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National Home Infusion Association
Providing solutions for the infusion therapy community

June 23, 2011

Mr. Marc Hartstein
Deputy Director, Hospital and Ambulatory Group, Center for Medicare
Mail Stop C4-01-26
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS Change Request 7397

Dear Mr. Hartstein:

Thank you and the other CMS staff for speaking with us on June 21st regarding the background and rationale for Change Request 7397, which provides that drugs inserted into an implanted pump in a physician's office must be billed as "incident to" a physician's service. We appreciated your candor and the clarity of your explanation.

In considering this issue after that telephone call, we believe there are several issues that should be worked through before this new policy is implemented, and for that reason we request that the policy under Change Request 7397 be delayed for another 45 days to ensure these issues are resolved.

The first issue pertains to the basic rationale for the conclusion that the drugs should be considered to be "incident to" a physician's service – that the insertion of the drugs into the implanted pump is performed by the physician, and thus the drugs and the pump are incidental to that physician service.

We understand the distinction you are making, but question how strong a basis that is for the change in policy. A physician is not essential for the insertion of drugs into implanted pumps – this procedure can be done by a trained registered nurse in the patient's home. Often a physician's office is the site of the drug insertion simply because the physician's office contains

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the necessary equipment [Medtronic SynchroMed® Programmer] to which a small pharmacy or home health agency may not otherwise have access. Since the physician's service is not an essential component for filling or re-filling the implanted pump, we question whether that is the appropriate place to draw the line between "incident to" and DME-covered infusion.

It appears to us that a far more straightforward, transparent and understandable policy would be that a pharmacy should be the biller for the patient-specific drugs it compounds. Such a policy also would be consistent with the unique role the infusion pharmacy plays in compounding the medications that are inserted into implanted pumps. Patients who receive an implanted pump for management of chronic pain often require specialized formulas of several different medications to adequately control their pain. Because these medications are being inserted into a pump where they will sit for up to 30 days as they are gradually dispensed, and because they are being delivered, in most cases, into the intrathecal space around the spinal cord, the compounded medication must be produced in compliance with USP Chapter 797 guidelines for high-risk sterile preparations. Few physicians have the clean rooms necessary for this level of pharmaceutical compounding, and thus, in the interest of patient safety, rely on external infusion pharmacies to produce the medication that will then be inserted into the implanted pump.

A second issue concerns the Drug Enforcement Administration's (DEA's) policies regarding the sale of patient-specific controlled substances to a physician. According to statute, dispensed controlled substances may be delivered only to the ultimate user. [21 U.S.C. 802(10)]. The provision in Change Request 7397 that requires the physician to purchase the drugs from the pharmacy is justified on the basis of a manual provision that provides an exception to the statutory prohibition stated above. [DEA Office of Drug Diversion, Pharmacists' Manual, Section XIII.] Before Change Request 7397 is implemented, we believe we all would benefit from greater certainty as to the legal effect of this manual's modification of a statutory requirement. The consequences to the physician and the pharmacy for non-compliance with DEA laws are significant.

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Our final issue concerns the notice of this pending Change Request. Based on feedback from our members, there appears to be some confusion as to the application and scope of this Change Request policy. Perhaps that relates to the initial change request that CMS subsequently clarified, but we are concerned that a number of our members who may be affected by this policy were not in contact with CMS and were not aware of the conversations you have had with several pharmacies. For that reason, we request a brief delay of 45 days regardless of your actions on the other points raised in this letter.

Sincerely,

Russ Bodoff

Russ Bodoff
CEO/President
National Home Infusion Association

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