



**Congress of the United States**  
**Washington, DC 20515**

June 28, 2011

Dr. Donald M. Berwick  
Administrator  
Centers for Medicare and Medicaid Services (CMS)  
Hubert H. Humphrey Building  
200 Independence Avenue, SW, Room 314-G  
Washington, DC 20201

Dear Dr. Berwick,

On June 29, 2011, the Centers for Medicare and Medicaid Services (CMS) will implement a change in Medicare reimbursement policy that puts beneficiary access to needed medications at risk.

For years, patients have received infusion medications directly from accredited infusion pharmacies to be used in implantable, intrathecal, pain pumps. This type of infusion therapy is critical for use in patients with chronic and/or severe pain attributed to many medical conditions. Pharmacies deliver infusion medications in the name of and for acceptance by the patient at the physician offices and bill Medicare directly. This arrangement has proved to be a tremendous benefit to patients and physicians because it assures that the proper handling and storage of controlled substances, as regulated by the Drug Enforcement Administration (DEA), is handled by the pharmacists trained and certified to do so.

It has recently been brought to our attention that a new CMS policy (Change Request 7397) will prohibit pharmacies from billing Medicare for these medications. Although no statutory change has been made to their regulations, CMS will reverse its 20 year policy on which many patients, physicians and pharmacies have relied. Since these complex, customized, high-risk, sterile compound pain management solutions must be prepared in a specially designed pharmacy by highly qualified pharmacists, this new policy effectively eliminates a pain management option that many patients and physicians count on every day.

To exacerbate the issue, many of these medications are considered “controlled substances” by the DEA and are highly regulated. One of the DEA regulations prohibits pharmacies from dispensing or selling these substances to physicians for “resale” to patients. If pharmacies cannot bill Medicare and physicians cannot resell or dispense these drugs to patients, patient access to these critical drugs will be severely restricted.

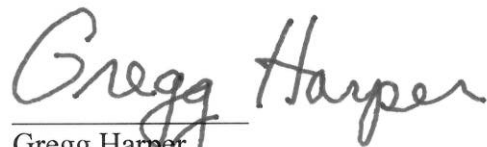
Quite frankly, it makes no sense. Prohibiting pharmacies from billing Medicare directly for these medications, as has been long-standing practice, will disrupt service to patients and create new possibilities for drug diversion and an increased risk for deadly infections by requiring drugs to be compounded outside of the pharmacy setting.

We ask that CMS halt the implementation of Change Request 7397 because of the detrimental effect it will have on patient access to needed pain care medication. At the very least, CMS should allow enough time for patient groups affected by this change to understand the implications the change will have on the ways they receive care. Further, Congress has not had sufficient time to examine this policy and fully understand its interactions with both current law and our local health care providers.

CMS's new interpretation of an existing regulation appears counter to statute and will have a severe impact on the thousands of fragile patients relying on this service. Additionally, this policy change would increase the risk for drug diversion and conflict with existing DEA regulations, restricting access for patients.

We look forward to working with you and your staff to ensure that this policy is not implemented or at the very least delayed to allow Congress enough time to understand how this change will impact patient groups, health care providers, and existing law.

Sincerely,




Gregg Harper  
Member of Congress



Martin Heinrich  
Member of Congress



Jo Bonner  
Member of Congress



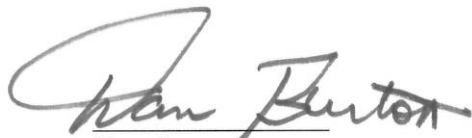
Steven M. Palazzo  
Member of Congress



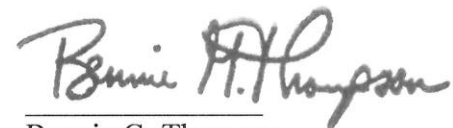
Ron Paul  
Member of Congress



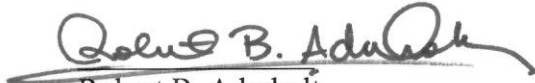
Mac Thornberry  
Member of Congress




Dan Burton  
Member of Congress



Bennie G. Thompson  
Member of Congress



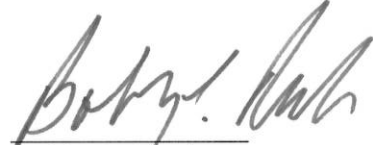
Robert B. Aderholt  
Member of Congress



Shelley Berkley  
Member of Congress



Adam Kinzinger  
Member of Congress



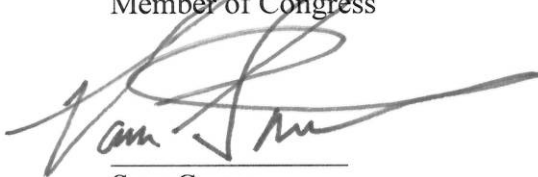
Bobby L. Rush  
Member of Congress



Leonard L. Boswell  
Member of Congress



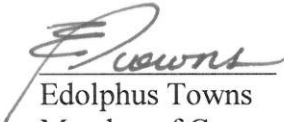
Terri A. Sewell  
Member of Congress



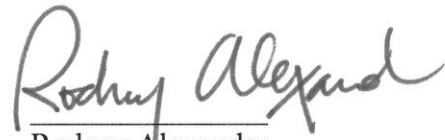
Sam Graves  
Member of Congress



Alan Nunnelee  
Member of Congress



Edolphus Towns  
Member of Congress



Rodney Alexander  
Member of Congress



Charles A. Gonzalez  
Member of Congress