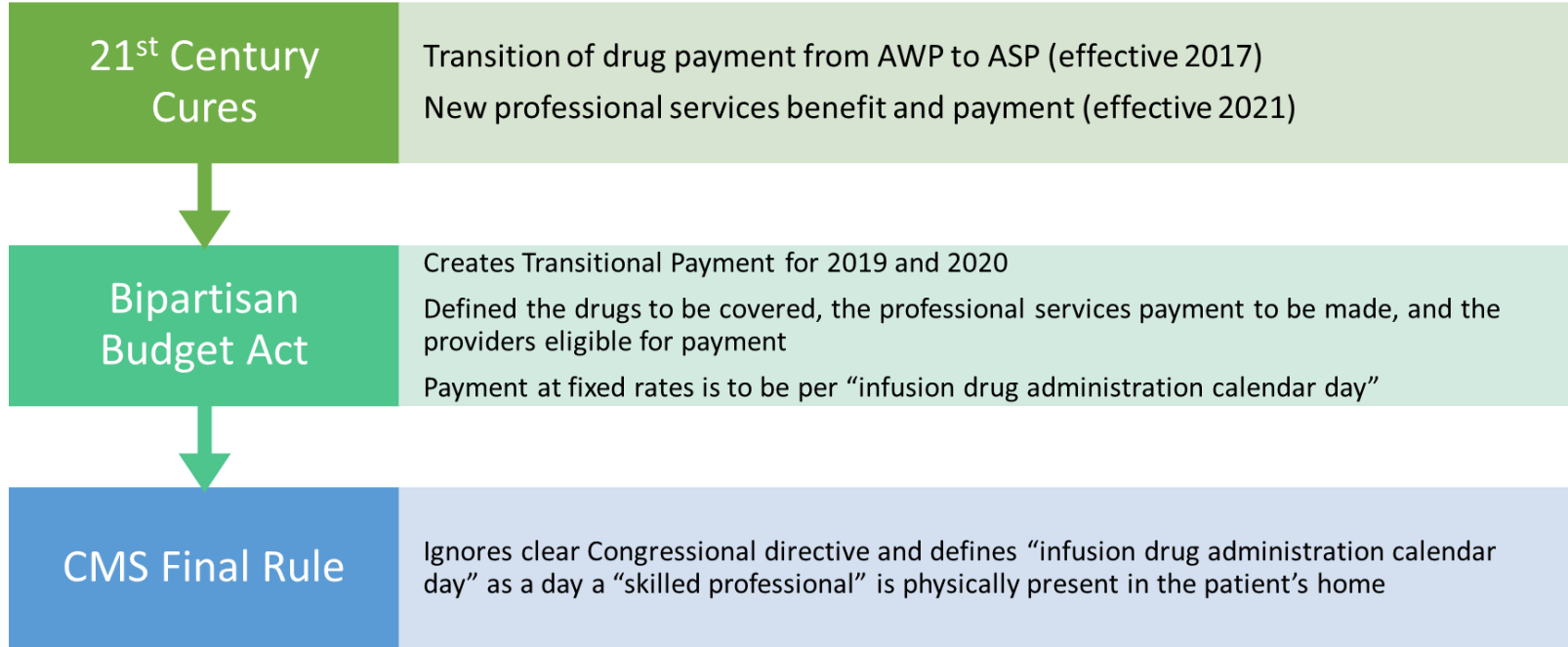


# NHIA v. Azar – Restoring Part B Reimbursement



*Educate. Engage. Empower.*

# The Path from CURES to Court



# The Litigation

On February 14, 2019, NHIA sues HHS challenging CMS's interpretation of "*infusion drug administration calendar day*."

- Agency action is "contrary to law"
- Agency action is "arbitrary and capricious"
- Rule violates legislative intent

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA	
NATIONAL HOME INFUSION ASSOCIATION, )	
1600 Duke Street, Suite 410 )	
Alexandria, VA 22314, )	
)	
Plaintiff, )	
)	
v. )	Case No. 1:19-cv-39
)	
ALEX M. AZAR II, )	
<i>in his official capacity as Secretary of</i> )	
<i>Health &amp; Human Services,</i> )	
U.S. Department of Health & Human Services, )	
200 Independence Avenue, S.W. )	
Washington, D.C. 20201 )	
)	
Defendant. )	
)	

# Summary of Arguments

- Reimbursement for “professional services, including nursing services”
  - does not mean only nursing services, and
  - does not include any physical presence requirement
- Congress directed that reimbursement occur on each “infusion drug administration calendar day”—i.e., each day an infusion drug was administered to a beneficiary

# What Will the Government Argue?

- Statute is ambiguous and court should defer to CMS's interpretation
  - 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 did Congress Say?

By limiting reimbursement to providers to "the day on which home infusion therapy services are furnished by skilled professionals in the individual's home" CMS will effectively gut the intent of the legislation. This physical presence requirement contradicts the intent in drafting and enacting this legislation and makes the reimbursement required by the bill inadequate.

In preparing this legislation Congress worked to mirror this benefit as closely as possible to private sector and other governmental home infusion programs. No other payors for home infusion (commercial plans, Medicare Advantage Plans, the Veterans Administration, or others) have such a requirement for a professional to be physically present in order to reimburse for the beneficiary's home infusion because pharmacy services are so vitally important to home infusion.

EARL L. "BUDDY" CARTER  
First District of Georgia  
ENERGY AND COMMERCE COMMITTEE  
SUBCOMMITTEE ON HEALTH  
SUBCOMMITTEE ON ENVIRONMENT  
SUBCOMMITTEE ON CONSUMER PROTECTION AND INVESTIGATIONS

Congress of the United States  
House of Representatives  
Washington, DC 20515-1001

WASHINGTON OFFICE  
432 Cannon House Office Building  
Washington, DC 20515  
(800) 375-8831  
SILVER SPRING OFFICE  
800 American Express  
Silver Spring, MD 20910  
(970) 392-4391  
BIRMINGHAM OFFICE  
1000 Northchase Drive  
Birmingham, AL 35202  
(800) 295-8831  
<http://BuddyCarter.Congress.House.gov>

The Honorable Seema Verma  
Administrator, Center for Medicare and Medicaid Services  
200 Independence Avenue  
Washington, D.C. 2

Dear Administrator

As the only pharma  
21<sup>st</sup> Century Cures  
Medicaid Services  
legislation is approp  
infusion starting in J

As part of the propo  
Prospective Paymen  
Refinements: Home  
Requirements: Hom  
of National securiti  
requirements to imp  
Century Cures Act  
cover "professional  
virtually eliminated  
reimbursement. It i  
The drugs that home  
including the comp  
services CMS has cr  
services.

By limiting reimburs  
furnished by skilled  
of the legislation. T  
enacting this legisla



HONORABLE PATRICK J. TIBERI  
MEMBER OF CONGRESS  
OHIO'S 12<sup>th</sup> DISTRICT  
2001 - 2018

August 17, 2018

The Honorable Seema Verma  
Administrator, Center for Medicare and Medicaid Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Administrator Verma:

I write as the former Representative of Ohio's 12th Congressional district and Chairman of the House Ways & Means Subcommittee on Health. I was the lead sponsor of H.R. 3163, the Medicare Part B Home Infusion Services Temporary Transitional Payment Act of 2017, which passed Congress as Section 50401 of H.R. 1892, the Balanced Budget Act of 2018 (Pub. L. 115-123). This legislation established a temporary payment to home infusion providers before the new payment structure begins in 2021, as authorized by Section 5012 of the 21st Century Cures Act (Pub. L. 114-255). I urge the Centers for Medicare and Medicaid Services (CMS) to appropriately implement this transitional payment and new reimbursement model to ensure vulnerable Medicare beneficiaries have access to critical home infusion services starting in January 2019.

The CY2019 Home Health Proposed Rule (CMS-1689-P) proposed to limit reimbursement to home infusion providers to "the day on which home infusion therapy services are furnished by skilled professionals in the individual's home." (83 Fed. Reg. 32464.) This physical presence requirement contradicts congressional intent when this legislation, both as introduced by me and as amended, passed the U.S. House and Senate. Our legislation created a structure for CMS to reimburse providers for their "professional services" – meaning the services that were delivered each day when a drug was infused at home.

# Where Do We Go From Here



- March -- the Government has to assemble the “administrative record” and file it with the Court
- March 1 -- NHIA’s opening brief filed
- April 1 -- The Government will oppose NHIA’s arguments, and move to dismiss on jurisdictional grounds – this is expected
- April 15 -- NHIA will Reply to the Government’s opposition on the merits, and oppose the Motion to Dismiss
- May 1 -- The Government will file on last brief on jurisdiction
- June/July the Court will hear argument, and then we await Judge Leon’s decision

# Outcomes

- If we win, providers re-file claims and are paid for each day patient is infused in the home – relief back to January 1, 2019
- If we lose, return to Congress to correct statute – relief is prospective (but right now CMS interpretation applies 2021 and after)





