



NHIA TALK INFUSION WEBINAR

What CMS' 2021 Home Health Payment Rule Means for Home Infusion

Today's Presenters



Connie Sullivan
President and CEO



Bill Noyes
Senior Vice President of
Reimbursement Policy



Shea McCarthy
Director Legislative Affairs, NHIA
Senior VP, Thorn Run Partners



NHIA TALK INFUSION WEBINAR

Agenda

- Overview of CY 2021 Home Health Proposed Rule as it relates to the permanent HIT Services
 - Rates and billing
 - Plan of Care Requirements
 - Professional Services
 - Supplier Requirements
- Legislative Update
- Litigation Update



CY 2021 Home Infusion Proposed Rule

Issued on June 25th, goes into effect Jan. 1, 2021

Outlines payment for home infusion therapy permanent benefit in CY 2021

Final Rule expected in November 2020



CY 2020 Home Infusion Reimbursement

- Reimbursement only occurs on a day when a professional is present in the patient's home
- 2020 rates based on 2020 PFS (4hrs)
 - 2020 Rates:
 - Category 1: \$ 138.24
 - Category 2: \$ 208.60
 - Category 3: \$ 234.60
- Within 30 days of drug
- 15 min increments



Like the Transitional
HIT Services, the
Permanent HIT
Services ONLY
apply to a subset of
Part B DME Infused
Drugs Covered
Under the External
Infusion Pump LCD

- Does not apply to...
- Parenteral Nutrition
- Enteral Nutrition
- IVIG
- Part D infused drugs



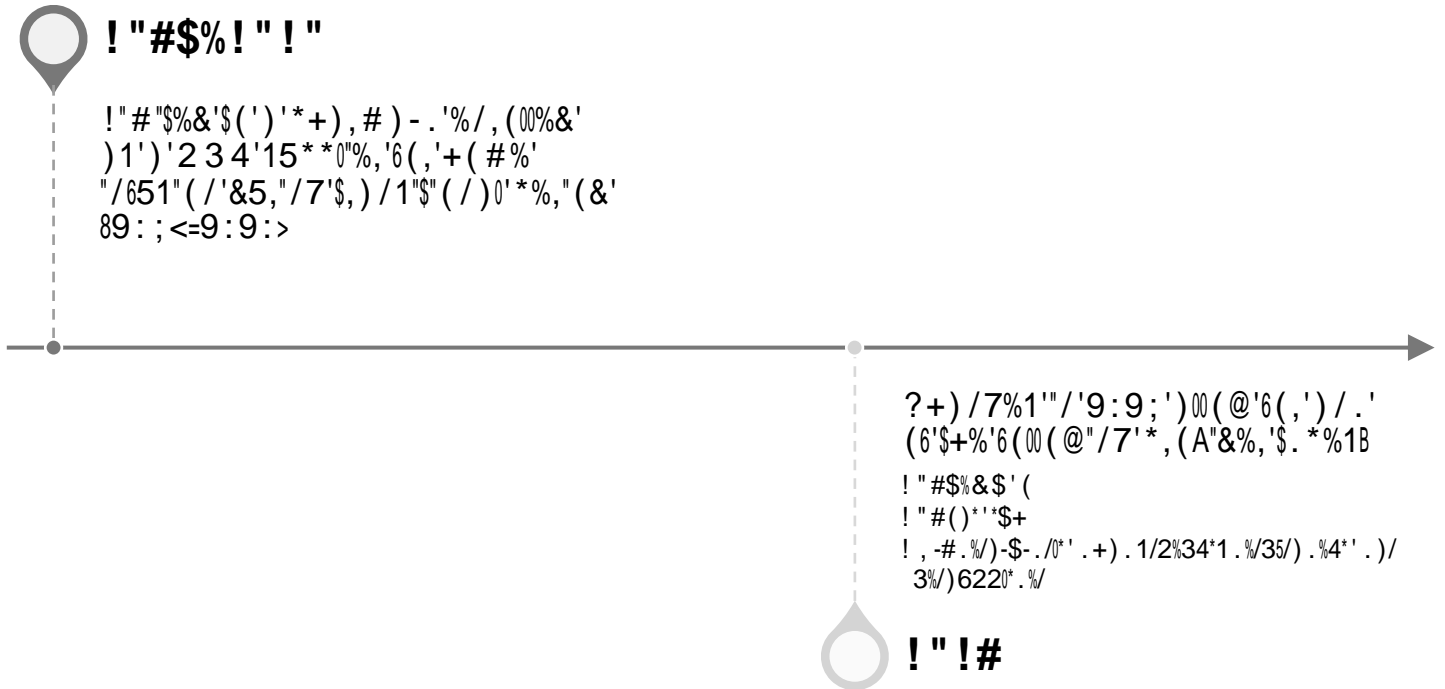
Permanent Benefit (2021 and Beyond)

- Maintains Payment Categories
 - Category 1: Antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs, and chelation drugs.
 - Category 2: Subcutaneous infusion therapy
 - Category 3: Chemotherapy
- Continues to bundle pharmacy professional services in unit of single payment, payable only on a day when a nurse is present in the patient's home and a drug is being administered that day
- Sets higher rate for first visits



Qualified Infusion Therapy Services Provider

CMS declined to add a new requirement that the home infusion therapy supplier be enrolled in the DME program



Qualified Provider

A home infusion therapy supplier under § 424.68, for purposes of § 424.68, would mean a supplier of home infusion therapy that meets all of the following requirements:

- Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.
- Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.
- Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.
- Is enrolled in Medicare as a home infusion therapy supplier consistent with the provisions of § 424.68 and part 424, subpart P.

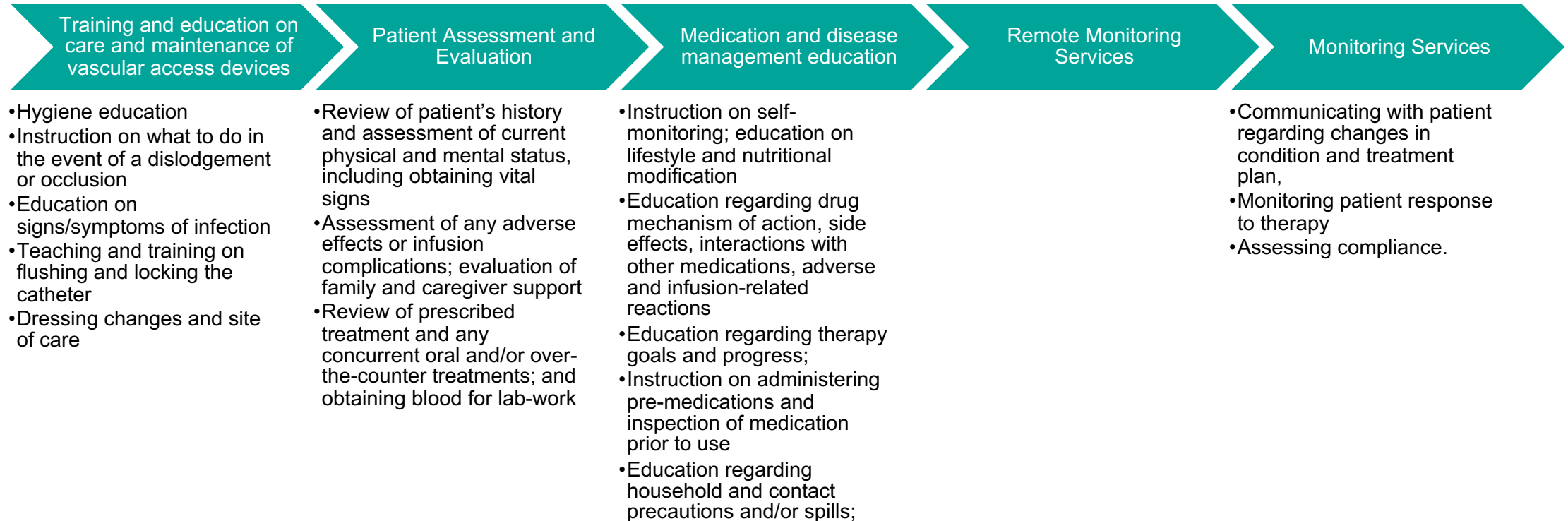


Professional Services

- Services are distinct from those required and paid under the DME benefit
 - Instruction on how to safely and effectively use the DME equipment
 - Compounding and dispensing



Professional Services – Final Rule



Plan of Care Elements

Must specify:

- Infused medication, dosage and frequency
- Type, duration and frequency of the services being provided
- Professional services to be utilized for treatment
- Care and services specific to the patient's needs
- Type of healthcare professional that will deliver each of the services



Plan of Care

- Must be signed by a physician
- No standard timeframe for regular review
- Statute does not require that the same physician establish the home infusion plan of care and order the DME
- CMS will consider in future rule-making whether an applicable provider (NP, PA) can update the plan of care

Individualized
Care Plan



Intersection with Home Health

All nursing will be provided under the new Home Infusion Therapy Benefit

Starting in 2021, a Medicare Certified Home Health Agency may not provide infusion-related nursing under the home health episode of care.

Patients do not need to be homebound to receive infusion nursing

Home Infusion Therapy Suppliers do not need to be Medicare Certified to provide nursing services



Accrediting Organizations (AO)

- AO Application Deadline was February 2020
- CMS is processing applications as they come in
- Approved programs
 - Joint Commission
 - ACHC
 - URAC
- Filed application, awaiting approval
 - The Compliance Team
 - CHAP
 - NABP
- Notice of HIT AO applications and approvals are posted in Federal Register



Payment Categories 2021

- Based on FIVE hours under the Physician Fee Schedule (PFS)
- First visit tied to evaluation and management payment differential (160%)
- Subsequent visit adjusted for budget neutrality (-3.75%)
- First visit billable only 60 days after patient is discharged from home infusion
- No coverage for Ziconotide, Floxuridine, Hizentra, or **Morphine administered intrathecal**

	First Visit*	Subsequent Visits*
Category 1 G0068	\$ 256.35	\$ 154.26
Category 2 G0069	\$ 358.59	\$ 215.78
Category 3 G0070	\$424.43	\$ 255.40

*Estimates based on CY 2020 PFS rates



Rate Adjusters

- Geographic Wage Index
 - Geographic Adjustment Factor (GAF)
 - 112 different locations
 - Budget neutral
 - High: Alaska 1.291
 - Low: Mississippi 0.893
 - $GAF * UnadjRate = Rate$ GAF i
 - The list of GAFs by locality for this proposed rule is available as a downloadable file at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html>.
- Annual adjustment based in Consumer Price Index for all urban consumers (CPI-U) – which can be negative.



Category 1

J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg
J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg
J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg
J2278	Injection, ziconotide, 1 microgram
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg

**NHIA TALK INFUSION WEBINAR**

Category 2	
J1555 JB ¹	Injection, immune globulin (cuvitru), 100 mg
J1559 JB	Injection, immune globulin (hizentra), 100 mg
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
Category 3	
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9200	Injection, floxuridine, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg



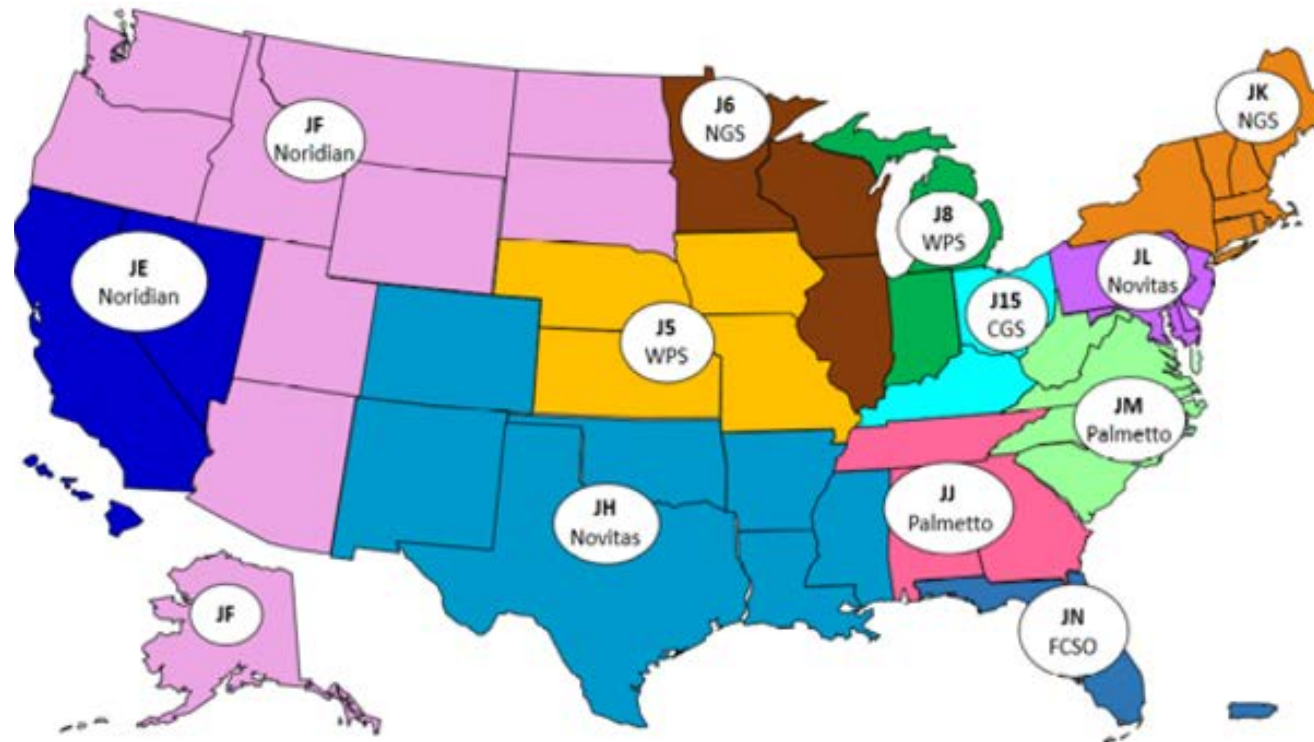
Enrollment

- Per CMS, entities will not be able to enroll with the A/B MACs as HIT Service providers until after the final rule is released – November 2020.
- CMS will expedite the sub-regulatory process
 - Providing instruction to the MACs as to how to implement and “stand up” this new benefit
 - Stakeholder education
- Effective date of enrollment (billing privileges) is 30 days prior to application filing date.
 - Under PHE 90 days prior to application filing date.



HIT Services Billed to the A/B MACs

- Register with A/B MACs using the [CMS-855B](#) form or electronic PECOS
- Must enroll in each Jurisdiction you wish to bill HIT Services, based on beneficiaries zip code
- Certify you meet enrollment requirements and standards detailed in 42 CFR **Part 424-P: Requirements for Establishing and Maintaining Medicare Billing Privileges**
- Pay Application Fee, \$595 in 2020



MAC Enrollment Screen

Limited, Moderate, High

Limited: Does not require a site visit (this is different from AO site visit)

Screening for Limited

1. Verifies that the provider or supplier meets all applicable federal regulations and state requirements for their provider or supplier type.
2. Conducts state license verifications.
3. Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.



Many Questions Remain

- Supplier type selection on 855B
- Practice location (bricks and mortar)
- Licensure – in all Jurisdictions?
 - Subcontracting
- Robustness of the network of providers?
 - “Using existing accreditation statistics and our internal data, we generally estimate that: (1) There are about 600 home infusion therapy suppliers that would be eligible for Medicare enrollment”

NHIA continues an open line of communication with CMS to voice our concerns



Enrollment 855B – Supplier Type

A. Type of Supplier

Check the appropriate box to identify the type of supplier you are enrolling as with Medicare. If you are more than one type of supplier, submit a separate application for each type. If you change the type of service that you provide (i.e., become a different supplier type), submit a new application.

Your organization must meet all Federal and State requirements for the type of supplier checked below.

TYPE OF SUPPLIER: *(Check one only)*

- | | |
|--|--|
| <input type="checkbox"/> Ambulance Service Supplier | <input type="checkbox"/> Mass Immunization (Roster Biller Only) |
| <input type="checkbox"/> Ambulatory Surgical Center | <input type="checkbox"/> Pharmacy |
| <input type="checkbox"/> Clinic/Group Practice | <input type="checkbox"/> Physical/Occupational Therapy Group in Private Practice |
| <input type="checkbox"/> Hospital Department(s) | <input type="checkbox"/> Portable X-ray Supplier |
| <input type="checkbox"/> Independent Clinical Laboratory | <input type="checkbox"/> Radiation Therapy Center |
| <input type="checkbox"/> Independent Diagnostic Testing Facility | <input type="checkbox"/> Other <i>(Specify)</i> :
<input type="text"/> |
| <input type="checkbox"/> Intensive Cardiac Rehabilitation | |
| <input type="checkbox"/> Mammography Center | |



855B – Service Area

SECTION 4: PRACTICE LOCATION INFORMATION *(Continued)*

D. Rendering Services in Patients' Homes

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	<input type="checkbox"/> CHANGE	<input type="checkbox"/> ADD	<input type="checkbox"/> DELETE
DATE <i>(mm/dd/yyyy)</i>			

Furnish the city/town, State and ZIP code for all locations where health care services are rendered in patients' homes. If you provide health care services in more than one State and those States are serviced by different Medicare fee-for-service contractors, complete a separate CMS-855B enrollment application for each Medicare fee-for-service contractor's jurisdiction.

If you are adding or deleting an entire State, it is not necessary to report each city/town. Simply check the box below and specify the State.

Entire State of

If you are providing services in selected cities/towns, furnish the locations below. Only list ZIP codes if you are not servicing the entire city/town.

CITY/TOWN	STATE	ZIP CODE



What can I be doing to prepare now?

- Talk with your AO regarding Medicare HIT Services accreditation.
- Become familiar with the A/B MAC Jurisdictions and map to your coverage areas.
- Review the 855B enrollment forms
- Evaluate whether or not you will apply to provide the HIT services – and to what geographic areas.
- If you do not plan to provide Medicare HIT Services consider if/how you will continue to provide the DME covered drugs, equipment and supplies.



Comments

- CMS is accepting comments on the final rule, specifically regarding making telehealth provisions permanent.
- Comments are due August 31, 2020.



Shea McCarthy

Director of Legislative Affairs, NHIA
Senior VP, Thorn Run Partners



NHIA TALK INFUSION WEBINAR

The Solution: Draft Legislation

- **Bill the Drug to Part D** – Home infusion providers are already able to acquire the majority of infused drugs through the Medicare Part D program.
 - Part D plan sponsors are required to maintain networks of home infusion pharmacies.
- **Bill the Services to Part B** – Provide direct reimbursement to the home infusion provider using existing service codes for home infusion.
 - Every day of infusion: G0068
 - Nursing days: G0070



Notable Supporters



Legislative Opportunity

- Congressional leaders will spend their two-week July 4th break discussing the framework of the next congressional spending package.
- Assuming Speaker Pelosi and Leader McConnell can reach a deal on Unemployment Insurance and business liability, key committees will be prepared to tack on additional policies into a broader package.
 - Congress will adjourn again for a month-long August recess, creating a hard deadline to reach a deal.
- Sen. Tim Scott (R-SC) is prioritizing the bill; the Senate Finance Committee will help decide its fate.



Connie Sullivan
President & CEO, NHIA



NHIA TALK INFUSION WEBINAR

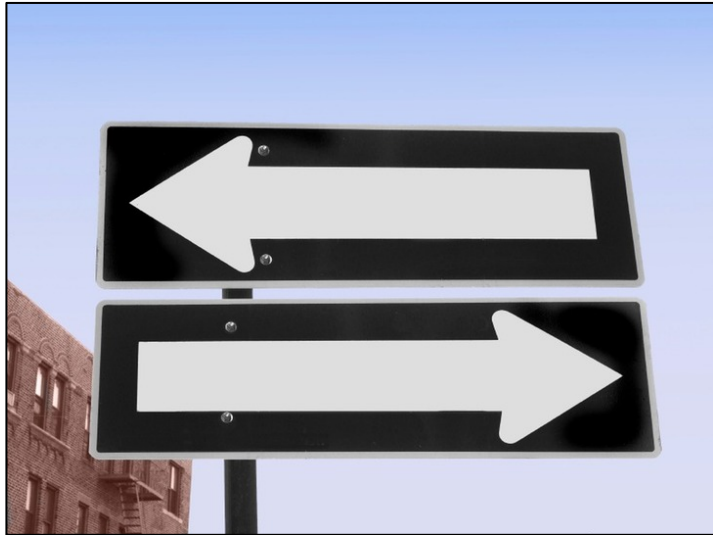
Summary of NHIA's Arguments



- 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
- Plain reading of the law does not require professional services to be furnished “in the home”



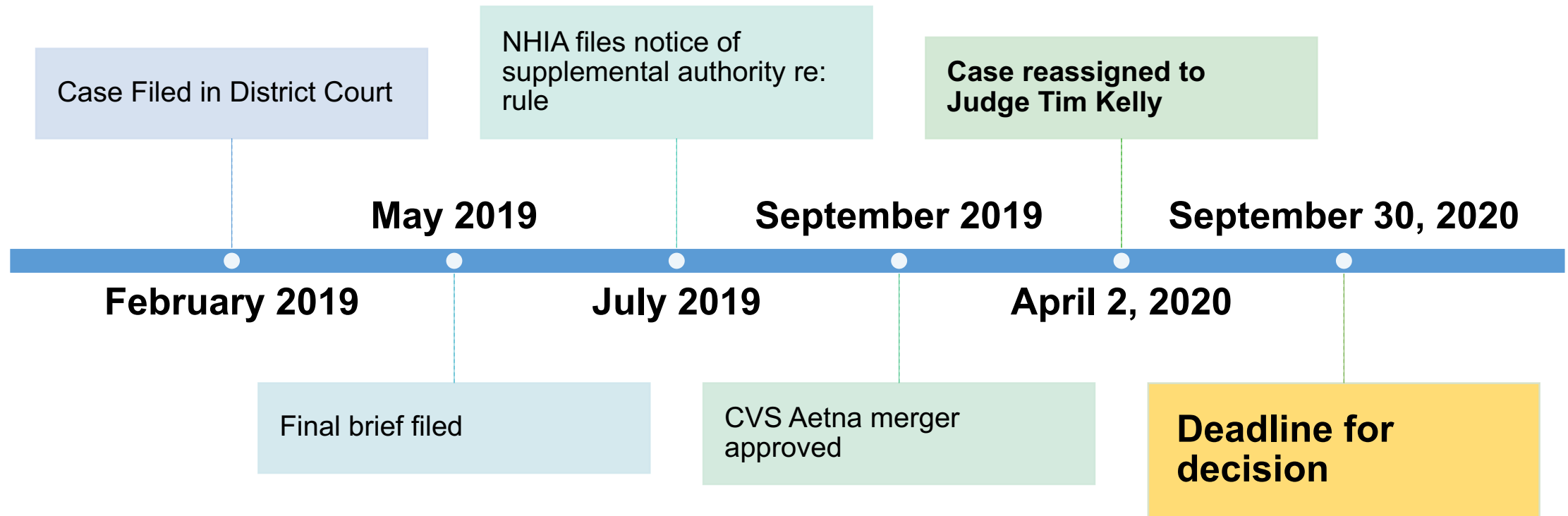
Summary of CMS' Arguments



- Law is ambiguous and court should defer to the agency
- 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

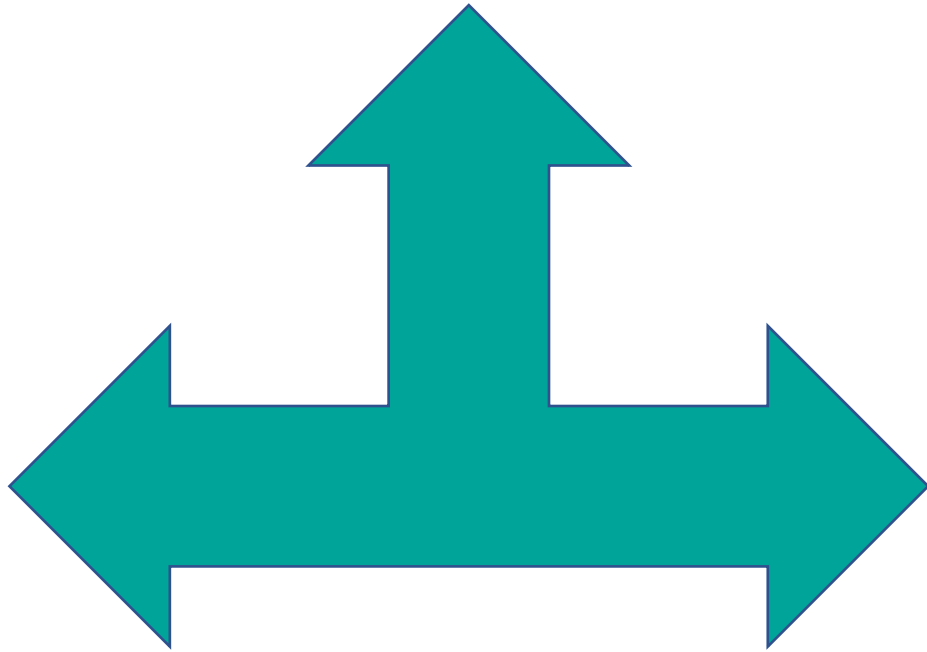


Litigation Status



NHIA TALK INFUSION WEBINAR

Potential Outcomes



- Court rules in our favor, requires reimbursement per infusion drug administration calendar day
- Court determines that CMS did not comply with the law, requires CMS to issue new regulation
- Court rules in CMS' favor
 - We seek immediate legislative relief



Impact on Cures

- Reaffirm Congressional intent
- Establish a precedent that HIT services are to be paid every day of infusion
- Does not require CMS to change their approach to the 2021 permanent benefit



Support our Fight for Medicare Coverage of Home Infusion Therapy

Donate to NHIA's PITCH In Campaign

Our PITCH In campaign raises funds to support the association's advocacy and legislative work, to ensure high-quality home infusion therapy is accessible to all.



In 2020, We Need Your Support

To commit to being a contributor at any level, please contact info@nhia.org.



NHIA TALK INFUSION WEBINAR