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Health, Education and Human Services Division

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October 11, 1996

The Honorable Fortney H. (Pete) Stark
Ranking Minority Member
Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Stark:

In 1995, Medicare part B allowances[1] for drugs, nutrients, and nutrient-related supplies totaled over $2.2 billion. For outpatient drugs alone, Medicare part B allowances rose from over $1.3 billion in 1994 to over $1.6 billion in 1995, an increase of over 26 percent. Your May 8, 1996, letter requested that we examine the reasonableness of Medicare's payment levels for outpatient drugs and liquid nutrients. Specifically, you asked that we gather information on (1) the Medicare allowances for outpatient drugs and liquid nutrients, (2) the cost at which Medicare providers and suppliers acquire these items, (3) the prices paid by other large purchasers, and (4) potential areas of fraud and abuse in Medicare billings for outpatient drugs and nutrients. This letter summarizes the information we have gathered to date, identifies the reasons why we have suspended our work, and informs you of our follow-up plans.

We reviewed Medicare regulations with officials of the Health Care Financing Administration (HCFA) and a HCFA contractor to determine how they set the Medicare payment levels for drugs and liquid nutrients. We reviewed reports on Medicare pricing for drugs and nutrients by the Office of the Inspector General (OIG) in the Department of Health and Human Services (HHS). We also obtained information compiled by a home infusion and nutritional service provider.

MEDICARE PAYMENT LEVELS FOR OUTPATIENT DRUGS

Medicare part B generally pays only for drugs that are incident to physician services and are not self-administered, unless specifically authorized by law.

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[1]Medicare allowances include the 80 percent Medicare pays directly to suppliers and the 20 percent copayment by the Medicare patient.

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Medicare coverage includes certain drugs used in conjunction with medical equipment, such as inhalation drugs used with a nebulizer pump. In setting payment levels, HCFA established a policy to reimburse outpatient drugs on the basis of estimated acquisition costs or national average wholesale prices (AWP). If a drug has multiple sources, Medicare payment levels are based on the median of the AWP for all generic sources.

The information we gathered provides three indications that Medicare payment levels for drugs may be too high. First, HCFA officials said that because of the difficulty of collecting acquisition cost data, Medicare contractors have been using AWPs to set Medicare payment rates. In contrast, under the Medicaid program, HCFA does not allow the states to routinely use AWPs to establish upper limits on their reimbursements for certain drugs.[2] In its instructions to the states, HCFA notes that "...there is a preponderance of evidence that demonstrates that such AWP levels overstate the prices that pharmacists actually pay for drug products by as much as 10 to 20 percent...."[3]

Second, the home infusion and nutritional service provider that we contacted had collected and analyzed Medicare and industry drug pricing data. Information from that provider indicated that for some drugs the Medicare payment levels, based on AWPs, are much higher than acquisition costs. The information collected by that provider, however, is now part of an ongoing Department of Justice matter under court seal. We decided to accede to the Justice Department's strong preference that we refrain from pursuing use of the data.

Third, reports issued in May and June 1996 by the HHS OIG show that HCFA's use of AWPs results in excessive Medicare payment rates for the drugs studied.[4] In the May report, the OIG compared Medicare payment levels for 17 drugs with the prices paid by state Medicaid programs for the same drugs. The Medicare allowances, based on

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[2]These drugs include brand-name drugs certified as medically necessary by a physician and drugs not marketed or sold by more than one manufacturer.

[3]The quoted material is from HCFA's State Medicaid Manual, Part 6, section 6305.1.

[4]Appropriateness of Medicare Prescription Drug Allowances, HHS OIG, OEI-03-95-00420 (Washington, D.C.: May 1996); A Comparison of Albuterol Sulfate Prices, HHS OIG, OEI-03-94-00392 (Washington, D.C.: June 1996); Suppliers' Acquisition Costs for Albuterol Sulfate, HHS OIG, OEI-03-94-00393 (Washington, D.C.: June 1996).

AWPs, were almost 15 percent higher than the state Medicaid allowances, which were based on a discounted AWP drug reimbursement formula. In June, the OIG reported that suppliers pay an average of $0.19 per milliliter (ml) to purchase albuterol sulfate (a nebulizer drug), though Medicare's allowed reimbursement ranged from $0.40 to $0.43 per ml. The OIG concluded that Medicare could have saved $94 million during the 14-month period of the OIG review if HCFA had based Medicare payment rates for albuterol sulfate on the average of surveyed supplier invoice costs.

HCFA concurred with the HHS OIG's recommendation that the agency reexamine its Medicare drug reimbursement methodologies with the goal of reducing payments for prescription drugs. HCFA has not yet acted to change the Medicare drug payment levels but is considering alternatives to the current reimbursement method.

HCFA has issued a revision to the Medicare Carriers Manual on the dispensing and billing of prescription drugs used in conjunction with medical equipment.[5] This revision stipulates that pharmacies dispensing these prescription drugs, such as nebulizer drugs, should bill and receive Medicare payments for those drugs. Nondispensing suppliers who furnish the medical equipment, such as nebulizer pumps, are prohibited from billing Medicare for these drugs. These requirements will be enforced beginning December 1, 1996.

MEDICARE PAYMENT LEVELS FOR LIQUID NUTRIENTS

Medicare covers enteral products (tube-fed liquid nutrients) for patients who cannot ingest food orally or whose digestive systems are impaired. In May 1996, the HHS OIG issued a report[6] recommending reduced Medicare payment levels for enteral nutrition. (The OIG is also planning a study on Medicare payment levels for parenteral nutrition, which is administered intravenously.) The OIG based its May 1996 recommendations on a survey of pricing information obtained from Medicare and non-Medicare payers and 140 retail pharmacies between September 1994 and August 1995.

For two types of enteral products commonly stocked by larger retail pharmacy chain stores, the OIG found that almost all 140 pharmacies surveyed charged less than the Medicare allowance. For example, for one type of enteral product, 98 percent of the pharmacies

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[5]This revision also applies to some nutrition products that are considered drugs.

[6]Payments for Enteral Nutrition: Medicare and Other Payers, HHS OIG, OEI-03-94-00021 (Washington, D.C.: May 1996).

charged less than the Medicare allowance, and almost half charged 10 to 20 percent less.

For some enteral products, the OIG also obtained the prices paid by nine other payers, including Medicare risk-contract health maintenance organizations (HMO), the Veterans Administration, a Blue Cross/Blue Shield plan, a private HMO, and state Medicaid agencies. For three products, the OIG reported that the other payers reimbursed on average 48, 23, and 17 percent less than Medicare's fee-for-service program. For example, a Medicare risk-contract HMO paid $.68 to $.78 for an enteral product that fee-for-service Medicare reimburses at $1.09. All the payers that negotiated contracts with suppliers had lower payment rates for enteral products than Medicare fee for service.

HCFA concurred with the OIG that the Medicare payment levels for enteral products were too high but noted that the methodology for setting payment rates for enteral products is mandated by legislation. HCFA is considering alternatives to the current reimbursement method for liquid nutrients. For example, HCFA plans to include enteral products in a competitive pricing demonstration project, which is allowed under its statutory authority. The demonstration project has been delayed until 1997, however. Also, HCFA reported that the administration had a budget proposal to freeze Medicare payment levels for enteral and parenteral nutrition at 1993 levels until 2002, but this proposal was not enacted.

REASONS FOR SUSPENDING FURTHER WORK

Some of the information we have gathered has led us to suspend further work on your request at this time for the following reasons: (1) The drug pricing information collected by the home infusion and nutritional service provider is part of an ongoing Justice Department matter under court seal. (2) The HHS OIG has recently completed reports on drugs and enteral nutrition pricing and plans additional work on parenteral nutrition pricing. Finally, (3) HCFA has concurred with the OIG's recommendations. Therefore, as agreed with your staff, we are suspending further work on your request. We are monitoring actions taken by the Justice Department and HCFA. We will periodically review their actions with your staff and discuss whether we should consider additional work.

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HCFA and Justice Department officials have reviewed a draft of this correspondence for accuracy, and we have incorporated their suggestions.

If you would like any additional information on these matters, please contact Edwin Stropko at (202) 512-7114 or William Reis at (617) 565-7488.

Sincerely yours,

Edwin P. Stropko for

William J. Scanlon
Director, Health Financing
and Systems Issues

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