Via Electronic Mail

November 6, 2014

Janna Raudenbush
Public Affairs Specialist
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue
Washington, DC 20201

Re: Comparison of dispensing fees under Medicare Part B with dispensing fees under Part D and state Medicaid programs

Dear Ms. Raudenbush,

Mark Wolfson had sent me your contact information as he was retiring. We recently read an OIG report that was of some concern to the industry and I felt compelled to respond. Can you please review and ensure this gets to the appropriate person at the OIG?

We are writing in response to the Office of Inspector General's (OIG's) recent report on spending for prescription drug dispensing fees under Medicare Part B.[1] The report examined the differences between the costs of dispensing fees for Part B drugs, including respiratory medications used with a nebulizer, and those under the Part D prescription drug benefit and state Medicaid programs. The study concludes that Medicare could save millions of dollars annually if its dispensing fees were aligned with dispensing fees under Medicate Part D or state Medicaid programs.

The report's conclusions are flawed, especially because the study did not consider pharmacies' costs to furnish respiratory drugs to Medicare beneficiaries. The average sales price (ASP) payment methodology in effect today is insufficient to cover the professional and support functions pharmacies must perform in order to furnish safe and effective respiratory drugs to beneficiaries. A major shortcoming in the OIG's

[1] Department of Health and Human Services Office Of Inspector General, "Medicare Part B Prescription Drug Dispensing And Supplying Fee Payment Rates Are Considerably Higher Than The Rates Paid By Other Government Programs," Audit (A-06-12-00038) (September 19, 2014).

1707 L Street, NW, Suite 350, Washington, DC 20036
Tel: 202-372-0107 fax: 202-835-8306 www.aahomecare.org

report is that it failed to account for pharmacies' costs to perform these activities. The dispensing fee for Part B drugs was meant to cover a portion of those costs so that beneficiaries would continue to have access to these cost effective therapies. We discuss our concerns in detail below.

1. **Dispensing fees for respiratory medications like albuterol sulfate and ipratropium bromide under Part B were designed to ensure that beneficiaries have access to these drugs in the home setting.**

By way of background, Congress adopted the ASP payment methodology under the Medicare Modernization Act (MMA) of 2003. The law requires Medicare to pay for certain Part B drugs at 106 percent (%) of the ASP for the drug, or ASP plus (+) 6%. Under this formula.

Before the MMA, Medicare reimbursed Part B drugs at ninety-five (95) percent (%) of the drug's average wholesale price (AWP) plus a $5.00 dispensing fee. AWP pricing, which was adopted by Congress under the Balanced Budget Act (BBA) of 1996, came under scrutiny because there could be significant spreads between the drug's AWP and the acquisition price for a drug. The size of the spread could also vary widely depending on the buyer's class of trade and bargaining power. We recognize that the AWP methodology was flawed, but the spread between the drug's acquisition price and its AWP, compensated suppliers for the costs inherent in furnishing respiratory medications to beneficiaries. These costs include important professional and support functions that pharmacies must perform to ensure the drugs' safety and effectiveness and which are not separately reimbursed by Medicare.

The ASP methodology was intended to closely align payment rates for Part B drugs with market prices plus a 6% margin. In the first quarter of 2005 the ASP payment rate for the two most common aerosol medications, albuterol sulfate and ipratropium bromide, was $0.05 per milligram and $0.45 per milligram respectively. These payment amounts would presumably also have included the $5.00 Part B dispensing fee in effect at that time. CMS, relying on studies by the General Accountability Office[2] and Muse and Associates,[3] correctly concluded that a higher dispensing fee was necessary to ensure that beneficiaries could continue to receive respiratory medication in their homes. So, in addition to the ASP payment for the drugs, CMS established a dispensing of $57.00 for a thirty-day (30) and $80.00 for a ninety-day (90) supply of respiratory drugs furnished in 2005.[4]

For 2006, CMS established a $57.00 dispensing fee for an initial 30 day supply of respiratory medications and a $33.00 dispensing fee for subsequent 30 day supplies and $66.00 for furnishing a 90-day prescription.[5]

[2] 'Medicare: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs'' (GAO–05– 72)

[3] "The Costs of Delivering Inhalation Drug Services to Medicare Beneficiaries," Muse and Associates for American Association for Homecare (August 2004) (Muse study).

[4] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, Final Rule, 69 Fed. Reg. 66236 at 66338 (November 15, 2004).

[5] Department Of Health And Human Services Centers for Medicare & Medicaid Services, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B, Final Rule, 70 Fed. Reg. 70116 (November 21, 2005).

2. There is no factual basis to support a comparison of Part B dispensing fees for albuterol sulfate and ipratropium bromide with dispensing fees under Medicare Part D and state Medicaid programs.

Comparing dispensing fees for Part B drugs with dispensing fees under Medicare Part D or state Medicaid programs is like comparing apples and oranges. The government's expenditures for dispensing fees under these programs are not in any way comparable. Part B pharmacies are "closed" pharmacies that have extensive overhead costs for complying with Medicare quality and supplier standards, accreditation and billing requirements.

The Part D drug benefit, in contrast, is modeled after drug benefits available in the private sector. Generally, beneficiaries choose from a number of competing plans depending on the plan's formularies and their need for specific drugs. Part D drugs are subject to real time claims adjudication which greatly reduces pharmacies' cost for billing and regulatory compliance. Part B pharmacies must comply with the Medicare supplier standards, accreditation standards and are subject to Medicare pre and post pay audits based on the medical necessity of the nebulizer used to administer the drugs.

In the 2005 physician fee schedule proposed rule, CMS explicitly asked pharmacies to comment on whether the Agency should implement a dispensing fee and, if so, what the fee should be. [6] AAHomecare responded to the request for comments with the Muse study which examined the impact of moving from the AWP pricing methodology to ASP and the costs to pharmacies of furnishing aerosol drugs to Medicare beneficiaries in 2005. [7] The Muse study demonstrates that the acquisition cost of the drugs is only a small part of the total cost of providing aerosol medications to Medicare beneficiaries in their homes. Respiratory drugs cannot be furnished effectively without a specialized pharmacy operation and adequate professional, administrative, and support personnel. These operational costs include administration, delivery, patient education, oversight, and monitoring in addition to the acquisition price of the drug.

The study concluded that in order to continue furnishing 2004 levels of service to beneficiaries using aerosol medications, suppliers would need to receive a dispensing fee of $68.10 per beneficiary service encounter, or each time the pharmacy billed a J code to the Medicare program.[8] In order to provide respiratory drugs to beneficiaries in their homes, pharmacies must perform the following steps: [9]

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[6] Department Of Health And Human Services Centers for Medicare & Medicaid Services
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, Proposed Rule, 69 Fed. Reg. 47488 (August 5, 2004)

[7] One hundred nine (109) pharmacies, representing 2,448 branch locations that provide respiratory and/or medical equipment under Part B, participated in the study. These 2,448 branches provided inhalation drug therapy services to 337,348 Medicare beneficiaries per month. These Medicare beneficiaries were estimated to be 61 percent of all Medicare inhalation drug therapy patients in the first quarter of 2004.

[8] With respect to the impact of adding a $68.10 dispensing fee to the ASP payment amount for respiratory drugs, the Muse study concluded, that based on CMS' projections, using data from the proposed rule, adding a $68.10 dispensing fee would result in savings of at least 4 billion over the ten year scoring window. In other words, the payment reduction resulting from switching from AWP to ASP was so steep that even with the addition of a dispensing fee of $68.10, the Medicare program would realize significant savings:

> According to the Notice of Proposed Rule Making (NPRM), released on August 5, 2004, Medicare allowed charges for albuterol sulfate and ipratropium bromide were $1.3 billion

Intake – Initial patient intake involves collecting information on patient demographics, verifying insurance, determining the clinical status of the patient, reviewing the physician's orders and assessing the appropriateness of the care as well as the potential for drug interactions, therapeutic duplications, and drug allergies, and coordinate the start of care. Intake may or may not involve face-to-face contact with the patient.

Compounding, Dispensing, and Pharmacy Assessment – Compounding may be required to cut dosage, concentrate therapy time (and increase compliance), combine therapies, improve clinical outcomes, and/or reduce side effects. Compounding requires the use of sterile procedures, clean rooms, specialty training, quality assurance validation, etc.

Delivery, Set-Up, and Patient Education – A home visit by a respiratory therapist or trained technician is required to set up and educate the patient on the use of the medical equipment used to nebulize the medications (including cleaning, disinfection, and maintenance).

Follow-Up and Compliance Monitoring – Appropriate clinical monitoring is essential to ensure the safe administration of aerosol drugs and to maintain quality of life to as high a degree as possible.

Quality Assurance, Accreditation, Licensing, and Regulatory Compliance – These administrative and support services include quality improvement programs, utilization review, medical records management, coordination of insurance benefits, claims processing, medical waste management, personnel management, inventory control, orientation programs for employees, and clinical development and continuing education programs for management and staff. Pharmacies must be licensed in every state in which they provide services and comply with Food and Drug Administration (FDA), state pharmaceutical board, and other regulatory procedures.

Medicare Billing and Compliance – Pharmacies that bill Medicare Part B for respiratory drugs must comply with 21 supplier standards as well as

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in 2003. These payments will fall by 89 percent to approximately $140 million in 2005, a $900 million reduction. The payment of $68.10 for services provided to Medicare beneficiaries would amount to $550 million in Medicare allowed charges, or about 61 percent of the reduction in allowed charges for inhalation therapy drugs. This results in approximately $350 million federal savings per year or more than $4 billion over the 10-year scoring window. However, using another set of numbers contained in the NPRM (total payments of $1.3 billion and an 89 percent reduction in these payments), the savings would be $7.0 billion over the 10-year scoring window.
Muse study at 2.

[9] A complete description of these administrative and support functions is available in the Muse study beginning on page 3.

documentation requirements that are more extensive than those imposed by other payers.

Other Direct and Indirect Costs and Expenses – Pharmacies incur both direct and indirect operating and administrative costs and expenses. These costs include pharmacy operating costs (personnel costs (e.g., pharmacists, technicians), warehouse, shipping, computer/technical support, management), freight costs (typically overnight or express delivery), facility costs (rent, utilities, telecommunications, capital expenditures, maintenance), information systems, and other administrative functions (quality improvement programs, accreditation, regulatory compliance, professional liability insurance, and other overhead costs).

The GAO also examined the costs to pharmacies of furnishing aerosol medications to beneficiaries in the home setting. Like Muse, the GAO concluded that pharmacies that furnished aerosol drugs could not continue to serve beneficiaries unless Medicare add an appropriate dispensing fee to the ASP payment for the drug. But the GAO report was inconclusive about the scope of services that should be paid under the dispensing fee, so CMS decided to adopt a dispensing fee for 2005 and revisit questions about what services should the Agency should cover under the dispensing fee the following year.

3. **CMS carefully considered the costs and scope of services necessary to furnish aerosol medications to Medicare beneficiaries before adding a dispensing fee to the ASP payment for the drugs.**

   Reducing dispensing fees for respiratory drugs furnished under Part B to the levels of Medicare Part D or state Medicaid programs will make it impossible for pharmacies to furnish these drugs to Medicare beneficiaries in their homes.

Medicare dispensing fees for respiratory drugs under Part B were established by CMS after careful deliberation and consultation with pharmacies via the rulemaking process. In the 2006 physician fee schedule proposed rule, CMS again explicitly asked pharmacies to comment, this time on the pharmacy services Medicare should cover under a dispensing fee. In response, AAHomecare submitted a follow-up study examining pharmacies' experience under ASP pricing and an add-on dispensing fee.[10] CMS rejected pharmacies' suggestion that the dispensing fee should cover a broad scope of services:

> A number of commenters suggested the dispensing fee be based on the total costs of supplying inhalation drugs indicated by the 2004 AAH report data. That data indicated that suppliers expend on average 63.5 minutes per new patient and 50 minutes per established patient per month on patient education, caregiver training, care coordination, and in-home visits. Such services represent pharmacy care management services, which (if included in dispensing fee payments) would extend the definition of dispensing fee beyond what we believe should be reasonably included within the scope this benefit.[11]

[10] "Examination of Inhalation Drug Services to Medicare Beneficiaries Under the Average Sales Price Reimbursement Methodology in Response to the CMS Notice of Proposed Rule Making (CMS-1502-P)," Muse and Associates for the American Association for Homecare (September 2005).
[11] 70 Fed. Reg. at 70226.

CMS also wanted to be sure the dispensing fee payment did not include payment for services that were paid included in the fee schedule payment for the nebulizer. So, CMS excluded patient training and education from the services covered under the dispensing fee. The dispensing fee for respiratory drugs under Part B is not the result of unintended disparities among different payment methodologies. The dispensing fees for respiratory drugs under Part B, Medicare Part D and state Medicaid programs are different because they are designed to cover and pay for the different services pharmacies under these programs perform. Pharmacies could not afford to furnish Part B respiratory drugs to Medicare beneficiaries if dispensing fees for these drugs were reduced to the levels of Medicare Part D or state Medicaid programs.

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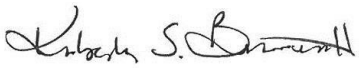
As we noted above, it is simply not possible to make a one-on-one comparison of the cost to government programs of dispensing fees for respiratory drugs under Part B and dispensing fees under the Medicare Part D prescription drug program or state Medicaid programs. Part B pharmacies must perform an array of professional and support services to safely and effectively furnish respiratory drugs to Medicare beneficiaries. The operations of these pharmacies differ vastly from the retail model of pharmacies paid under Medicare Part B.

We hope you find the discussion above useful. Thank you for taking the time to review our concerns. Please feel free to contact me if you have any questions or comments.

Sincerely,



Kimberley S. Brummett, MBA
Vice President of Regulatory Affairs