DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

AUG 22 2006

The Honorable Charles E. Grassley
United States Senate
Washington, D.C. 20510-6200

Dear Senator Grassley:

Thank you for your letter regarding compounding of inhalation drugs. I will respond to those matters that fall within the responsibilities of the Centers for Medicare & Medicaid Services (CMS), and Dr. Von Eschenbach will write you separately on matters in the purview of the Food and Drug Administration (FDA).

We share your concern for the safety of drugs used by Medicare beneficiaries. As I will discuss below, we plan to make changes in how Medicare pays for compounded inhalation drugs. I believe that these changes will contribute to addressing some of the concerns you raise. However, I should also note that CMS can only directly affect its own programs. These drugs are also used, of course, by many patients who are not the beneficiaries of our programs. We, and they, rely on the FDA and on regulation and licensure of pharmacies by States as the principal avenues for ensuring drug safety.

While we believe most patients' needs can be met with commercially manufactured products, we believe that it may be medically appropriate for some patients to receive compounded drugs in certain situations, such as when they are allergic to "inactive" ingredients in the manufactured forms. Small-scale compounding of such drugs is sometimes referred to as "traditional" compounding. We think it is appropriate for Medicare Part B to pay for compounded drugs (when they meet other criteria for coverage) to ensure Medicare beneficiaries have access to clinically appropriate drugs in such cases.

You asked whether CMS will be considering modifications to how Medicare pays for inhalation drugs. Medicare covers inhalation drugs under Part B when medically necessary and used with a nebulizer, which we pay for as a piece of durable medical equipment (DME). With two exceptions, Medicare, at present, pays under Part B for compounded and non-compounded forms of inhalation drugs under the same billing codes and at the same payment rates. We plan to distinguish the compounded and non-compounded forms of additional inhalation drugs for Part B payment purposes in the future.

Doing so requires creation of additional codes. The non-compounded form would continue to be paid on the basis of average sales price (ASP) plus 6 percent, as prescribed by the statute. Since manufacturer ASP data is not available for compounded drugs, the claims for separately

identified compounded forms of a drug would be priced manually by the Medicare carriers based on invoices submitted by suppliers, most probably at significantly lower payment rates.

This payment methodology requires special claims processing, and we need to consider the volume of claims and other particular characteristics of the drugs, as well as the effect on carrier workloads and budgets. At present, we cover 37 inhalation drug codes, many with quite small volumes. We will undertake a review of these drugs in the next few months and determine where new codes should be introduced. To maximize the overall improvement in coding accuracy, we anticipate that concentrating on the highest volume compounded inhalation drugs, at least initially, would likely be the most appropriate course. We expect to issue implementing instructions and coding revisions by the end of October so the codes would be ready for implementation on January 1, 2007. We will educate physicians and suppliers about any coding changes to help ensure that they are using the proper codes when billing for inhalation drugs.

We believe that this step will establish more appropriate payment rates for compounded drugs and thus remove any inappropriately large financial incentives that may be leading to substitution of compounded forms of inhalation drugs for non-compounded forms of the same drug in instances where such a substitution may not be justified by the issues of medical appropriateness mentioned above. Insofar as compounded forms of these drugs are being provided largely to secure payment levels that are high relative to the costs of producing the compounded form of the drug, we would expect this change to have significant effect on the form in which these drugs are provided.

We believe CMS should take this step and see the results before we consider whether to take any additional steps. The questions in your letter suggest several other possibilities. The following paragraphs discuss each in turn.

- "What is CMS' position on accreditation of compounding pharmacies in order to receive Medicare reimbursement?"

Entities dispensing drugs (compounded or non-compounded) covered by Medicare in connection with DME will be required to meet the accreditation requirements and quality standards applicable to DME suppliers mandated by section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The requirements for accreditation were finalized in a final rule placed on display August 1 and published in the "Federal Register" on August 18. The quality standards were issued on August 15 and are available on the CMS web site. CMS intends to emphasize accreditation first in those areas that will be part of the DME competitive bidding program. This program will initially affect DME suppliers in 10 cities in 2007.

The quality standards will reflect good business practices and are designed to ensure that beneficiaries receive the right equipment and training to meet their needs. However, they are not intended to delve into issues of product quality at the level of drug safety. As I noted above,

CMS relies on State licensure of pharmacies and FDA oversight of manufacturers to insure safety of prescription drugs paid for by Medicare.

- "My staff were told that the Medicare reimbursement rate for inhalational drugs is a major driving force for large volume compounding of such drugs, and these large providers can be identified easily by CMS' DME regional carriers. As the agency responsible for oversight of DME suppliers, how often does CMS conduct audits of DME suppliers that provide compounded medications, and how are these audits initiated? Does CMS coordinate with FDA on audits and inspections?"

The CMS oversight of suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) is, at present, aimed at determining whether the suppliers are legitimate and have the appropriate characteristics to be enrolled in the Medicare program. The suppliers must meet 21 standards relating to furnishing DMEPOS, such as: minimum amounts of liability insurance, maintaining a physical location, and having a beneficiary complaint process. Conformity with these standards is reviewed by the National Supplier Clearinghouse, CMS' designated enrollment contractor for suppliers of DMEPOS. CMS has no ongoing activities aimed at review of the compounding of drugs and currently no regular form of coordination with FDA in this area.

- "What is CMS' position on maintaining reimbursement for nebulizers in Medicare Part B but restricting reimbursement for the inhalational drugs to Part D?"

Section 1860D-42(c) of the Social Security Act, added by the MMA, required that the Secretary prepare a report that "makes recommendations regarding methods of providing benefits under . . . Part D . . . for outpatient prescription drugs for which benefits are provided under Part B." The report was transmitted to Congress on March 7, 2005.

As the report discusses, Part B now pays for 13 categories of drugs, including those provided in conjunction with DME, such as inhalation drugs. The report examined uses of the drugs, dispensing patterns, and how claims are paid. It considered the possible effects of consolidating coverage under one program, including financial impacts on the Federal budget and on spending by beneficiaries. Our recommendation was to take no action until CMS had at least 2 years of experience with the Part D program. This period was both to allow for further study of the financial impacts of any such changes on beneficiaries and on the Federal budget, and to avoid adding to the complex task for Part D sponsors of developing initial bids and administering the new Part D benefit.

- "Has CMS considered requiring a determination of medical necessity for compounded inhalational drugs?"

We assume you are suggesting that we might seek to identify those cases where "traditional" compounding would be clinically appropriate and presumably to deny payment in the absence of such a finding. We do not now know the volume of drug claims that are for compounded forms,

but we believe it may be substantial. Nor do we know what proportion of claims for compounded drugs that we pay would be considered to be appropriate if we were to articulate clinical standards for use of compounded drugs as opposed to non-compounded drugs – this proportion might also be high. The workload implications of requiring medical review for a large number of claims would be substantial. Such a policy might thus have a modest effect, but at a high cost of implementation. Making the coding and payment changes described above, however, would provide the basis for assessing the possible desirability of such a policy.

Thank you for your interest in this important area of Medicare payment policy. I believe that the payment changes discussed above will be a substantial help in addressing some of the concerns you raise.

Sincerely,

Mark B. McClellan, M.D., Ph.D.