WHITE PAPER

Policy Impacts on Medicare Beneficiary Access to Part B DMEPOS Home Infusion Therapy

NHIA
National Home Infusion Association

Executive Summary

The Part B Durable Medical Equipment and Prosthetics/ Orthotics and Supplies (DMEPOS) benefit serves an important need in the Medicare program by creating home infusion access for a small number of highly vulnerable beneficiaries who rely on continuous infusions of life-saving medications.

Over the past 5 years, competitive bidding, drug pricing changes mandated by 21st Century Cures, and other policies implemented by the Centers for Medicare and Medicaid Services (CMS) have reduced the rate of reimbursement for each component of the DMEPOS home infusion program, which has in-turn reduced overall benefit utilization. Fewer than 16,000 beneficiaries were served in 2018, the most recent year from which utilization data is publicly available. This represents a 25.2% decline over the 5 years from 2014 to 2018.

Home infusion provider participation also declined between 2014 and 2018 with 52% fewer suppliers billing for DMEPOS infusion therapies. Flawed implementation of the temporary professional services benefit created by the Bipartisan Budget Act of 2018 has done little to reverse the trend, despite Congress' intent to maintain participation in the benefit. 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 benefit 21st Century Cures Act that began in January 1, 2021 is likely to result in further declines in utilization due to low provider enrollment. To date, fewer than 250 individual supplier locations have enrolled to provide Part B home infusion therapy (nursing) services under the new benefit.

NHIA has long held that reducing drug payments without implementing a sufficient service payment to the home infusion pharmacy (supplier) would result in less access to home infusion for Medicare beneficiaries. Over the 5-year study period, the combined Medicare spend for pumps, supplies, and drugs has been reduced by 58%. Average pre-Cures spending (2014-2016) on the benefit was nearly $200M per year higher than post-Cures (2017-2018). Policy decisions by CMS have resulted in driving patients out of the home and back into facilities for care, where costs to the Medicare program are higher. NHIA believes the Part B DMEPOS home infusion benefit is failing to meet the current needs of Medicare beneficiaries and is too flawed to serve as a basis for broader coverage. Legislation is urgently needed to protect Medicare beneficiary access to home infusion services under the Part B DMEPOS benefit, and a new straightforward, equitable solution to improving access to home infusion for all Medicare beneficiaries should be pursued through the Centers for Medicare and Medicaid Innovation (CMMI).

> The Part B DMEPOS home infusion benefit is failing to meet the current needs of Medicare beneficiaries and is too flawed to serve as a basis for broader coverage.

BACKGROUND

Medicare Part B offers coverage for infusion pumps as items of durable medical equipment (DME) under the Durable Medical Equipment and Prosthetics/Orthotics and Supplies (DMEPOS) benefit. The same benefit also covers certain drugs, catheter supplies, and the cassettes or bags required for the effective use of the infusion pump. Over the past 5 years, several policy changes implemented by the Centers for Medicare and Medicaid Services (CMS) have reduced the rate of reimbursement for each component of the program, which has in-turn reduced utilization. CMS's recent implementation of coverage for home infusion therapy services as a nursing benefit has resulted in continued declines in beneficiary access. The decline of Part B home infusion participation is not reflective of broader industry trends. A report published by the National Home Infusion Foundation in 2020 shows overall industry growth exceeded 300% during the past decade, largely driven by higher demand for home-based care and cost savings.[1]

NHIA has analyzed publicly available data obtained from CMS, as well as proprietary claims data, which support the hypothesis held by NHIA and other industry stakeholders that reducing drug payments without implementing a sufficient professional services payment results in an unsustainable benefit and negatively affects patient access to home infusion. As members of the U.S. Senate pointed out in a 2018 letter to CMS, implementation of Cures "contradicts [the] intent in drafting and enacting this legislation and makes the reimbursement required by the bill inadequate." NHIA will introduce legislation in 2021 to intervene on behalf of vulnerable seniors who depend on home infusion to avoid extended hospitalization or admission to skilled facilities.

IMPACT OF COMPETITIVE BIDDING ON DMEPOS HOME INFUSION

The external infusion pumps and supplies (EIP) product category was only included in Round One Recompete (R1RC) of the Medicare Competitive Bidding Program. The R1RC was in place from January 1, 2014 through December 31, 2016 and included 9 competitive bidding areas (CBAs). CMS reports indicate that the resulting savings from the EIP product category was the lowest compared with the other product categories in the R1RC, which may explain why EIP was not included in any of the subsequent rounds of the program (see Exhibit 1).

Beginning January 1, 2016, CMS made nationwide adjustments to the DMEPOS fee schedules for all items that were competitively bid, including the external infusion pump and supply items. Between 2014 and 2018, the average annual supplier monthly rental payment for ambulatory infusion pumps (E0781) fell by 16%, decreasing from $185.52 to $159.42, while the payment rate for syringe pumps (E0779) remained stable averaging $11.28. Reimbursement for ambulatory pumps (K0455) used to deliver medications for pulmonary arterial hypertension (PAH) also remained relatively flat.

Supplier payment amounts for pump bags and cassettes, as well as catheter supplies dropped by 39% and 23% respectively over this same period. The impact of competitive bidding on home infusion pumps and supplies from 2014 to 2016 cannot be directly assessed because insulin pump supplies were billed using the same codes. However, the

EXHIBIT 1

DMEPOS Competitive Bidding Program: Round One Recompete (R1RC) Average Savings[2]

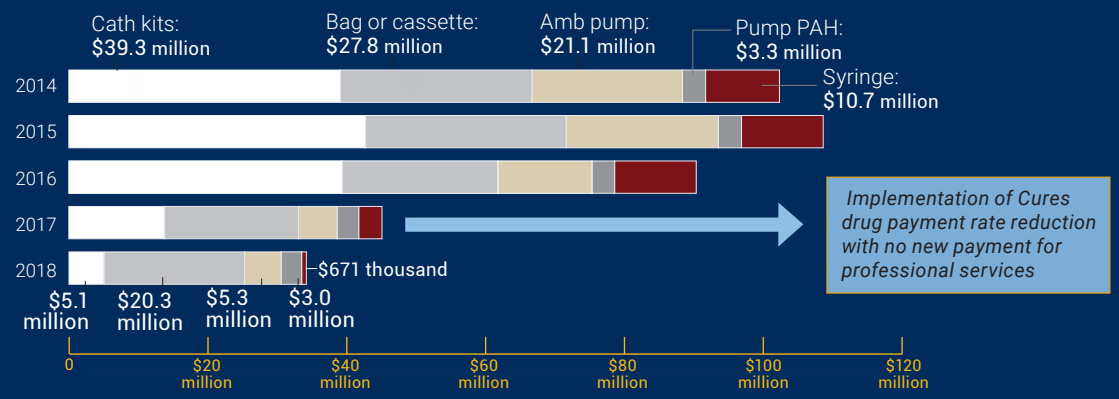
Enteral Nutrients, Equipment and Supplies	External Infusion Pumps and Supplies	General Home Equipment and Related Supplies and Accessories	NPWT Pumps and Related Supplies and Accessories	Respiratory Equipment and Related Supplies and Accessories	Standard Mobility Equipment and Related Accessories	**Overall Average**
41%	21%	47%	42%	40%	34%	37%

* Weighted average savings based on weighted percentage reductions in Medicare allowed payment amounts for items in each product category. Weights used in calculating average reductions were the same weights assigned to each code as part of the Request for Bids.

31% decrease in spending on equipment and supplies from 2017 to 2018 (after insulin items were given separate codes) is related to the drop in benefit utilization and can be attributed to other CMS policy changes toward home infusion. It is important to note that R1RC single payment amounts and the subsequent nationwide rates were based on bids submitted by suppliers prior to the shift to Average Sales Price (ASP)-based pricing required under 21st Century Cures, when they were receiving Average Wholesale Price (AWP)-5% for the drugs.

EXHIBIT 2

Annual Medicare Supplier Payments for Infusion Pumps and Supplies



* Insulin items removed in 2017

21ST CENTURY CURES

Signficant decreases in reimbursement for Part B home infusion drugs, implemented as a result of 21st Century Cures, have been among the largest drivers of payment reductions for home infusion providers. In 2013, the Office of Inspector General (OIG) completed a study titled, "Part B Payments for Drugs Infused Through Durable Medical Equipment" that studied AWP-based payment methodology. The report determined that Medicare payment amounts for DME infusion drugs exceeded the corresponding ASP by 54—122% annually, and that Medicare spending on DME infusion drugs would have been reduced by 44% ($334 million) between 2005 and 2011 had payment been based on ASPs.[3] However, it is important to note the study limitations disclose that OIG did not assess the professional services associated with home infusion therapy. In its suggestions for moving away from AWP-based payments, the OIG included a recommendation that home infusion drugs and equipment be included in future rounds of competitive bidding — even as the report acknowledged that professional services play an important role in maintaining access and safety. The OIG report also makes no mention of the implications of "class of trade" on beneficiary access. Class of trade designations allow manufacturers to charge home infusion pharmacies significantly higher prices for drugs compared to physicians and hospitals, therefore home infusion suppliers rely more on service fees to cover costs.

> 98% of all Medicare DME-infused drug spend is for 4 drugs.

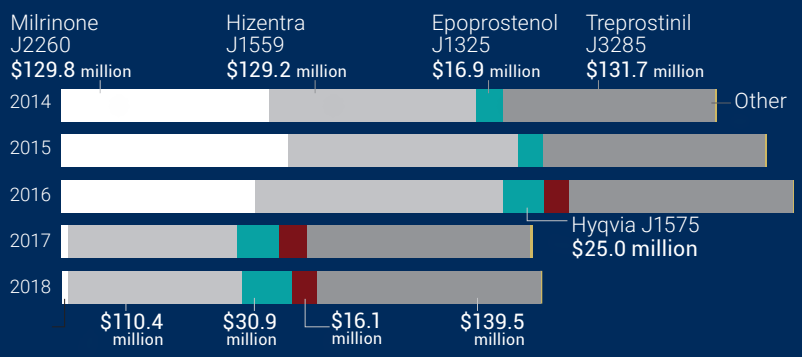
While CMS did not pursue competitive bidding for home-infused drugs, the agency captured the drug savings in 2016 when Congress passed Cures, reducing the reimbursement for home infused drugs from AWP-5% to ASP+6%. To ensure continued access to home infusion, Congress mandated that CMS establish a new payment for the professional services associated with providing home infusion. The drug price reductions took effect in 2017, while the home infusion therapy (HIT) service payment wasn't to be added until 2021. However, Congress later acknowledged that the 4-year gap in coverage for services would result in patients losing access, and lawmakers ultimately attempted to bridge the gap by passing legislation to create a temporary transitional benefit. Specifically, the Bipartisan Budget Act of 2018 provided a temporary services benefit for 2019 and 2020, which established a precedent for the permanent benefit that began on January 1, 2021.

In 2017, the first year of ASP-based pricing, Medicare drug payments dropped 34% by over $160 million. While the majority of the decrease was derived from payments for milrinone (-97%), a drug used to treat end-stage heart failure, other drug therapies were also impacted, including inexpensive generic drugs such as acyclovir (-82%), deferoxamine (-49%), and 5-FU (-60%). The graph in Exhibit 3 illustrates how drug spending in Part B was distributed pre- and post-Cures.

All drug spending in Part B since 2014 has been concentrated on a small number of products. Nearly 98% of all Medicare DME-infused drug spend is for 4 drugs: epoprostenol, treprostinil, Hizentra®, and Hyqvia®. Hizentra and treprostinil alone make up 82% of drug spending. The post-Cures average annual Medicare allowable per beneficiary increased for epoprostenol ($37,759; 16%), treprostinil ($147,236; 4.5%) and Hyqvia ($48,081; 7.7%). The average post-Cures allowable for Hizentra decreased by 30% ($39,327). Utilization of epoprostenil and treprostenil for PAH also remained

EXHIBIT 3

Annual Medicare Spending on DMEPOS Drugs, 2014-2018



relatively unchanged over the 5-year period. PAH therapies are unique from all other Part B drugs in that they are part of manufacturer sponsored distribution program (similar to the insulin pump model), use a proprietary pump, and distribution is limited to 2 specialty pharmacy providers.

OTHER POLICIES

While payment policies for home infusion drugs and professional services have negatively affected beneficiary access, so have other Part B DME policies. For instance, MLN SE1609 - *Medicare Policy Clarified for Prolonged Drug and Biological Infusions Started Incident to a Physician's Service Using an External Pump*, clarified billing processes for prolonged drug and biological infusions started "incident to" a physician's service using an external pump, noting that they cannot be billed on suppliers' claims to DME MACs.[4] This effectively removed coverage for home administration of fluorouracil (5-FU), a treatment that entails administering a loading dose in a clinic followed by a multi-day continuously infused maintenance dose. The practice of connecting patients in clinic using a pump and drug supplied by the home infusion pharmacy stemmed from the (pre-Cures) lack of coverage for nursing when patients do not meet Part A homebound criteria. In 2014, patients needing 5-FU, a Category 3 drug under Cures, represented by far the highest number of Part B beneficiaries (12,469, or 59%), yet the overall spend on the drug barely registered in the analysis at just over $1 million. The total Medicare annual spend for 5-FU dropped to $422K in 2018 and to $65,378 in 2019. In fact, 5-FU has had the lowest per-beneficiary annual allowable of all Part B DMEPOS drugs over the 5-year period.

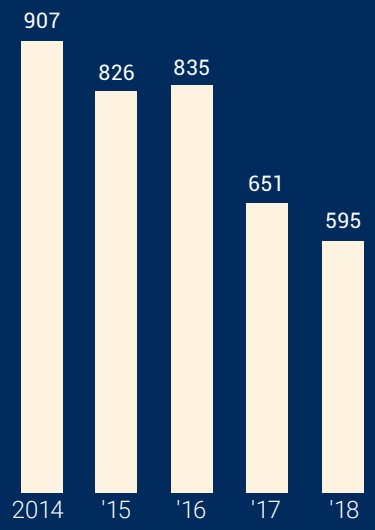
TABLE 1

Average Annual Medicare Allowable per Beneficiary for Common DMEPOS Drugs						
		2014	2015	2016	2017	2018
Dobutamine	J1250	$849	$1,014	$922	$1,188	$1,008
Milrinone	J2260	$64,178	$62,969	$60,448	$3,553	$1,719
Hizentra	J1559	$55,342	$56,520	$56,630	$38,915	$39,738
Hyqvia	J1575	N/A	N/A	$44,623	$43,656	$52,506
Epoprostenol	J1325	$33,706	$32,206	$31,757	$38,074	$37,443
Treprostinil	J3285	$133,544	$144,466	$144,775	$147,276	$147,196
5-FU	J9190	$119	$123	$117	$104	$107
Deferoxamine	J0895	$8,641	$8,818	$9,475	$4,813	$6,315
Acyclovir	J0133	$1,877	$2,115	$1,773	$294	$225
Gancyclovir	J1570	$1,026	$1,040	$1,187	$2,412	$2,040
Hydromorphone	J1170	$4,245	$4,344	$5,031	$7,016	$5,464

SUPPLIER PARTICIPATION IN PART B DMEPOS

EXHIBIT 4

Total Suppliers Billing Medicare Part B for Ambulatory Infusion Pumps (E0781)

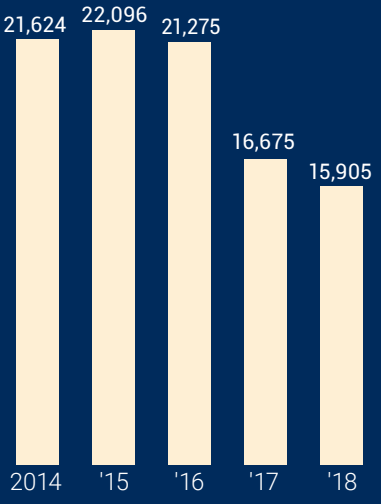


Equipment used across multiple drug therapies, E0781 – Ambulatory Infusion Pump, can be used as an indicator of the number of suppliers participating in the DMEPOS home infusion benefit. Based on this data, home infusion supplier participation decreased by 52% (from 907 to 595 suppliers) between 2014 and 2018 (see Exhibit 4). This trend is expected to continue into 2021 with the implementation of the professional services benefit created by Cures, which limits nursing to Part B HIT services providers who meet new accreditation requirements and who enroll with the AB Medicare Administrative Carriers (MACs) in order to bill for nursing services. Providers that choose not to enroll in the HIT services benefit may ultimately be forced out of providing the drug, pumps, and supplies due to a lack of available nursing.

BENEFICIARIES SERVED

EXHIBIT 5

Home Infusion Part B DMEPOS Beneficiaries by Year



*Based on utilization of DMEPOS drugs.

Over the past 5 years, the end result of CMS' policies is a major reduction in the total number of beneficiaries receiving home infusion under Medicare Part B DMEPOS. The largest drop (21.6%) occurred from 2016 to 2017, the same time that Cures and MLN SE1609 took effect. The U.S. Census Bureau estimates the 65-and-older population grew by 34% from 2010 to 2019, and yet 25% fewer beneficiaries are using the Part B home infusion benefit.[5] Interestingly, utilization of inotropic drugs dobutamine and milrinone remained relatively consistent from 2014 to 2018, despite the dramatic reduction in payment rates. NHIA hypothesizes the reason for this is the unique role home infusion plays for this patient population. First, ethical considerations prevent transferring patients unless a comparable service provider is identified. Second, these critically ill patients cannot be easily served in office-based or outpatient settings due to their acuity, indefinite length of therapy, and the frequency of cassette/bag changes (daily in most cases). Finally, many skilled facilities do not accept patients on inotropic therapies. These factors create

pressure for home infusion providers to continue accepting these patients despite the low reimbursement. Since this population is small (3,601 in 2018), many suppliers have continued services and are absorbing the financial losses.

TABLE 2

Beneficiary Utilization for Top DMEPOS Drugs						
		2014	2015	2016	2017	2018
Dobutamine	J1250	615	666	846	826	768
Milrinone	J2260	2,023	2,248	2,549	2,506	2,833
Hizentra	J1559	2,984	3,249	3,507	3,512	3,551
Hyqvia	J1575	0	0	715	766	753
Epoprostenol	J1325	643	633	631	582	551
Treprostinil	J3285	1,264	1,223	1,239	1,213	1,217
5-FU	J9190	12,469	12,592	10,474	5,939	4,939
Deferoxamine	J0895	333	270	200	184	153
Acyclovir	J0133	89	132	126	133	178
Gancyclovir	J1570	351	321	320	350	373
Hydromorphone	J1170	195	349	290	268	148

HOME INFUSION THERAPY PROFESSIONAL SERVICES (NURSING SERVICES)

In 2019, CMS implemented the temporary benefit for home infusion therapy professional services. Contrary to Congress' intent, CMS defined the benefit around nursing services and limited payment to the days when a skilled professional is face-to-face providing care in the home. With a few exceptions, this interpretation of a billable "home infusion calendar day" has largely resulted in market consolidation and fewer beneficiaries using the service.

A review of claims data from 2019 shows an average of 2,001 (SD=747) monthly claims submitted for home infusion services (G0068, G0069, G0070). The mean number of beneficiaries receiving professional services (nursing) per month in 2019 was 688 (SD=156). The total Medicare spend on home infusion professional services in 2019 was estimated by NHIA to be just $4.2 million.

An inability for home infusion providers to submit service claims when patients were in a Part A home health episode may have hindered utilization during the transition. Even so, this number is low considering home infusion providers could bill for services without having to enroll or demonstrate special accreditation to participate in the program.

In January 2021, the permanent benefit created by Cures began, however it required suppliers to enroll with the AB MACs (as opposed to the DME MACs) in order to submit claims, as well as demonstrate an additional accreditation specific to Part B home infusion therapy. Cures broadened the definition of a home infusion therapy services supplier to include physicians,

home health agencies, and others—in addition to infusion pharmacies. If CMS' goal was to recruit nursing agencies to the benefit, the effort appears to be falling short. To date, only 41 nursing agencies in 12 states have enrolled to provide services, and 59% of the 41 are located in just 3 states. As of mid-March, less than 250 total suppliers (including pharmacies) have enrolled nationwide.[6] NHIA believes that future beneficiary access to home infusion under Part B will depend on the DME pharmacy's ability to secure nursing care which can no longer overlap with Part A home health. Achieving sufficient participation in both DMEPOS home infusion and Part B home infusion therapy services to maintain beneficiary access will be challenging given the small number of potential beneficiaries and low reimbursement compared to the expense of achieving and maintaining accreditation.

CONCLUSION

The collective impact of CMS' home infusion-related policies, from competitive bidding to the implementation of the home infusion professional services benefit, has resulted in less beneficiary utilization and provider consolidation. Between 2014 and 2018, beneficiary utilization decreased by 25.2%, and pharmacy (supplier) participation dropped 52%. Over a 5-year period, the combined Medicare spend for pumps, supplies, and drugs has been reduced by 58%. Average pre-Cures spending (2014-2016) on the benefit was nearly $200M per year higher than post-Cures (2017-2018). The professional services payment created by Congress with 21st Century Cures, as implemented by CMS, has resulted in lackluster participation by pharmacy and home health agencies. The Part B DMEPOS benefit serves an important need in the Medicare program by creating home infusion access for a small and highly vulnerable population and NHIA believes the benefit is failing to meet current needs of Medicare beneficiaries and is too flawed to serve as a basis for broader coverage.

RECOMMENDATIONS

NHIA has been persistent in its message that home infusion is most successful as a pharmacy-led service and that providers need to be paid for each day the drug is infused, regardless of whether a nurse is present. Medicare policies have dramatically reduced overall program spending and the result is to push patients to other sites of care where costs to the Medicare program are higher. For patients with end-stage heart failure, home infusion is life-sustaining and often, their only option for care. For others, home infusion greatly improves their quality of life and avoids daily trips to a physician office or outpatient clinic.[7]

The Part B DMEPOS benefit is a poor substitute for a straightforward, equitable home infusion benefit. Despite its flaws, it has served a small, but extremely vulnerable Medicare population reliant on continuous infusions of life-sustaining drugs. Without

a better alternative, even these patients will struggle to find providers. The viability of the current benefit depends on CMS finally recognizing the need to modify the definition of "home infusion calendar day" and pay for services provided remotely, each day the drug is administered. Efforts by CMS to re-frame the benefit as an offering by home health (Cures), physicians (CMS' April 6, 2020 iterim final rule with comment period), and DME is failing patients, as none thus far have improved access.[8] Congress intended for service payments to be made to pharmacies for every day of infusion, as they are in the commercial sector. In fact, Cures encouraged CMS look to the private sector when constructing the Part B Home Infusion Therapy Services benefit, yet CMS went in a different direction.

It is also crucial that CMS recognize the limitations of structuring a home infusion benefit around an item of DME and fragmenting reimbursement. Broader home infusion access will not be successful under the current construct and NHIA envisions a more comprehensive approach involving a demonstration program through the Centers for Medicare and Medicaid Innovation. While commercial payers are modifying benefit design to incentivize beneficiaries to use the home site of care, CMS policies have pushed beneficiaries back to facilities. NHIA will continue to advocate for viable, comprehensive coverage of home infusion therapy for all Medicare beneficiaries.

While commercial payers are modifying benefit design to incentivize beneficiaries to use the home site of care, CMS policies have pushed beneficiaries back to facilities.

References

1. National Home Infusion Foundation. *Infusion Industry Trends* 2020:Alexandria, VA.
2. Centers for Medicare and Medicaid Services (CMS). *DMEPOS Competitive Bidding Program R1RC Weighted Average Savings.* Available at: https://dmecompetitivebid.com/Palmetto/Cbicrd1Recompete.Nsf/files/R1RC_
3. Office of the Inspector General (OIG). *PART B Payments for Drugs Infused Through Durable Medical Equipment* (OEI-12-12-00310). February 2013. February 2013. Available at: https://oig.hhs.gov/oei/reports/oei-12-12-00310.pdf
4. MLN Matters® Number: SE1609, *Medicare Policy Clarified for Prolonged Drug and Biological Infusions Started Incident to a Physician's Service Using an External Pump*, June 6, 2019. Available at: www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1609.pdf
5. United States Census Bureau 65 and Older Population Grows Rapidly as Baby Boomers Age (https://www.census.gov/newsroom/press-releases/2020/65-older-population-grows.html) Accessed 3/27/21)
6. Shaw G. *Home infusion therapy accreditation rolls out: Compliance a must under CMS regulations. Specialty Pharmacy Continuum.* February 3, 2021. Available at: https://www.specialtypharmacycontinuum.com/Operations-Management/Article/02-21/Home-Infusion-Therapy-Accreditation-Rolls-Out/62543
7. Polinski JM, Kowal MK, Gagnon M, et. al. Home infusion: Safe, clinically effective, patient preferred, and cost saving. 2017. *Healthcare*, 5(1-2), 68-80. doi:10.1016/j.hjdsi.2016.04.004
8. Centers for Medicare & Medicaid Services; Medicare and Medicaid Programs; *Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency*; 85 Fed. Reg. 19230 (April 6, 2020)

About NHIA

NHIA represents companies that provide infusion therapy to home-based patients as well as companies that manufacture and supply infusion and specialty pharmacy products. For additional information about this report contact **Connie.Sullivan@nhia.org**. For more information about NHIA visit www.nhia.org.