DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

MAY 23 2013

Michael S. Carome, M.D.
Deputy Director, Health Research Group
Public Citizen
1600 20th Street, NW
Washington, DC 20009

Dear Dr. Carome:

Thank you for your letter regarding coverage and payment of compounded drugs provided by compounding pharmacies found to be in violation of the Federal Food, Drug and Cosmetic Act (FFDCA). The Centers for Medicare & Medicaid Services (CMS) greatly appreciates you bringing these concerns to our attention.

We share your concern for the safety of drugs used by Medicare beneficiaries. The recent tragedy involving contaminated drugs produced by the New England Compounding Center (NECC) has raised questions that must be addressed about the safety of compounded drug products on the market. We agree that there must be sufficient regulatory oversight and control over compounding pharmacies to ensure that safety and payment decisions are appropriately aligned.

Recent media articles and Congressional inquiries have raised questions about how Medicare covers and pays for compounded drugs. While we believe that most patients' needs can be met with the Food and Drug Administration (FDA)-approved drug products, we also believe that it is medically appropriate for some patients to receive compounded drugs in certain situations, including when patients are allergic to inactive ingredients in FDA-approved drug products, or when dosage forms or strengths of drugs that are needed by the patient are not available in FDA-approved drug products. In such cases, we think it is appropriate for Medicare to pay for compounded drugs (when they meet other criteria for coverage and payment) to ensure that beneficiaries and recipients have access to clinically appropriate drug therapies.

In general, in order for an item or service to be considered for Medicare coverage, the item or service must fall within at least one benefit category established in the Social Security Act, must not be specifically excluded by the Act, and must be "reasonable and necessary" for the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body member. Medicare covers items and services when specifically required by statute or by using several policy options which include national coverage determinations (NCDs), local coverage determinations (LCDs), rulemaking and claim-by-claim adjudication.

Any member of the public may ask CMS to open an NCD analysis. We have no current NCD requests related to compounded drugs. In addition, Medicare Administrative Contractors (MAC)

use LCDs to specify under what clinical circumstances a service is considered reasonable and necessary for payment within their jurisdiction. CMS utilizes program manuals to provide guidance and oversight of the LCD development process, and respects the MAC's authority to develop LCDs so long as they do not conflict with applicable national coverage determinations, regulations, or other formal authoritative CMS direction.

Traditional pharmacy compounding is the combining, mixing, or altering of ingredients by a licensed pharmacist in response to a prescription to create a medication tailored to the needs of an individual patient. Compounding certain sterile products, such as intravenous nutrition, and repackaging certain medications to prepare patient-specific doses, are an essential part of the provision of care in certain clinical situations, and we believe that it is important to provide payment for drugs when they must be prepared in this manner. We also recognize the importance of protecting patients from the risks that arise from compounding that exceeds the bounds of traditional pharmacy compounding. It should be noted that where a drug is not safe, the product should not be on the market.

You inquired about CMS's coordination with the FDA with respect to chapter 15, section 50.4.7 of the Medicare Benefit Policy Manual that would deny Medicare payment for compounded drugs furnished by a pharmacy found to be in violation of the FFDCA. While this provision of the manual is for the FDA, pharmacies, patients, physicians, Medicare contractors and others report potential violations of the FFDCA to CMS, we are unaware of any reports that have come to CMS or that Medicare has ever denied payment for Part B drugs under this provision.

It is important to note that these provisions of Chapter 15 apply only in limited situations. With the exception of compounded drugs and some repackaged items, the majority of drugs paid under Part B are commercially available products that are purchased by a physician's office, administered in the office or clinic setting, and billed by the physician or other provider. Medicare payments for drugs used in the office or clinic setting are made to physicians who bought and administered the drugs; payments are rarely made directly to pharmacies, even in situations where a pharmacy has compounded the drug and sold it to the physician's office. The provisions in Chapter 15 are not likely to affect the majority of drugs purchased for use in the office setting. Even if CMS were to decline payment under Chapter 15 to a physician who bought and administered the drugs, the effect of these provisions on compounding pharmacies would not be immediate.

You also inquired about what proportion of Medicare beneficiaries who receive spinal epidural steroid treatment receive compounded drugs and also the extent to what degree Medicare beneficiaries were affected by the recent NECC incident. We cannot confirm the number of beneficiaries that received the drugs prepared by NECC because the Medicare Part B claims processing systems do not track the specific drug product that was bought by a physician or other provider and administered to a beneficiary. In other words, we do not track the identity of manufacturers or pharmacy compounders of drugs used in physicians' offices in our claims payment systems. We expect that individual physicians are familiar with the compounding pharmacies that they use.

We believe that in situations where a pharmacy has been found to be in violation of the FFDCA, regulatory authorities—such as the FDA or state health departments and boards of pharmacy—should have sufficient regulatory authority to stop the sale of unsafe drugs from continuing. We will continue to work with the FDA to ensure the denial of Medicare payments for compounded drugs made by pharmacies that violate the FFDCA.

I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. We will continue to work with the FDA to ensure the denial of Medicare payments for compounded drugs made by pharmacies that violate the FFDCA. Please do not hesitate to let us know if you or your staff have any further questions.

Sincerely,

Jonathan D. Blum
Acting Principal Deputy Administrator &
Director, Center for Medicare