McDonald Hopkins LLC
Attorneys at Law

300 North LaSalle
Suite 2100
Chicago, Illinois 60654

P 312.280.0111
F 312.280.8232

Direct Dial: 312.642.6705
E-mail: cmackelvie@mcdonaldhopkins.com

June 1, 2011

VIA FEDEX

Donald M. Berwick, M.D.
Acting Administrator
Department of Health and Human Services
Centers for Medicare and Medicaid Services
200 Independence Ave. SW
Room 314G
Washington, DC 20201

Re: CMS Change Request 7397

Dear Dr. Berwick:

Please be advised that McDonald Hopkins LLC represents Vital Care, Inc. ("Vital Care"), which owns or franchises a multitude of professional home infusion pharmacies throughout various locations in the United States. Specifically, Vital Care is situated in seventeen states with 77 pharmacy locations. Several of Vital Care's locations engage in patient specific compounding of sterile medication preparations ("DEA Controlled Drugs") that are used for pain control by way of implanted infusion pumps and administered intrathecally. Over 300 patients in the following states are served by Vital Care pharmacy locations: Alabama, Mississippi, Nebraska, Georgia, Florida, Louisiana, Oklahoma and Tennessee. Vital Care is similarly situated to a number of other professional home infusion pharmacies in the United States.

Vital Care believes a new policy interpretation of the Centers for Medicare and Medicaid Services ("CMS") - Change Request 7397: (i) improperly expands the "incident to" regulations or CMS misunderstands the underlying factual scenario, (ii) requires a notice and comment period in accordance with the Administrative Procedures Act ("APA") prior to its implementation, (iii) is contrary to federal Drug Enforcement Administration ("DEA") requirements, and (iv) endangers the public health. Vital Care is concerned that this policy interpretation may have been made in absence of considering all relevant factors. Therefore, it is very important to provide additional information that is germane to this issue.

A. Facts

The issue at hand relates to payment for the above described DEA Controlled Drugs used in conjunction with surgically implanted infusion pumps. The DEA Controlled Drugs are prepared by professional home infusion pharmacies specializing in the provision of clinically complex medications. These DEA Controlled Drugs must be compounded by specially trained infusion pharmacists in a sterile environment in accordance with detailed clinical guidelines designed to protect the patient community, commonly referred to as USP 797. The DEA Controlled Drugs that Vital Care and the other professional home infusion pharmacies in the United States prepare are patient specific and are not batch or standard produced. As already stated, the DEA Controlled Drugs are infused intrathecally to the patient via implanted infusion pumps, which are covered by Medicare as durable medical equipment ("DME").

During the therapy using an implanted infusion pump, the pump is continuously and automatically administering the DEA Controlled Drugs into the patient in their home. This continuous administration through the mechanism of a pump makes the DEA Controlled Drugs "self-administered."

Pursuant to Medicare Part B rules, pharmacies can be paid for certain classes of drugs including immunosuppressive drugs, oral anti-emetic drugs oral anti-cancer drugs and drugs self administered through any piece of DME, such as the implanted infusion pumps. Claims for these drugs are generally submitted to the DME MAC,A/B MAC or carrier. The DME MAC, A/B MAC, or carrier will make payment for these drugs, when deemed to be covered and reasonable and necessary, to the pharmacy. The pharmacy must take assignment [Preamble to Transmittal 2214 to CMS Pub. 100-04, May 13, 2011].

The process by which Vital Care dispenses, delivers and bills for the DEA Controlled Drugs used in a patient's implanted intrathecal infusion pump is as follows:

1. The patient selects the pharmacy that will be the supplier of the DEA Controlled Drugs and authorizes the pharmacy to bill on his/her behalf.

2. The physician writes a prescription for the DEA Controlled Drugs to refill the implanted infusion pump.

3. The pharmacy dispenses the DEA Controlled Drugs for use in the implanted infusion pump to the Medicare beneficiary upon receipt of a patient-specific prescription/order by the patient's treating physician.

4. The Medicare beneficiary executes an assignment of benefits which allow the pharmacy to bill Medicare for the DEA Controlled Drugs.

5. The pharmacy delivers the DEA Controlled Drugs in the name of and for the acceptance by the Medicare beneficiary at the patient's treating physician's medical office;

6. The physician fills or refills the implanted pump reservoir with the DEA Controlled Drugs and the pump administers the medication in the patient's home over a 30-180 day period.

7. The pharmacy bills the Part B carrier for the DEA Controlled Drugs and the physician bills the Part B carrier for personally rendering professional service of refilling the pump reservoir.

It should be noted that the physician has no financial connection to the DEA Controlled Drugs. The physician neither purchases, nor bills Medicare for, the DEA Controlled Drugs. This allows the physician prescriber to focus solely on the beneficiary's medical needs and not be influenced by financial considerations.

B. Change Request 7397

There is a requirement of DMEPOS and/or CMS supplier standards that suppliers must be compliant with all federal, state, and local laws. 75FR 52629 (August 27, 2010), 75 FR24437 (May 5, 2011).

In Change Request 7397 issued by CMS on May 13, 2011, CMS has stated that it will not, as of June 29, 2011, reimburse the professional home infusion pharmacies that provide the DEA Controlled Drugs, and will only pay physician based clinics in accordance with regulations commonly referred to as "[i]ncident to Physician Services."

Below is the policy contained in Change Request 7397.

Pharmacies, Suppliers and Providers may not bill Medicare Part B for drugs dispensed directly to a beneficiary for administration "incident to" a physician service, such as refilling an implanted drug pump. These claims must be denied. (See Medicare Claims Processing Manual, Publication 100-04, Chapter 17, section 50.B and Medicare Benefit Policy Manual, Publication 100-02, Chapter 15, sections 50.3.)

Pharmacies may not bill Medicare Part B for drugs furnished to a physician for administration to a Medicare beneficiary. When these drugs are administered in the physician's office to a beneficiary, the only way these drugs can be billed to Medicare is if the physician purchases the drugs from the pharmacy. In this case, the drugs are being administered "incident to" a physician's service and pharmacies may not bill Medicare Part B under the "incident to" provision. (See Medicare Benefit Policy Manual, Publication 100-02, Chapter 15, sections 50.3 and 60.1.)

C. Vital Care's Position

1. CMS' Change Request 7397 is either a significant expansion of the "[i]ncident to" rules or CMS misunderstands the factual scenario.

> *"...may not bill Medicare Part B for drugs dispensed directly to a beneficiary for administration "incident to" a physician service, such as refilling an implanted drug pump."*

"Incident to a physician's professional services" is defined at § 1395x(s)(2)(A) and codified at 42 C.F.R. §§410.10 and 410.26 and the *Medicare Benefit Policy Manual*, CMS Pub. 100-02, Ch. 15, § 50. To be covered, incident to the services of a physician, services or supplies must be:

- Integral, although incidental, parts of the physician's professional service;
- provided without charge or included in the physician's bill;
- of a type that are commonly furnished in physician's offices or clinics;
- furnished under the physician's direct personal supervision; and
- furnished by the physician or by an individual who qualifies as an employee of the physician. [Pub. 100-02, Ch. 15, § 60.1]

Services and supplies are covered only if they are incident to covered physicians' services. Drugs furnished incident to a physician's services are not included in the physician's fee schedule payment. Instead, Medicare pays for them separately. [42 C.F.R. §414.36]. To be considered "incident to" a physician's services, a drug must be of a kind that is commonly furnished in a physician's office and is commonly rendered without charge or included in a physician's bill. [Soc. Sec. Act § 1861(s)(2)].

"Incident to physician services" has existed since Medicare first became operational in July of 1966. There has always been a fundamental confusion on the part of Medicare since there are two 'incident to' Part B benefit categories in the Medicare statute; §1395x(s)(2)(A) services and §1395x(s)(2)(B) of the Social Security Act.

"Incident to physician services" rules do not apply to this scenario because the compounded DEA Controlled Drugs in question are consumed in the home, not the physician office. They are also not provided without charge or included in the physician's bill. Moreover, such complicated DEA Controlled Drugs are not commonly prepared and provided in physicians' offices. This is the critical distinction that CMS has failed to consider. Additional differences between DEA Controlled Drugs dispensed to Medicare beneficiaries by professional home infusion pharmacies such as Vital Care and the basic "incident to" coverage requirements are: the DEA Controlled Drugs dispensed by Vital Care are not an integral part of the physician's personal professional services, the physician does not manage the services and the physician does not provide direct supervision of the self-administered Drug.

Vital Care's position is the physicians' act of filling or refilling the pump is a "physician services" and thus has its own benefit category under the Social Security Act, 42 U.S. § 1395x(v)(i)(s). We believe that there is no authority at all in the Medicare Act or its rules that requires a physician to bill for the drugs as a condition precedent to billing for personal services that constitute the refill CPT codes. Moreover, there is guidance in the Medicare Benefits Policy Manual to the contrary. See CMS Pub. 100-02, Ch. 15 & 60.1. The fact that a physician handles the drug does not in our view convert a physician's personal service or the drugs into "incident to" services.

To include the DEA Controlled Drugs provided by professional home infusion pharmacies such as Vital Care and other similarly situated pharmacies as "incident to a physician's personal professional services" is a significant expansion of the "incident to" category. ***This is not a clarification of existing policy, but rather CMS is making new regulations.***

CMS has been paying for this service for many years. Vital Care's first payment for this service was in 1990. The filling or refilling of the implanted intrathecal pump is not the same as "administration" of the DEA Controlled Drugs.

The DEA Controlled Drugs at issue are not injected or infused and are not coded or billed as such. The claims for those services are specifically designated as filling or refilling, and not administration. The blurring of the distinction between filling or refilling and administration is significant if it causes CMS to conclude that a pump filled or refilled by a physician no longer delivers DEA Controlled Drugs considered "self administered." In that instance, the transmittal authorizing pharmacies to bill for the "self administered" DEA Controlled Drugs might no longer apply; coverage of the pharmacy provided DEA Controlled Drugs would be the void. However, we do not share that view. We believe that permitting the pharmacy to bill for the DEA Controlled Drugs and the physician to bill for the professional service best ensures that the party best informed about the goods and services is billing the program for them.

2. CMS is promulgating a new regulation and as such, under the APA such a pronouncement must go through a formal Notice and Comment period.

Whether billed by the pharmacy, or by the physician, the DEA Controlled Drugs must be inserted in a pump that "administers" the drug automatically. When a physician bills for a fill or refill, the DEA Controlled Drugs at issue are no less "self-administered" than when the beneficiary or caregiver fills or refills the pump. There is no change in the DEA Controlled Drugs delivered, the dosage or their purpose.

Since the Medicare statute authorizes the Department of Health & Human Services ("HHS") to issue regulations when those changes are substantive and affect the legal rights of private parties, HHS is required to follow the Notice and Comment procedure of § 553 of the Administrative Procedure Act ("APA").

The APA's informal rulemaking process is simple and flexible, consisting of only three procedural requirements. First, HHS must give prior notice, which is accomplished by publication of an item in the *Federal Register*. The notice must contain "either the terms or substance of the proposed rule or a description of the subjects and issues involved" as well as a reference to the legal authority for issuing the regulation and information about the publication participation. 5 U.S.C.A. § 553(b). Next, after publication of the notice of rulemaking, HHS must "give interested persons an opportunity to participate" through submission of written comments containing data, views or arguments. 5 U.S.C.A. § 553(c). Finally, after HHS has considered the public comments, it must issue with its final regulations "a concise general statement of ...basis and purpose." See Auto Parts & Accessories Ass'n v. Boyd, 407 F.2nd 330, 338 (D.C.Cir 1968).

If CMS is going to reclassify the patient specific DEA Controlled Drugs prepared, individually by professional home infusion pharmacies as 'incident to a physicians professional services," it must abide by the APA's notice and comment period. Accordingly, Vital Care respectfully requests that CMS withdraw Change Request 7397 scheduled to be effective June 29, 2011, and asks that HHS publish this proposed change first as proposed rules in the *Federal Register*, have the notice contain the requisite notice and comment period and consider industry stakeholder comments, and then publish this as a new regulation in the *Federal Register* if it survives after the notice and comment period.

3. CMS' Change Request 7397 is contrary to Federal Law

> *"...the only way these drugs can be billed to Medicare is if the physician purchases the drugs from the pharmacy."*

The DEA Controlled Drugs are patient specific, compounded, sterile preparations pursuant to a valid prescription. Selling them to anyone other than the end user - including a physician - is in violation of federal law, as cited by the DEA in the following excerpt:

> "Under current Federal Law, a pharmacy may not dispense a patient-specific prescription for a controlled substance to a doctor for administration to the patient."
>
> "Title 21, United States Code (USC) 802 (10) requires that dispensed controlled substances be delivered to the ultimate user as defined (21 USC 802 (27)). This does not include the prescribing practitioner (21 USC 802 (27))."

4. A Danger To The Public Health

Without the ability to bill and be paid by the Medicare carrier, the professional home infusion pharmacies must seek payment directly from the patient, which is both contrary to the law and even if it were not, often not feasible. When faced with having to pay out of pocket, patients

typically either refuse therapy or seek this care in an alternative environment. Thousands of patients across the country are receiving care in the manner described in this letter, and this CR puts these patients at risk.

5. Conclusion

There is no down side to directly reimbursing professional home infusion pharmacies for the DEA Controlled Drugs. Change Request 7397 does not address any new benefit category as the DEA Controlled Drugs are already covered by Medicare, rather it only changes the direction of payment to the applicable party.

Your assistance is sought in ensuring that the patients requiring these home infusion DEA Controlled Drugs continue to have access to safe, effective and affordable care. **Specifically, we are respectfully requesting that CMS immediately reverse Change Request 7397 (which will otherwise be enacted June 29, 2011) because it (i) either confuses the underlying factual scenario or improperly expands the "incident to" regulations, (ii) requires a notice and comment in accord with the APA period prior to its enactment, (iii) is contrary to federal DEA requirements, and (iv) endangers the public health.**

Thank you in advance for your consideration of this matter and urgent action.

Should you have any questions concerning this matter, please do not hesitate to contact me.

Sincerely,

Charles MacKelvie

Charles F. MacKelvie

CFM/sc

cc: Dr. Logan Davis, Vital Care, Inc.