

### By US & Electronic Mail

April 18, 2024

Owen Foster, Chair Green Mountain Care Board 144 State Street Montpelier, Vermont 05602 owen.foster@vermont.gov

Re: The University of Vermont Medical Center Inc.
Request for Jurisdictional Determination – Home Infusion Therapy

Dear Chair Foster:

By way of this letter, the University of Vermont Medical Center Inc. ("UVM Medical Center") responds to the questions of the Green Mountain Care Board (the "Board") dated March 14, 2024. The questions are included below in bold type followed by each response.

1. Specify the number of individuals currently served in the infusion therapy program and the number of individuals you expect to serve in year 1, 2, and 3 in the home infusion therapy program.

UVM Medical Center has operated a Home Infusion *Pharmacy* that provides drugs, durable medical equipment ("DME"), and related medical supplies to patients since 1994. This is not a new service.

The proposed new service would be a separately accredited and Medicare enrolled Home Infusion Therapy *Nursing* Service to administer those drugs to patients at home. As it stands, across the State of Vermont, there is a shortage of designated agency nursing staff to deliver this vital service to patients in their homes, which is the more appropriate, affordable, and convenient site of care.

UVM Medical Center's existing Home Infusion Pharmacy provides home infusion drugs, DME, and supplies to a daily average of 169 patients. Of these 169 patients, only 35 are receiving therapies that also require in-home specialty infusion therapy nursing services (meaning, the drugs cannot be self-administered). Currently, for this subset of patients, the Home Infusion Pharmacy provides the drugs, DME, supplies, and nurses employed or contracted by a designated agency administer the infusion drugs to the patients at home.

In total, the Home Infusion Pharmacy received 58 referrals for specialty (home) infusions in FY23. Of the 58 referrals:

- 27.5% (14) were declined by the designated agencies because the agencies did not have nurses available to administer the specialty infusions;
- 41% (24) of those referrals were accepted (i.e., the Home Infusion Pharmacy provided the drugs and supplies, and a designated agency administered the drugs); and
- 31% (18) of those ultimately were not filled by the Home Infusion Pharmacy due to insurance coverage or patient choice.

The proposed Home Infusion Therapy Nursing Service would, depending on designated agency availability and patient choice, begin by transitioning responsibility for the currently active 35 specialty infusion pharmacy patients at start of year 1 and would expect to increase by an estimated 38 patients each year: by end of year 1 (73), year 2 (111) and year 3 (149). As we expand access to home infusion services in the state, we would expect the Home Infusion Pharmacy patient census to also increase by approximately 38 patients each in years 1 (207), 2 (245), and 3 (283). In providing this information, however, we would ask that the Board limit its analysis to the scope of 18 V.S.A. § 9434(b)(3), which only looks to the operating expenses for the first two fiscal years of a proposed service that has not otherwise been offered by the hospital within the past three fiscal years.

2. Explain in detail whether these same individuals are currently or would receive infusion therapy services at UVM Medical Center if the home option was not developed. Also explain whether the costs associated with the medical supplies and drugs for infusion therapy are currently being incurred for individuals who will migrate or be served in the new home infusion therapy option and identify what the incremental costs for medical supplies and drugs are for the home infusion therapy program.

### The Home Infusion Pharmacy has been in existence for more than three fiscal years.

It is important to distinguish between the existing Home Infusion Pharmacy and the proposed Home Infusion Therapy Nursing Service. These two services are often referenced jointly as "home infusion services;" however, each is a distinct service line that requires separate accreditation, enrollment, and billing. Pursuant to 18 V.S.A. § 9434(b)(3), the services for which UVM Medical Center seeks a jurisdictional opinion are limited to the proposed Home Infusion Therapy Nursing Services, which were "not offered or employed, either on a fixed or a mobile basis, by the hospital within the previous three fiscal years."

UVM Medical Center has offered its Home Infusion Pharmacy service (drugs, DME, and supplies) on a continual basis for nearly three decades. The new proposed Home Infusion Therapy Nursing Service is limited to the delivery of professional services, i.e., the administration of the specialty infusion drugs in the home by trained nurses. Therefore, in determining whether UVM Medical Center will exceed the operational expense limit of \$1,200,000.00 for each of the next two budgeted fiscal years, the Board should consider only UVM Medical Center's costs to provide the proposed Home Infusion Therapy Nursing Service, and the Board should not consider costs associated with drugs, DME, and supplies the Home Infusion Pharmacy already provides.

Approximately 14 of the estimated 38 annual incremental patient referrals indicated in response to the above Question 1 would not be serviced by the Home Infusion Pharmacy if the Home Infusion Therapy Nursing Service is not developed due to the lack of available nursing staff to provide

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<sup>&</sup>lt;sup>1</sup> 18 V.S.A. § 9434(b)(3).

services in each patient's geographic area. The remaining estimated 24 annual incremental new referrals would be patients that the Home Infusion Pharmacy would be able to service for drugs, DME and medical supplies, because specialty infusion nursing services are available in the patient's geographic area. The 35 active pharmacy patients who could transition to our Home Infusion Therapy Nursing Service already receive drugs, DME and supplies from the Home Infusion Pharmacy.

There are no direct incremental costs for drugs, medical supplies, or DME for the proposed Home Infusion Therapy Nursing Service. As explained in greater detail below, the drugs, DME, and supplies are all items that UVM Medical Center is currently accredited and enrolled with payers to provide. The costs for those items would be part of the trajectory for expected growth in a service line—the Home Infusion *Pharmacy*—that has existed for many years at UVM Medical Center, which would continue to provide such items to all patients referred to it, pending nurse availability, within the state.

# The Proposed Home Infusion Therapy Nursing Services are distinct from the Home Infusion Pharmacy.

The proposed Home Infusion Therapy Nursing Service involves accreditation, enrollment, and billing that is distinct from that required to operate the Home Infusion Pharmacy. As a Joint Commission accredited and Medicare enrolled provider, the Home Infusion Pharmacy's current taxonomy codes<sup>2</sup> are limited to (i) Home Infusion Pharmacy, (ii) Community/Retail Pharmacy, (iii) Durable Medical Equipment & Medical Supplies, and (iv) Parenteral & Enteral Nutrition.<sup>3</sup>

A facility that seeks to become a Pharmacy/DME provider requires accreditation<sup>4</sup> and subsequent enrollment with the DME Medicare Administrative Contractor ("MAC") to bill for pharmacy services. When patients are covered by Medicare, the Pharmacy/DME services are provided by the Home Infusion Pharmacy and then billed to the DME MAC. For patients with commercial insurance, the drug, DME, and supplies provided by the Home Infusion Pharmacy are billed primarily through the medical benefit, utilizing a J code (drug) and S code (per diem, which includes administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment). In some situations, when mandated by the payer, the services are split-billed, and the J code (by way of the National Drug Code) is billed to the pharmacy benefit and the S code is billed to the medical benefit. The Home Infusion Pharmacy provides a bundled service inclusive of drugs and supplies; therefore, we always bill for both, in line with applicable government and/or commercial payer requirements.

# The Proposed Home Infusion Therapy Nursing Service requires additional accreditation and enrollment.

Medicare further differentiates the services that UVM Medical Center presently provides and bills for as a Pharmacy/DME provider from the proposed Home Infusion Therapy Nursing Service. As part of the 21<sup>st</sup> Century Cures Act, the Centers for Medicare & Medicaid Services ("CMS") added the "home infusion therapy" benefit, which became effective January 1, 2021. The Medicare home

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<sup>&</sup>lt;sup>2</sup> A "taxonomy code" is a code that describes the Provider or Organization's type, classification, and the area of specialization.

<sup>&</sup>lt;sup>3</sup> See Exhibit B.

<sup>&</sup>lt;sup>4</sup> See Exhibit C.

infusion therapy benefit is for coverage of home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously, or subcutaneously through a pump that is an item of DME. "Home infusion therapy" is defined to include the following items and services: the professional services (including nursing services), furnished in accordance with the plan, training, and education (not otherwise included in the payment for the DME), remote monitoring, and other monitoring services for the provision of home infusion therapy furnished by a qualified home infusion therapy supplier in the patient's home.<sup>5</sup>

Enrollment as a Home Infusion Therapy ("HIT") supplier requires an additional accreditation category from The Joint Commission (HIT infusion nursing) and subsequent enrollment with the Medicare A/B MAC to bill for home infusion therapy nursing services. UVM Medical Center intends to comply with all state and federal requirements in its efforts to expand Vermonters' access to home infusion therapy nursing services, including the obtaining the HIT infusion nursing accreditation and enrolling with Medicare as a Home Infusion Therapy (nursing) provider. This would result in an additional taxonomy of Home Infusion (251F00000X).

As noted by CMS in a 2021 Home Infusion Benefit FAQ:

The home infusion therapy services benefit provides a separate payment in addition to the existing payment made under the DME benefit, thus explicitly and separately paying for the infusion therapy services furnished in the patient's home by a qualified home infusion therapy supplier. Therefore, the professional services covered under the DME benefit are not covered under the home infusion therapy services benefit. While the two benefits exist in tandem, the services are unique to each benefit and billed and paid for under separate payment systems. The home infusion therapy services benefit is a separate payment in addition to the existing payment for the DME external infusion pump, supplies (including the furnishing of the home infusion drug), and related services covered under the DME benefit<sup>6</sup>.

Further, the proposed Home Infusion Therapy Nursing Service is also billed separately to commercial payers using the CPT codes 99601 and 99602, and, notably, these codes describe drug administration only:

CPT codes 99601 and 99602 are used to encode high-tech RN services—provided by a RN with special education, training and expertise in home administration of drugs via infusion, home administration of specialty drugs, and/or home nursing management of disease state and care management programs. Typical services include evaluation and assessment, education and training for the patient or caregiver, inspection and consultation of aseptic home environment, catheter insertion, and patient assessment.<sup>7</sup>

Because UVM Medical Center has offered Pharmacy/DME services through its Home Infusion Pharmacy since the 1990s and because this service is distinct from the proposed Home Infusion Nursing Service which has an operating expense under \$1.2M for years 1 and 2, the proposed Home Infusion Nursing Service does not constitute a "new healthcare project" under 18 V.S.A. § 9434(b)(3).

<sup>&</sup>lt;sup>5</sup>42 U.S.C. § 1395x(iii)(2).

<sup>&</sup>lt;sup>6</sup> CMS, Home Infusion Therapy Services Benefit Beginning January 2021 Frequently Asked Questions (June 2022) (emphasis added).

<sup>&</sup>lt;sup>7</sup> National Home Infusion Association, *National Coding Standard for Claims under HIPAA* at 19 (Jan. 1, 2024).

3. Address Rule 4.000, Section 4.202 (1) by explaining whether all annual operating expenses to make the service fully operational for the home infusion therapy program are included in the Annual Operating Cost spreadsheet (Exhibit A) included in your letter dated March 6, 2024. Please specify the current annual operating expenses for the total infusion therapy program, including medical supplies and drugs, and the costs in excess of that to offer the home infusion therapy program.

The total operating expenses incurred in FY23 for the Home Infusion Therapy Department—which is limited to Home Infusion Pharmacy services—were \$6.10M. The breakdown of those expenses is as follows: \$1.43M for salaries and fringe benefits; \$3.93M for drugs and med/surg supplies; and \$0.75M for all other supplies and services to support the Department.

The costs to provide the proposed Home Infusion Therapy Nursing Services are included in the revised Exhibit A, included herein. The revision includes the fees necessary for accreditation by The Joint Commission and Medicare, which we inadvertently failed to include in our original submission and consist of \$2,695.00 for the initial accreditation survey plus a recurring annual fee of \$5,995.00 for The Joint Commission and a one-time enrollment fee of \$709.00 for Medicare. The updated annual operating expenses for year 1 are \$475,832.10 and \$582,756.43 for year 2, well below the \$1.2M annual threshold set out in 18 V.S.A. § 9434(b)(3).

Please let us know if we can answer any further questions. Thank you for your consideration.

Sincerely,

Amanda S. Angell

Associate General Counsel

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The University of Vermont Health Network

Enclosure

cc: Michael Barber

Donna Jerry

Stephen Leffler, MD

# Exhibit A – Operating Costs

Operating Costs (expenses):		Latest Actuals (12 mos)	Year one of Proj (12 mos)	Year 2 (12 mos)	Year 3 (12 mos)
Staffing Expenses					
	Salaries per FTE	\$0	\$319,114	\$425,485	\$531,856
	Fringe Benefits/Health Insurance	\$0	\$86,161	\$114,881	\$143,601
	Professional Insurance	\$0	\$0	\$0	\$0
	Staff Travel	\$0	\$4,540	\$6,810	\$9,057
	Consultant Expenses & Travel	\$0	\$30,000	\$0	\$0
	Subscriptions/Dues	\$0	\$0	\$0	\$0
	Payroll Taxes	\$0	\$0	\$0	\$0
	Training (Materials)	\$0	\$750	\$250	\$250
	Other (specify):	\$0	\$0	\$0	\$0
		\$0	\$0	\$0	\$0
		\$0	\$0	\$0	\$0 \$0
Operation Expenses					
	Administrative Expenses	\$0		\$0	\$0
	Office Supplies and Expenses	\$0	\$1,800	\$300	\$300
	Depreciation	\$0	\$0	\$0	\$0
	Interest	\$0	\$0	\$0	\$0
	Advertising/Marketing/Printing	\$0	\$0	\$0	\$0
	Vehicle Expense/Auto Insurance	\$0	\$0	\$0	\$0
	Rent/Lease Expense	\$0	\$0	\$0	\$0
	Utilities/Telephone/Internet Expenses	\$0		\$5,930	\$6,770
	Computer/Hardware/Software	\$0	\$4,275	\$1,425	\$1,425
	Building Maintenance and Repair	\$0	\$0	\$0	\$0
	Property Taxes	\$0	\$0	\$0	\$0
	Legal Services	\$0		\$0	\$0
	Billing/Accounting Services	\$0		\$21,681	\$28,835
	Security Services	\$0	\$0	\$0	\$0
	Clinical Expenses	\$0	\$0	\$0	\$0
	Medical Supplies/Medications	\$0	\$0	\$0	\$0
	Laundry, Linens & Uniforms	\$0	\$0	\$0	\$0
	Equipment Lease/Maintenance	\$0	\$0	\$0	\$0 \$0 \$0 \$0
	Health Information Technology/EHR	\$0	\$0	\$0	\$0
	Food Preparation/Related Costs	\$0	\$0	\$0	\$0
	Facility or Equipment Costs	\$0	\$0	\$0	\$0
	Other Insurance	\$0	\$0	\$0	\$0
	Other (specify): Accreditation and				
	Medicare Enrollment	\$0	\$9,399	\$5,995	\$5,995
		\$0	\$0	\$0	\$0
		\$0	\$0	\$0	\$0
Total Operating Costs:		\$ -	\$ 475,832.10	\$ 582,756.43	\$ 728,089.79

# **Exhibit B – Current Home Infusion Pharmacy Taxonomies**

#### **UVM MEDICAL CENTER** LBN UNIVERSITY OF VERMONT MEDICAL CENTER INC 1 S PROSPECT ST **SUITE 1413** BURLINGTON, VT 05401-3456 A Phone: 802-847-5519 Fax: 802-847-5518 Website: Specialty Taxonomy Code Specialty Code Provider Type ★ Home Infusion Therapy Pharmacy 3336H0001X 58 Medical Supply Company with Pharmacist Community/Retail Pharmacy 3336C0003X 58 Medical Supply Company with Pharmacist Durable Medical Equipment & Medical Supplies 332B00000X 54 Other Medical Supply Company Parenteral & Enteral Nutrition 87 All Other 332BP3500X Suppliers ★ Indicates primary specialty

## Exhibit C - Current Home Infusion Pharmacy Joint Commission Accreditations

## The University of Vermont Medical Ctr Home Infusion Pharmacy

1 South Prospect Street, Suite 1413 Burlington, VT, 05401

#### Available Services

- · Durable Medical Equipment
- Enteral Equipment and/or Supplies
- Enteral Nutrients
- External Infusion Pump Supplies
- · External Infusion Pumps
- Infusion Pharmacy
- Parenteral Equipment and/or Supplies
- · Parenteral Nutrients
- Pharmacy, Clinical Consulting Services
- · Pharmacy/Dispensary, General Services
- · Sterile Medication Compounding
- Supplies

## STATE OF VERMONT GREEN MOUNTAIN CARE BOARD

In re:	The University of Vermont Medical Center Inc.	)	Docket No. GMCB-010-24con
	Development of a Home Infusion Therapy Program	)	
	Project Cost: \$466,433	)	

AMANDA S. ANGELL, ESQ., being duly sworn, states on oath as follows:

- 1. My name is Amanda S. Angell, Esq. I am Associate General Counsel for the UVM Health Network. In that capacity I have reviewed UVM Medical Center's response to the Green Mountain Care Board's Request for Additional Information Q.001 (March 14, 2024) regarding the above-referenced docket (the "Response").
- 2. My personal knowledge of the truth, accuracy and completeness of the information contained in the Response is based upon either my actual knowledge of the subject information or, where identified below, upon information reasonably believed by me to be reliable and provided to me by the individuals identified below who have certified that the information they have provided is true, accurate and complete, does not contain any untrue statement of a material fact, and does not omit to state a material fact necessary to make the statement made therein not misleading.
- 3. I have evaluated, within the 12 months preceding the date of this affidavit, the policies and procedures by which information has been provided by the certifying individuals identified below, and I have determined that such policies and procedures are effective in ensuring that all information submitted or used by UVM Medical Center in connection with the Certificate of Need program is true, accurate, and complete. I have disclosed to the Board of Trustees all significant deficiencies, of which I have personal knowledge after diligent inquiry, in such policies and procedures, and I have disclosed to the Board of Trustees any misrepresentation of facts, whether or not material, that involves management or any other employee participating in providing information submitted or used by UVM Medical Center in connection with the Certificate of Need program.
- 4. The following certifying individuals have provided information or documents to me in connection with the Response, and each such individual has certified, based on their actual knowledge of the subject information or, where specifically identified in such certification, based on information reasonable believed by the certifying individual to be reliable, that the information or documents they have provided are true, accurate and complete, do not contain any untrue statement of a material fact, and do not omit to state a material fact necessary to make the statement made therein not misleading:
  - (a) Melissa McGraw, Manager, Network Home Infusion Services

5. In the event that the information contained in the Response becomes untrue, inaccurate or incomplete in any material respect, I acknowledge my obligation to notify the Green Mountain Care Board, and to supplement the Response, as soon as I know, or reasonably should know, that the information or document has become untrue, inaccurate or incomplete in any material respect.

Amanda S. Angell, Esq.

On April 18, 2024, AMANDA S. ANGELL, ESQ. appeared before me and swore to the truth, accuracy and completeness of the foregoing.

Marie Mc Nemy
Notary Public
My commission expires 1/31/2025

Notary Public State of Vermont

Marie McHenry

Commission \* No. 157.0005167\*