JOE FIANDRA ACCESS TO HOME INFUSION ACT (H.R. 5397) BILL SUMMARY

The Joe Fiandra Access to Home Infusion Act (H.R. 5397) was introduced in the House of Representatives in September of 2023, and mirrors a 2020 proposed rule from the Centers for Medicare and Medicaid Services (CMS) to modify the DMEPOS external infusion pump benefit. Since introduced, H.R. 5397 has been amended from the original text that matched the 2020 rule. The intent of the legislation is to make it possible for additional drugs and biologics to be added to the Part B DMEPOS external infusion pump benefit by modifying the "appropriate for use in the home" requirement for durable medical equipment (DME) if each of the following criteria are met:

1. The FDA approved prescribing information instructs that the drug associated with the pump should be administered by or under the supervision of a health care professional (HCP), and
2. A home infusion therapy supplier administers or supervises the administration of the drug or biologic in a safe and effective manner in the patient's home, and
3. The FDA prescribing information instructs that the drug be infused at least 12 times per year:
    a. intravenously or subcutaneously; **or**
    b. at infusion rates that the Secretary determines would require the use of an external infusion pump.

As CMS explained in their final rule in 2020, this previous attempt to modify the definition of "appropriate for use in the home" was never finalized due to stakeholder concerns about pumps being used inappropriately to prompt coverage for home infusion, it being a narrow policy that would not expand access for many beneficiaries, the higher cost to beneficiaries, and a need to understand which drugs and biologics would be included.

WHO SUPPORTS H.R. 5397?

The legislation is supported by a handful of drug manufacturers, the trade association BIO, and some patient groups who believe this policy will make their drugs eligible for home infusion by adding them to the Part B DMEPOS benefit. The bill was introduced in the House of Representatives by Rep. Brian Fitzpatrick (R-PA) and Rep. Neal Dunn (R-FL).

WHAT DRUGS WOULD BE IMPACTED BY H.R. 5397?

The original rule published by CMS used patisiran (Onpattro® by Alnylam) as an example of a drug that would meet the revised criteria. Patisiran's approved labeling states that it should be infused by a HCP every 3 weeks over approximately 80 minutes, at an initial infusion rate of 1 mL/min (60 mL/hr) for the first 15 minutes, then increase to 3 mL/min for the remainder of the infusion. Other drugs being targeted by this bill have infusion rates ranging from 20 to 167 mL/hr. **Based on the current language, any HCP-administered drug or biologic administered IV or SC at least 12 times per year could qualify.** It is difficult to know the full extent of the drugs that could qualify for

the benefit under this policy as it also depends on how CMS defines the infusion rates that require the use of an external infusion pump. NHIA believes that the policy has the potential to create a path to coverage a broad range of drugs and biologics used for many chronic medical conditions, many of which would not typically require a pump for administration. Drugs added to DMEPOS using this pathway are no longer eligible for coverage under Part D where patient out of pocket costs are capped at $2000 per year starting in 2025.

WHAT CONCERNS DOES NHIA HAVE ABOUT H.R. 5397?

NHIA has several concerns about this approach to expanding coverage for home infusion. First and foremost, the DMEPOS infusion benefit is centered around the use of the pump, with the drug coverage being secondary to the item of DME. Today, the criteria for use of an external infusion pump in the home requires a patient to use the equipment *independently* — eliminating the need for a provider to be physically present during each infusion. The newly proposed eligibility requirement that an HCP administer or "supervise" the administration is in direct conflict with the current policy that a patient use the DME independently to administer the drug. Additionally, pumps in home infusion are generally reserved for specific situations such as continuous or extended infusions (e.g., parenteral nutrition, inotropic medications, opioids for pain) or when administering drugs three or more times per day (e.g., certain antibiotics). NHIA has a practice standard outlining the situations where pumps are recommended.

Second, the home infusion therapy (HIT) services benefit that was intended to cover all professional services related to the provision and administration of DMEPOS infusion drugs has failed to garner sufficient provider participation. Currently, CMS offers no separate payment for non-nursing days to cover the extensive pharmacy professional services, severely limiting access to the drugs included in the benefit. Therefore, most states have few if any providers offering HIT services to Medicare beneficiaries. A fair services payment is critical to ensuring access in Part B due to the drug payment model based on Average Sales Price, which for infusion pharmacies is often near, or below the drug acquisition cost. If additional drugs are added to the benefit, there is no guarantee that a provider will be available to serve beneficiaries with home infusion. The charts in Appendix I illustrate the very limited number of beneficiaries served in 2021 with HIT services, along with the limited number of providers participating across states.

The third major concern is that making a drug eligible for Part B DMEPOS renders it ineligible for coverage under the Medicare Part D benefit, even if there is little to no access in Part B. While coverage for home infusion under Medicare Part D is a challenge in its own right — given that there is no complete benefit for the necessary supplies and services — many patients find that the drug coverage in Part D is more favorable than in Part B as Medicaid, employer-based coverage, or Medicare Advantage plans often offer coverage for the services and supplies that are not covered by traditional Medicare. Unfortunately, as detailed in Section 20.2 of the Medicare Part D manual, drugs covered under the Part B DMEPOS benefit are not allowed to be covered by Part D plans. Therefore, once new drugs are added to the DMEPOS benefit, they will no longer be available through existing coverage

pathways, and the only way that beneficiaries would have access is by using a pump (even when the pump is unnecessary to accomplish the administration).

Finally, NHIA is concerned about the potential impact on patient's out-of-pocket costs under this legislation, as **the (very) modest savings projected by CBO is attributable to Medicare beneficiaries bearing a higher share of cost-sharing.** CMS has also concluded, "the beneficiary would be responsible for a larger portion of the total costs" and "estimate[d] savings of roughly $3 million in CY 2021… is largely attributable to the differential in cost sharing between the hospital outpatient setting and the home." Beneficiaries without supplemental insurance would be at a particular disadvantage, especially once the catastrophic out-of-pocket responsibilities in Part D are eliminated starting in 2024.

Other Bills Would Expand Part B DMEPOS, Why Is NHIA So Concerned About H.R. 5397?

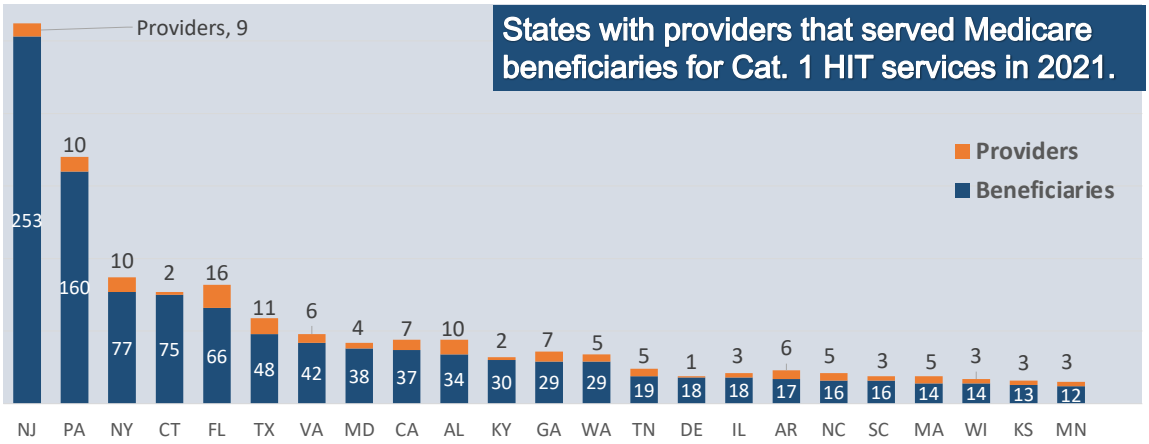
Other groups such as the GBS/CIDP Foundation and Alpha-1 Foundation have also introduced bills to add drugs for specific conditions to Part B DMEPOS. NHIA has generally not supported any effort to expand home infusion access through the Part B external infusion pump benefit and prefers a more comprehensive approach to improving access for the nearly 300 drugs infused at home today for patients with commercial insurance, including those that do not require the use of an external infusion pump. For the reasons outlined above, NHIA believes H.R. 5397 could have major unintended consequences and pull many drugs and biologics into the Part B DMEPOS benefit, reducing access for beneficiaries due to higher out-of-pocket costs and lack of provider participation.

What Is NHIA's Solution To The Lack of Medicare Coverage For Home Infusion?

A bill introduced in early 2023, the Expanding Care in the Home Act (H.R. 2853), outlines a comprehensive approach to creating a Medicare home infusion benefit that provides access for a much wider range of infused therapies. NHIA believes the drug coverage should remain in Part D with a wrap-around supplies and services benefit in Part B. Additionally, NHIA is working to fix CMS's flawed implementation of the HIT services benefit with the Preserving Patient Access to Home Infusion Act (H.R. 4104, S. 1976).

APPENDIX I: HIT PROVIDERS AND UTILIZATION BY STATE – 2021

Category 1 (G0068) HIT Providers & Utilization by State - 2021



Source: https://data.cms.gov
*Beneficiary counts are based on the state where the provider is located.
**States not listed either had zero or fewer than 11 total beneficiaries receiving services.
***According to the 2023 CMS HIT Monitoring report, which includes data through June 2022, the following states had no HIT Category 1 providers: AK, CO, MT, ND, NM, SD, VT, and WY.

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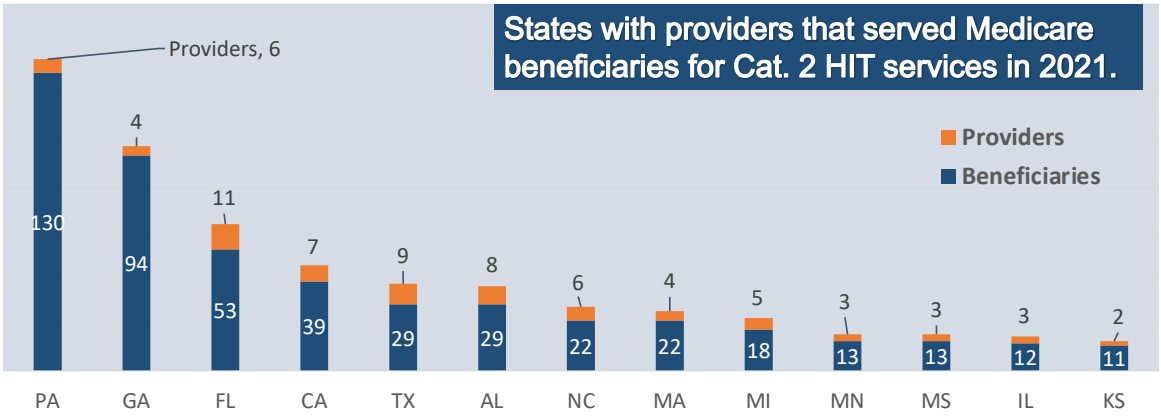
Category 2 (G0069) HIT Providers & Utilization by State - 2021



Source: https://data.cms.gov
*Beneficiary counts are based on the state where the provider is located.
**States not listed either had zero or fewer than 11 total beneficiaries receiving services.
*** According to the 2023 CMS HIT Monitoring report, which includes data through June 2022, the following states had no HIT Category 2 providers: AK, DE, MT, ND, SD, UT, VT, and WY.

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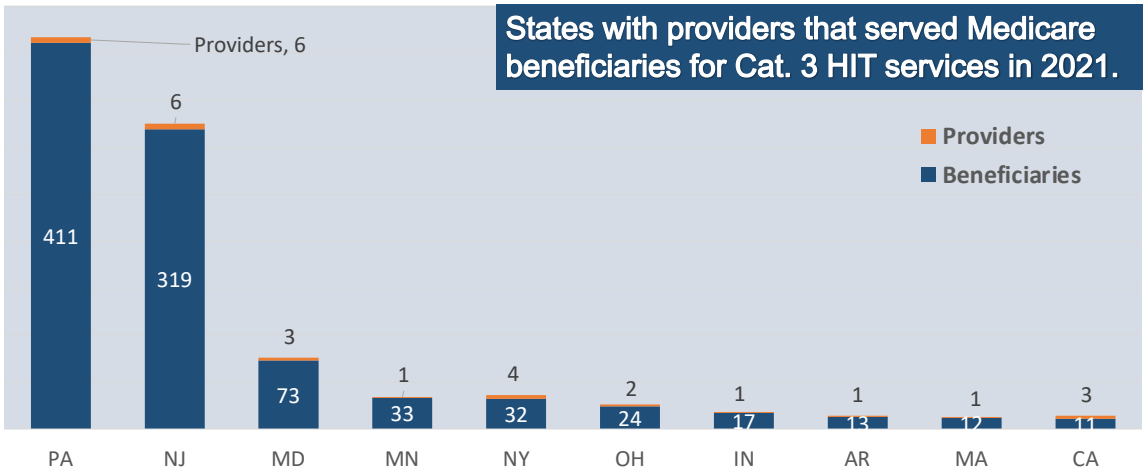
Category 3 (G0070) HIT Providers & Utilization by State - 2021



Source: https://data.cms.gov
*Beneficiary counts are based on the state where the provider is located.
**States not listed either had zero or fewer than 11 total beneficiaries receiving services.
***According to the 2023 CMS HIT Monitoring report, which includes data through June 2022, the following states had no HIT Category 3 services: AK, CO, CT, GA, HI, IL, KS, OK, MI, MS, MT, ND, NE, NV, SD, UT, VT, and WY

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