



Via Electronic Transmission

May 9, 2016

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2390-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS1670-P Proposed rule for Medicare Part B Drug Payment Demonstration¹

Dear Administrator Slavitt:

The American Association for Homecare (AAHomecare) is writing in response to the Centers for Medicare and Medicaid Services' (CMS') request for comments on a proposed demonstration to revise Part B Medicare prescription drug payments under the Agency's Center for Medicare and Medicaid Innovation (CMMI). CMS proposes to implement the demonstration in two phases. The first phase will target the current reimbursement model that pays suppliers, providers and pharmacies the average sales price (ASP) of the drug plus a 6 percent (%) mark-up. CMS proposes to implement a second phase using value based purchasing (VBP) strategies to reduce costs for Part B drugs. CMS anticipates the demonstration will begin soon after the Agency finalizes this proposed rule.

AAHomecare is the national association representing suppliers of durable medical equipment prosthetics, orthotics and supplies (DMEPOS). AAHomecare is the only national association representing every line of service within the homecare community. AAHomecare members include inhalation drug manufacturers and the specialized pharmacies that furnish these drugs to beneficiaries in their homes.

We urge caution with any attempts to modify the dispensing fee for Part B inhalation drugs. Unlike retail pharmacies, Part B pharmacies have an expanded scope of service that is necessary to ensure inhalation

¹ Department of Health and Human Services, Medicare Program, Part B Drug Payment Model, proposed rule, 80 Fed. Reg. 13229 (March 11, 2016).

drugs beneficiaries receive in their homes are safe and therapeutically effective. CMS explicitly designed dispensing fees to cover the costs of professional and support services pharmacies incur in furnishing inhalation drugs to beneficiaries in their homes. These services include intake, delivery, pharmacy assessment, patient education, and monitoring patients to ensure compliance.

Replacing dispensing fees with VBP strategies of unknown value would seriously diminish pharmacies' ability to service Medicare beneficiaries.

The demonstration would also override several provisions of the Social Security Act and Medicare regulations that were the result of carefully thought out planning by Congress and the Administration. Eliminating or reducing dispensing fees for Part B inhalation drugs represents a significant revision to what has been a longstanding and successful reimbursement policy for aerosol medications. This radical change would occur virtually without public notice except for the limited notice requirements of the Administrative Procedures Act.

CMS' current approach stands in sharp contrast with the Agency's approach in 2004 when it considered pharmacies' ability to furnish inhalation drugs under an ASP + 6% payment model plus a modest \$ 5.00 dispensing fee. At that time, CMS engaged pharmacies to determine the appropriate level of reimbursement they needed to continue meeting the needs of beneficiaries who depend on inhalation drugs.

A rush to eliminate dispensing fees for inhalation drugs and replace them with yet unproven VBP strategies would be shortsighted. We recommend that CMS reconsider any plans it may have to eliminate or reduce the dispensing fee for Part B inhalation drugs.

- I. CMS should not replace dispensing fees for inhalation drugs with unproven VBP strategies.**
- A. Pharmacies that furnish inhalation drugs lack the ability and the incentive to steer patients to more costly drugs with higher margins.**

The concerns that CMS believes create problems under Medicare's current payment model for Part B drugs do not apply to reimbursement for inhalation drugs. The dispensing fee for inhalation drugs does not vary depending on the drugs' ASP. And unlike Part B drugs that physician's prescribe and directly administer, pharmacies cannot prescribe the inhalation drugs they furnish. They have a limited role in selecting the inhalation drugs beneficiaries receive. A pharmacy may review a physician's prescription to check for adverse interactions with other drugs, screen for allergies or confirm a dose is accurate, but the pharmacy cannot alter a prescription without a physician's approval. So pharmacies furnishing inhalation drugs lack both the ability and any incentive to steer patients to drugs that may have higher ASPs.

Medicare does not pay an administration fee to pharmacies for furnishing inhalation drugs. Medicare pays pharmacies a dispensing fee that is not tied to a drug's ASP. The only variable in the dispensing fee amount is whether the beneficiary is new or established and whether he or she receives a 30 or a 90-day drug supply. Conflicts of interest that could drive the choice of drugs with higher ASPs should not be a concern for pharmacies that furnish inhalation drugs.

- II. If CMS reduces or eliminates the dispensing fee for inhalation drugs, pharmacies will be unable to cover the costs of furnishing these drugs to Medicare beneficiaries, creating a hurdle to access and unfairly shifting to beneficiaries the costs for these important therapies.**
 - A. CMS designed dispensing fees for inhalation drugs like albuterol sulfate and ipratropium bromide to ensure beneficiaries continue to have access to these drugs in their homes.**

By way of background, Congress adopted the ASP payment methodology under the Medicare Modernization Act (MMA) of 2003. 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 inhalation 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 (GAO)² and Muse and Associates,³ concluded that without a higher dispensing fee beneficiaries might lose access to inhalation drugs. So for drugs furnished in 2005, CMS established a dispensing of \$57.00 for a thirty-day (30) and \$80.00 for a ninety-day (90) supply of inhalation drugs in addition to the ASP + 6% payment.⁴ In 2006, CMS revised the dispensing fee amount to \$57.00 for the initial 30 day supply of inhalation drugs, \$33.00 for each subsequent 30 day supply and \$66.00 for a 90-day supply.

- 2. A reimbursement model like those under Medicare Part D or state Medicaid programs is unworkable for Medicare respiratory inhalation drugs because pharmacies must perform an array of professional services to ensure that the inhalation therapies beneficiaries receive in their homes are safe and effective. The costs pharmacies incur for these professional and support services are not reflected in the acquisition price of the drugs.**

Comparing dispensing fees for Part B drugs with dispensing fees under Medicare Part D or state Medicaid programs is not possible because the delivery models are so dissimilar. Expenditures for

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).

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. These pharmacies are held to high standards for quality assurance by state licensing agencies and accrediting bodies.

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 and pharmacies may typically autofill prescriptions. Part B pharmacies, in contrast, must call patients before dispensing refills. And these pharmacies must comply with the Medicare supplier standards, accreditation standards and they are subject to contractor pre and post pay audits based on the medical necessity of the nebulizer used to administer inhalation drugs.

In the 2005 physician fee schedule proposed rule, CMS explicitly asked inhalation pharmacies to comment on whether the Agency should implement a dispensing fee and, if so, what the fee should be.⁵ 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.

The Muse study shows that drug acquisition costs are only a small part of the total cost of providing aerosol medications to beneficiaries in their homes. Inhalation drugs require a specialized pharmacy operation that includes adequate professional, administrative, and support personnel. Drug delivery, patient education, oversight, and monitoring are among the services that account for operational costs in addition to the acquisition price of the drug.⁶

The study concluded that to continue furnishing 2004 levels of service to beneficiaries needing 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. In order to provide respiratory drugs to beneficiaries in their homes, pharmacies perform the following:

- **Intake** – Pharmacy staff collects information on patient demographics, verifies insurance, ascertains the clinical status of the patient and coordinate the start of care. Intake may or may not involve face-to- face contact with the patient.
- **Pharmacy Assessment** – The pharmacist screens for adverse drug interactions, duplication or the potential for allergic reactions, confirms the dose and communicates with the physician to address any concerns with the prescription.
- **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 and disinfection).
- **Follow- Up and Compliance Monitoring** – Appropriate clinical monitoring is essential to ensure the safe administration of aerosol drugs and to maintain the patient’s quality of life remains as high as possible.

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).

⁶ *Muse Study*.

- **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 supplier standards as well as documentation requirements that are more extensive than those imposed by other payers. Pharmacies must confirm beneficiaries’ need for a refill before shipping refills and they must confirm and document the beneficiary’s medical necessity for the drug at least once a year. Pharmacies are also subject to Medicare contractor pre and post payment audits for the nebulizer that administers the drug and the medications.
- **Other Direct and Indirect Costs and Expenses** – Pharmacies incur both direct and indirect operating and administrative costs and expenses. These costs include operating costs (personnel costs (e.g., pharmacists, technicians), warehouse, shipping, computer/technical support and management), freight costs (typically overnight or express delivery); facility costs (rent, utilities, telecommunications, capital expenditures and maintenance); information systems, and other administrative functions (quality improvement programs, accreditation, FDA regulatory compliance, professional liability insurance, and other overhead costs).

The General Accountability Office (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 adds an appropriate dispensing fee to the ASP + 6% 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 the services the fee should cover 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.

CMS created the dispensing fee for respiratory drugs under Part B only after careful deliberation and consultation with pharmacies via the rulemaking process. In the 2006 proposed physician fee schedule 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.⁷ CMS rejected pharmacies’ suggestion that the dispensing fee should cover a broad scope of services, stating:

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

⁷ 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).

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.⁸

The dispensing fee for respiratory drugs under Part B is not the result of unintended disparities among different payment methodologies. When CMS revisited the dispensing fee amount in 2006, the Agency wanted to ensure the payment did not include services Medicare already reimburses under the fee schedule payment for nebulizers. So, CMS excluded patient training and education from the services covered under the dispensing fee.

Unlike the dispensing fees Medicare pays under Part D and dispensing fees that state Medicaid programs pay, CMS explicitly intended that dispensing fees for inhalation drugs cover and pay for the services inhalation pharmacies perform. These pharmacies could not afford to furnish inhalation drugs to Medicare beneficiaries in their homes if the dispensing fee for these drugs were reduced to the levels of those under Medicare Part D or state Medicaid programs.

B. Part B inhalation drugs save money by reducing hospital admissions and outpatient physician and Emergency Department visits.

1. Chronic obstructive pulmonary disease (COPD) is a chronic, progressive condition that is the third leading cause of death in the United States, accounts for a significant portion of expenditures under Medicare Part A, physician visits under Part B and has been identified by Medicare as a condition that will trigger readmissions penalties.

COPD includes chronic bronchitis and emphysema and has been defined recently as the physiologic finding of nonreversible pulmonary function impairment. COPD is the third leading cause of death in the world and the only leading cause of death for which both prevalence and mortality are rising. Diagnosed COPD afflicts over 14 million people in the United States and it is anticipated that another 16 million individuals have not been diagnosed. Characterized by severe airflow limitation resulting from chronic inflammation of the airways, decrease in functional lung tissue and the dysfunction of pulmonary blood vessels, the airflow limitation caused by COPD is progressive. The clinical course of COPD is characterized by chronic disability with intermittent acute exacerbations that occur more often during the winter months. The World Health Organization (WHO) has projected that COPD will rank fifth in 2020 as a global burden of disease

In 2010, the cost of COPD in the United States was projected to be approximately \$50 billion, which includes \$20 billion in indirect costs and \$30 billion in direct health care expenditures. These costs can be expected to continue to rise with this progressive disease. Costs increase with increasing severity of disease, and hospital stays account for the majority of these costs.⁹

While inhalation drugs are not a cure, they can effectively manage COPD symptoms in the outpatient setting and reduce the need for more expensive interventions such as hospital admissions and ER visits. Respiratory inhalation medications are a recommended intervention in the “GOLD” initiative, the Global Strategy for Diagnosis, Management, and Prevention of COPD.¹⁰

⁸ 70 Fed. Reg. at 70226.

⁹ The clinical and economic burden of chronic obstructive pulmonary disease in the USA Anthony J Guarascio, Shauntá M Ray, Christopher K Finch, Timothy H Self Clinicoecon Outcomes Res. 2013; 5: 235–245. Published online 2013 June 17. doi: 10.2147/CEOR.S34321 PMID: PMC3694800.

¹⁰ Global Initiative for Chronic Obstructive Lung Disease, available at: <http://goldcopd.org/>

2. Clinical experience strongly supports inhalation drug therapy as the treatment of choice for individuals with moderate to severe COPD.

Very few effective therapies have been developed for COPD. Nebulizers deliver medications used in the prevention and treatment of the symptoms of COPD. Bronchodilators (Beta2-agonists) such as albuterol and levalbuterol relax the smooth muscles around the bronchi. Ipratropium bromide is an anticholinergic that promotes bronchodilation by blocking acetylcholine, which causes the airways to constrict.

Albuterol and ipratropium bromide, alone or in combination, are among the most commonly prescribed medications for inhalation therapy. Studies have demonstrated greater effectiveness in treating COPD when ipratropium bromide and albuterol are combined. According to the WHO's GOLD initiative: "These medications are central to symptom management in COPD." The Gold initiative also recognizes that "inhaled therapy is preferred" for the treatment of COPD.

C. The VBP strategies CMS proposes to implement under Phase II of the demonstration will diminish beneficiary access to respiratory drugs appropriate for their specific conditions.

1. Reference pricing and similar proposals are blunt tools that will jeopardize patient care

CMS proposes to test "value-based" approaches to care, including reference pricing in place of dispensing fees for respiratory drugs. Because reference pricing will likely lead to serious patient access concerns, CMS should not finalize this proposal.

According to the proposed rule, reference pricing will provide "equal payment for therapeutically similar drug products."¹¹ But it is unclear how the Agency will determine which drugs are therapeutically similar or how "similar" the drugs must be. The proposal for reference pricing would not target drugs that are therapeutically "equivalent," only drugs that achieve "generally similar" therapeutic effects as the reference drug. It is not wise to assume that "similar" treatments are interchangeable. Individual patients may tolerate the same drug differently. And patients can have different contraindications or side effects from the same drug. The effectiveness of "similar" drugs can also vary depending on the manner or frequency of their administration. The most vulnerable Medicare beneficiaries may be the most susceptible to inconsistencies in the safety and effectiveness among "similar" drugs.

Reference pricing would hamper physicians' ability to prescribe the most appropriate drug for each patient. Physicians, who purchase the medication and *subsequently* receive reimbursement for its administration, must be reimbursed for the medication at a level that keeps them whole. In addition to the clinical concerns discussed above, reimbursing a physician for a group of medications at one rate would make it extremely difficult for the physician to provide any medications that cost more than the CMS-determined payment level. Physicians would be unable to subsidize the cost of a more expensive, but clinically appropriate, drug for their patients. So doctors would be incentivized to stop prescribing certain clinically-appropriate drugs based on a reimbursement policy, instead of whether a drug is therapeutically appropriate for a patient.

A reference pricing model shifts to beneficiaries the burden of getting the most appropriate drug for their condition. Beneficiaries who need a drug other than the reference drug would have to use a burdensome medical exceptions process to qualify for coverage. This represents an additional layer of time, expense, and complexity for patients and their doctors that would create a dangerous barrier to

¹¹ 81 Fed. Reg. at 13243.

access, especially for the frail elderly, the most vulnerable among Medicare beneficiaries. And access restrictions on clinically appropriate treatments can have costly consequences, including relapses, hospitalizations and trips to the emergency department, all of which increase overall medical costs.¹²

If CMS intends to use reference pricing to implement policies like the least costly alternative (LCA), it is important to recall that these policies were resoundingly rejected by the Federal Courts. In 2009, the District of Columbia Circuit Court of Appeals held that the Agency's LCA policy did not comply with the Social Security Act's mandate requiring the Secretary to pay for covered items and services under the reimbursement methodologies Congress created. Since then, Congress has shown no interest in giving the Secretary authority to implement a LCA mechanism. And CMS has conceded it has no authority to apply LCA policies without approval from Congress. CMS does not explicitly address LCA in the proposed rule, but the mechanism and impact of reference pricing are substantially equivalent to requiring beneficiaries to use the LCA. CMS should not attempt to circumvent the Medicare statute and the circuit court's mandate by implementing an LCA policy under a different name.

2. Reference pricing and similar strategies are based on arbitrary measures of drugs' comparability.

Aside from the legal impediments to using these strategies, the underlying concern is that any assessment of drugs' comparability is essentially arbitrary and unproven, especially for individual patients who may have a need for a drug with a different profile from that of the reference drug.

For example CMS proposes to rely on tools like the one developed by the Institute of Clinical and Economic Review which purports to compare drugs' clinical and cost effectiveness in the hopes of steering physicians to prescribe drugs that represent the best value for patients. But efforts to determine comparability of drugs according to their effectiveness reduce patients to a "one-size-fits-all" model that overlooks individual patient needs and responses to individual drugs. This model also runs contrary to advances in medicine that emphasize individualized treatment to the individual and would unfairly shift to beneficiaries the cost of appropriate individualized therapies.

III. Conclusion CMS should withdraw the proposed rule, especially as it pertains to Part B inhalation drugs.

To the extent the proposed demonstration would reduce or eliminate dispensing fees for Part B inhalation drugs, it would be a radical departure from the reimbursement scheme Congress and the Administration carefully designed in 2004. Reducing or eliminating dispensing fees for inhalation drugs is unnecessary and threatens the ability of pharmacies to furnish these drugs and beneficiaries' access to the most appropriate therapy for their condition. Part B inhalation drugs have proven to be a cost effective therapy for managing the complications of COPD which result in significant costs to Medicare

¹² See, e.g., West, J.C., et al., *Medication Access and Continuity: The Experiences of Dual-Eligible Psychiatric Patients During the First 4 Months of the Medicare Prescription Drug Benefit*, 164 AM. J. PSYCHIATRY 789 (May 2007) (concluding that among patients with a medication access problem, nearly 30 percent experienced a significant adverse clinical event and nearly 20 percent visited the emergency room); West, J.C., et al., *Medicaid Prescription Drug Policies and Medication Access and Continuity: Findings from Ten States*, 60 PSYCHIATRIC SERVICES 601, 608–09 (May 2009) (evaluating psychiatric patient medication access problems, including prescription of a medication not clinically preferred, and finding that such access issues have "may have significant cost implications" and are "associated with significant adverse effects" for patients); See, CONG. BUDGET OFFICE, OFFSETTING EFFECTS OF PRESCRIPTION DRUG USE ON MEDICARE'S SPENDING FOR MEDICAL SERVICES 3 (2012), *available at*: <https://www.cbo.gov/sites/default/files/43741-MedicalOffsets-11-29-12.pdf> (noting that decreased usage of prescription drugs due to less generous drug coverage is associated with an increase use of other medical services and describing how CBO will account for this offsetting effect when scoring proposals affecting Medicare drug coverage).

under Part A for hospitalizations and Emergency Department visits as well as costs for more frequent physician outpatient visits under Part B.

AAHomecare is also troubled by the Agency's aggressive timeline for implementing this demonstration, especially considering the limited opportunity CMS has afforded us to weigh in on the proposal. And the demonstration would apply to all Part B drugs in every part of the country with the exception of areas designated as controls. We believe a more cautious and restrained approach is warranted given the very serious consequences for beneficiary access that are likely to result, especially if CMS were to reduce or eliminate dispensing fees for inhalation drugs.

In light of our comments above, AAHomecare recommends that CMS refrain from implementing any proposal that would reduce or eliminate dispensing fees for inhalation drugs. Thank you for the opportunity to submit these comments. Please feel free to contact me should you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberley S. Brummett". The signature is fluid and cursive, with the first name being the most prominent.

Kimberley S. Brummett, MBA
Vice President for Regulatory Affairs