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Navigating Regulatory Pitfalls at the Nexus Between Home Health and Infusion

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Jaya F. White, Quarles & Brady LLP | **Kiel Zillmer**, Quarles & Brady LLP



Traditional home health has experienced significant change in recent years, driven primarily by the expansion of creative business models, including a home infusion model where a health care practitioner administers infusion medications in a patient's home. While the home health industry has expanded, the laws, regulations, and certifications applicable to traditional home health have not caught up with this evolution. To further complicate the matter, infusion providers are now exploring yet another service delivery mechanism—the ambulatory infusion suite (AIS)—in which infusion treatment is administered at a designated site outside of a patient's home. Operating in a gray area where the legal landscape has not kept pace requires infusion providers to analyze all potentially applicable laws and associated requirements and make determinations regarding the best path forward to ensure compliant business operations.

Traditional Home Health

To fully comprehend the challenges infusion providers are now facing, it is important to understand the regulatory environment to which providers have become accustomed. To receive home health services under the Medicare Part A benefit, patients must meet two separate criterion to be considered “homebound”¹: first, they must have a “face to face” certification related to the primary reason the patient requires the home health services by a qualified practitioner,² and, second, the patient must be certified to need at least one of the identified home health services, such as intermittent skilled nursing services.³ To be Medicare-certified, however, the home health agency itself must provide skilled nursing services in addition to at least one other therapeutic service, such as physical therapy or medical social services.⁴ Medicare also requires that at least one of the services be directly provided by the agency itself, but the second service or any additional services can be provided “under arrangements” with another agency.⁵

The Medicare Part A-certified home health agency differs in multiple respects from the infusion industry. To address this divergence, effective January 1, 2021, the Centers for Medicare & Medicaid Services (CMS), introduced a new enrollment type specifically for home infusion therapy providers under Medicare Part B—the home infusion therapy or HIT benefit.⁶ The HIT benefit is for coverage of home infusion therapy-associated professional services, including nursing services and education, related to the intravenous or subcutaneous administration of certain drugs and biologicals through a pump that is an item of durable medical equipment (DME).⁷ This payment is in addition to the DME payment for the infusion pump or any related supplies, including the prescription drugs. Unlike patients receiving home health services under Part A, patients receiving home infusion therapy services under the HIT benefit do not need to meet a “homebound” requirement. Home infusion therapy agencies also often only provide the one skilled nursing service, the infusion.

To be enrolled as a home infusion therapy provider under the Medicare Part B HIT benefit, the home infusion provider must become accredited with one of the Medicare-approved accreditation organizations,⁸ which creates an additional step to receiving reimbursement for the infusion nursing and education services. As discussed in more detail below, while time-consuming and costly, accreditation with a Medicare-approved organization may help address certain state issues, which tie Medicaid enrollment to Medicare-certification.

Home Infusion Provider Licensure

The path to payment for the administration of infusion services under the HIT benefit is a positive step for the industry, but Medicare reimbursement is only one component of the regulatory landscape governing the infusion industry and does not address other critical issues, such as potential licensure required under state law. In fact, the Medicare definition of a “qualified home infusion therapy supplier” refers to, in part, a “pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services.”² Although these are broad parameters, they do not fully account for the state agency-wide license considerations required for health care practitioners entering patients’ homes.

How do home infusion providers fit within the broader home health context? The state licensure landscape in the home infusion industry is far from uniform, and in fact the overwhelming majority of states do not address infusion at all. While home infusion providers—and, in particular, those originating from the pharmacy industry or those that partner with specialty pharmacies—are distinct from the traditional home health model, many states nonetheless require licensure as a home health agency in order to provide such services in a state.

The determination of whether a license is even required for infusion providers depends upon the specific facts and circumstances, and the legal definitions for each provider type. For example, many states define home health agency to apply to agencies that provide multiple services, including both skilled nursing services and at least one other therapy service, such as occupational therapy or speech therapy.

Arizona is an example of this type of licensure category. That state defines a home health agency as an agency that “is primarily engaged in providing skilled nursing services and other therapeutic services.”¹⁰ In states with statutory and regulatory language similar to Arizona, an agency that only provides the home infusion nursing component can position itself as not requiring licensure because of the limited scope of services being provided. In other words, the infusion provider does not provide nursing “in addition to” another service.

Other states, however, require licensure if an agency provides any type of service in the home, and may even have a special license category limited to just the home nursing component. States in this category include Kansas (which defines a home health agency to include an agency that “provides for a fee one or more home health services,” with home health services including nursing and other therapeutic services¹¹) and Illinois (which has multiple license categories including one specific to just nursing services¹²). In these states, language such as the “one or more” language used in Kansas triggers licensure based on the one service provided.

A smaller subset of states will require licensure if an entity, such as a specialty pharmacy, merely contracts with a separate nursing agency, triggering licensure for engaging in the relationship. Both California and New York are states where the contracting or arranging for a service requires licensure for both the entity actually providing the nursing services and the entity that contracted it out. California defines a home health agency as an organization “which provides, or arranges for the provision of, skilled nursing services, to persons in their temporary or permanent place of residence.”¹³ Similarly, New York defines a home care services agency as an organization that is “primarily engaged

in arranging and/or providing directly or through contract arrangement one or more of the following: Nursing services, home health aide services, and other therapeutic and related service . . . to persons at home.”¹⁴

Finally, an even smaller group of states specifically license home infusion providers or provide an express exception for infusion providers.¹⁵ As of this writing, only two states fall within the former category: Kentucky (which licenses “ambulatory infusion agencies” that provide infusion services in patient’s homes or in outpatient locations¹⁶) and Montana (which licenses “home infusion therapy agencies,”¹⁷ requiring the services of a pharmacist in charge, a role that a provider handling only the infusion administration may not have).

The state infusion licensure landscape is further complicated by other issues such as geographic limitations and certificate of need restrictions, which may still apply even if the entity contracts out the nursing component. For example, both New York and Rhode Island have comprehensive certificate of need restrictions related to the licensure of home health agencies.¹⁸ Facing these significant barriers to entry, providers seeking to do business in those states will need to strategize on potential alternatives, such as determining whether there are any exceptions to the certificate of need requirements.¹⁹

It is worth noting that, with the proliferation of mail-order pharmacies, state boards of pharmacy have already contemplated providers being out-of-state and shipping medications into a state with non-resident pharmacy licensure requirements. However, this non-resident option is not available for the home infusion industry, and geographic limitations to a license, including potential surface area or county restrictions,²⁰ must be considered by infusion providers seeking to provide services on behalf of specialty pharmacies that may have licensure across all 50 states.

State Medicaid Program Complications

While CMS has recognized a need for a separate benefit related to infusion services, state Medicaid programs, similar to state licensing agencies, may not yet have fully recognized and embraced this unique industry. For example, Indiana Medicaid recently issued a bulletin announcing that it will be requiring home health providers enrolled in the Indiana Health Coverage Programs (IHCP) to also be Medicare-certified as of July 1, 2026.²¹ This IHCP bulletin, which consists of only a couple short paragraphs, references enrollment as a Medicare Part A (traditional home health) provider, and does not expand to other Medicare provider or supplier types, such as a supplier under the Part B HIT benefit. As noted above, infusion providers that only provide the one nursing service and service patients that are not “homebound” will not meet the conditions of participation for a Medicare Part A home health provider. As such, it remains to be seen how this Indiana Medicaid enrollment requirement will affect home infusion providers in the state in 2026 and beyond.

Ambulatory Infusion Suite Model

In addition to the home infusion model, pharmacies are continuing to explore novel infusion medication administration models, including delivery to AIS. If licensure requirements for home infusion are not always clear, licensure for the AIS model is even more limited or not directly applicable to the model. Providers entering the AIS space need to contend with a proliferation of recent regulatory guidance related to different provider types, which while distinct from the home health

industry, still warrant review to ensure compliance. The medical spa (med spa) and intravenous (IV) hydration and therapy businesses have caught the attention of regulators, and states are attempting to achieve greater control in these areas with broad generalizations that may impact the AIS model.

For example, in July 2024 the Rhode Island Department of Health (RIDOH) issued guidance²² focused on the expansion of med spas and IV therapy businesses, which broadly encompasses those entities that provide patients with IV fluids with or without medications, vitamins, minerals and/or amino acids. Although the RIDOH references that these services are often treated as spa treatments rather than medical procedures, they intersect the specialties of medicine, nursing, and pharmacy and could potentially include the delivery and administration of prescription drugs as in an AIS model.

Depending upon the underlying ownership structure, the scope of services offered, and the professional licensure (if any) held by the owners of the business, the guidance document also makes clear that these IV therapy providers (and by potential extension, infusion therapy providers) may require licensure with the RIDOH, including as organized ambulatory care facilities (OACFs). Licensure as an OACF requires prior review by the Rhode Island Health Services Council, a 30-day public comment period, and approval by the licensing agency.

Similar to steps taken in Rhode Island, the Kentucky Boards of Medical Licensure, Nursing and Pharmacy issued a joint statement²³ directed at the retail IV therapy business model and not, specifically, the infusion industry. Unlike Rhode Island, however, the Kentucky guidance does not contemplate a specific facility licensure requirement for such businesses. The resource document instead discusses what falls within the scope of practice of individual licensed health care professionals that provide services on behalf of IV therapy businesses and that the practice of creating IV therapies could constitute compounding and the practice of pharmacy. Importantly, the model outlined in the Kentucky guidance (which pertains to practitioners compounding in an IV therapy clinic) can be distinguished from the infusion industry. Unlike compounding on-site, the infusion industry utilizes pharmacists in a licensed pharmacy setting to compound the drugs for further administration in the AIS. Nonetheless, entities looking to operate businesses within the AIS model should review this statement to ensure that the anticipated service offerings will not implicate and run afoul of the documented concerns pertaining to IV therapy businesses.

Both Ohio and Wisconsin also promulgated advisory materials in 2025 aimed specifically at IV therapy businesses that could touch on the infusion industry. The Ohio Boards of Medicine, Pharmacy, and Nursing issued a joint regulatory statement pertaining to retail IV therapy clinics.²⁴ As with the other states discussed above, this guidance makes similar statements that operating a retail IV therapy clinic may involve the practice of medicine, nursing, and pharmacy, all of which require a license and adherence to a scope of practice under state law. Similar to the guidance issued by Kentucky, much of the Ohio statement addresses what constitutes compounding. However, Ohio also includes a reference that is particularly relevant to the AIS model. Storing compounded drugs on-site for any period of time (e.g., the day of an infusion appointment) will require licensure with the Ohio Board of Pharmacy as a terminal distributor of dangerous drugs. Also in line with other states, Ohio makes clear that standing orders are not permitted for the recommendation, compounding, and administration of IV medications under state law.

On October 22, 2025, various professional boards within the Wisconsin Department of Safety and Professional Services released a joint advisory opinion regarding IV hydration therapy businesses.²⁵ While Wisconsin's guidance does not reference any required facility licensure, it does note that "IV hydration therapy fluids and additives are prescription drugs requiring purchase and storage by a qualified practitioner which may include a physician, PA [physician assistant], or APNP [advanced practice nurse prescriber]." The opinion does, however, acknowledge that a registered nurse with appropriate training and experience may administer the treatment.

Conclusion

The traditional home health industry is in a state of flux, especially as it contends with the increased use of home infusion services. Providers looking to enter the industry lack definitive guidance on critical issues, including reimbursement and licensure requirements. This does not even take into account other important considerations that providers face when seeking to establish home health businesses such as potential corporate practice of medicine limitations and fraud, waste, and abuse prohibitions. The uncertainty in the home health industry is further compounded when infusion providers consider offering other novel business strategies like the AIS model. It is imperative that entities carefully review applicable statutes and regulations and stay up to date on all guidance materials released by regulatory bodies to ensure that contemplated business models are operated in a compliant manner. Failure to do so could result in discipline by licensing authorities, diminished reimbursement, or other adverse enforcement actions. Given the recent and rapid developments in this space, the home health industry will certainly continue to evolve, requiring providers to remain vigilant and diligent to promote compliance and sustainability.

Jaya White is a Chicago-based Health & Life Sciences partner at Quarles & Brady who represents a wide range of health care providers in regulatory and transactional matters. She also has ample experience advising pharmacy, physician, wholesale distribution and infusion providers in a broad array of issues. Jaya is national chair of the firm's Long-Term Care and Senior Housing Practice. She can be reached at jaya.white@quarles.com and her LinkedIn profile is <https://www.linkedin.com/in/jayawhite/>.

Kiel Zillmer is a Milwaukee-based Health & Life Sciences partner at Quarles & Brady, as well as a member of the firm's Long-Term Care and Senior Housing Practice. He provides counsel to hospitals and health care providers to achieve their business objectives while minimizing unnecessary risk, including advising on regulatory compliance and transactional matters. He can be reached at kiel.zillmer@quarles.com and his LinkedIn profile is <https://www.linkedin.com/in/kiel-zillmer-74368563/>.

*This Feature Article is brought to you by the **Post-Acute and Long Term Services Practice Group: Randall Fearnow (Chair); Brittney Cafero-Mieckowski, Children's Hospital of Philadelphia (Vice Chair); Judith Eisen, Garfunkel Wild PC (Vice Chair); Emily Solum, Husch Blackwell LLP (Vice Chair); Jaya White, Quarles & Brady LLP (Vice Chair); and Denise Bloch (Vice Chair).***

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- 1 See, e.g., U.S. Dep’t of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., *Medicare Benefit Policy Manual, Chapter 7 - Home Health Services*, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c07.pdf>.
- 2 42 C.F.R. § 424.22(a)(v) (2025).
- 3 U.S. Dep’t of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., *Medicare Benefit Policy Manual, Chapter 7 - Home Health Services*, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c07.pdf>.
- 4 42 C.F.R. § 484.105(f)(1) (2025).
- 5 *Id.*
- 6 42 U.S.C. § 1395x(iii) (2022).
- 7 *Id.*
- 8 42 C.F.R. § 486.505 (2025) (defining “qualified home infusion therapy supplier”); see also U.S. Dep’t of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., *Home Infusion Therapy Services Benefit Beginning January 2021, Frequently Asked Questions*, <https://www.cms.gov/files/document/home-infusion-therapy-services-benefit-beginning-2021-frequently-asked-questions.pdf> (last updated June 2022).
- 9 42 U.S.C. § 1395x(iii)(3)(D)(i) (2022).
- 10 ARIZ. REV. STAT. ANN. § 36-151(5)(a).
- 11 KAN. STAT. ANN. § 65-5101.
- 12 “Home Nursing Agency -- an agency that provides services directly, or acts as a placement agency, in order to deliver skilled nursing and home health aide services to persons in their personal residences.” Ill. ADMIN. CODE tit. 77, § 245.20 (2025).
- 13 CAL. HEALTH & SAFETY CODE § 1727(a).
- 14 N.Y. PUB. HEALTH LAW § 3602(2).
- 15 The definition of home health agency in Indiana provides an exception for “a person that only administers home infusion therapy based on a specialty medication prescription received from a pharmacy.” IND. CODE § 16-27-1-2.
- 16 902 KY. ADMIN. REGS. 20:450.
- 17 “Home infusion therapy agency” means a health care facility that provides home infusion therapy services. MONT. CODE ANN. § 50-5-101(22). “Home infusion therapy services” means the preparation, administration, or furnishing of parenteral medications or parenteral or enteral nutritional services to an individual in that individual’s residence. The services include an educational component for the patient, the patient’s caregiver, or the patient’s family member. MONT. CODE ANN. § 50-5-101(23).
- 18 See N.Y. Dep’t of Health, Licensed Home Care Services Agencies (LHCSAs), [https://www.in.gov/medicaid/providers/files/bulletins/BT202595.pdf](https://www.health.ny.gov/facilities/home_care/lhcsa/#:~:text=Licensed%20Home%20Care%20Services%20Agency,homecareliccert@health.ny.gov;216 R.I. CODE R. 40-10-17.4.1(B); N.Y. PUB. HEALTH LAW § 3606 (McKinney 2014).</p><p>19 N.Y. PUB. HEALTH LAW § 3611-a (McKinney 2014) (citing certain exceptions to the certificate of need requirements for changes of ownership or operator).</p><p>20 “Parent home health agency” means the primary home health agency which establishes, maintains and assures administrative and supervisory control of branch offices. The service area of a parent home health agency may not extend beyond four hours surface travel time from the agency unless the agency serves a rural, scarcely populated area pursuant to Section 74663. CAL. CODE REGS. tit. 22, § 74607 (1997).</p><p>21 Indiana Health Coverage Programs, <i>IHCP will require home health agencies to be enrolled with Medicare by July 1, 2026</i> (June 26, 2025), <a href=).

- 22 R.I. Dep't of Health, *Rhode Island Department of Health Guidance Document Regarding the Operation of Medical Spas and Intravenous (IV) Therapy Businesses*,
<https://health.ri.gov/sites/g/files/xkgbur1006/files/publications/guidance/Medical-Spa-and-IV-Therapy-Business.pdf>.
- 23 Commonwealth of Ky., *Joint Statement of the Kentucky Boards of Medical Licensure, Nursing and Pharmacy Regarding Retail IV Therapy* (Mar. 28, 2025),
<https://kbn.ky.gov/KBN%20Documents/Joint%20Statement%20-%20IV%20Hydration%20Clinics.pdf>.
- 24 Ohio Bd. of Pharmacy, *Joint Regulatory Statement of the State Medical Board of Ohio, Ohio Board of Pharmacy, and Ohio Board of Nursing Regarding Retail IV Therapy Clinics* (May 15, 2025),
<https://www.pharmacy.ohio.gov/documents/pubs/special/ivtherapy/joint%20regulatory%20statement%20on%20the%20operation%20of%20retail%20iv%20therapy%20clinics%20in%20ohio.pdf>.
- 25 Wis. Dep't of Safety and Prof'l Serv., *Joint Advisory Opinion of the Wisconsin Examining Boards of Medical, Nursing, Pharmacy, and Cosmetology, the Physician Assistant Affiliated Credentialing Board, and the Wisconsin Controlled Substances Board Regarding IV Hydration Therapy Business* (Oct. 22, 2025),
https://dsps.wi.gov/Documents/BoardCouncils/IAC/202510_IV-Hydration-Guidance-IAC.pdf.

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1099 14th Street NW, Suite 925, Washington, DC 20005 | P. 202-833-1100

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