

Gregg Harper
Congress of the United States
Third District, Mississippi

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COMMITTEES: ENERGY & COMMERCE, ETHICS, AND HOUSE ADMINISTRATION
SUBCOMMITTEES: ELECTIONS (House Administration) Chairman
COMMERCE, MANUFACTURING & TRADE (Energy & Commerce) and ENVIRONMENT AND THE ECONOMY (Energy & Commerce)

PROTECT PATIENTS WITH CHRONIC PAIN

Ask CMS To Halt Policy Restricting Patients' Access To Compound Pain Medications

Dear Colleague,

Effective June 29, 2011, the Centers for Medicare and Medicaid Services (CMS) will impose a new payment policy change that will negatively impact some of Medicare's most vulnerable beneficiaries – those with chronic and/or severe pain. This change disrupts a reimbursement system that has been in place for 20+ years. CMS' new payment change will prohibit pharmacies from billing Medicare for compounded pain medications, and instead puts that responsibility on physicians. Due to the nature of the medications, which are considered "controlled substances" by the Drug Enforcement Administration (DEA), the compounds are highly regulated.

Because of the interplay between DEA regulations governing controlled substances, physicians cannot resell or distribute this pain medication to patients directly. As a result, CMS' policy not only tramples upon statute, but deprives patients access to critical pain care medication because pharmacies will no longer be able to bill for these drugs and physicians will be unable to provide them to patients according to DEA regulations.

I urge you to join me in signing the letter below to CMS Administrator Dr. Donald M. Berwick. The letter asks him to halt this payment policy change, or at the very least give Congress enough time to understand how this will impact patient groups, health care providers, and existing law.

To sign this letter, or for additional information, please contact Adam Buckalew by telephone at (202) 225-5031 or email at adam.buckalew@mail.house.gov by Tuesday, June 28, at 12:00 p.m.

Sincerely,



Gregg Harper
Member of Congress

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June 28, 2011

Dr. Donald M. Berwick
Administrator
Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

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

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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,

A handwritten signature in black ink that reads "Gregg Harper". The signature is written in a cursive, flowing style.

Gregg Harper
Member of Congress