ASRS American Society of Retina Specialists

May 9, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

By Electronic Delivery

Re: Medicare Program Part B Drug Payment Model [CMS-1670-P]

Dear Acting Administrator Slavitt:

On behalf of the American Society of Retina Specialists (ASRS), its members and their patients, we submit the following comments on the Centers for Medicare & Medicaid Services (CMS) Medicare Program Part B Drug Payment Model [CMS-1670-P]. The ASRS is the largest retinal organization in the world, representing over 2700 fellowship-trained members. Retina specialists are board-certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases.

ASRS SUPPORTS CMS' GOALS BUT NOT THE CURRENT PROPOSAL

The ASRS supports CMS stated goals of "improving incentives for the best clinical care" and desire to "drive the prescribing of the most effective drugs."[1] We also wholeheartedly support the alternative payment model framework offered by the Medicare Payment Advisory Commission (MedPAC) Commissioners at its December 2014 meeting and agree a successful alternative payment system must:

- Provide sufficient incentive for providers to maximize health outcomes and value while reducing costs;
- Ensure that payment policies do not compromise quality of care or limit patients' treatment options;
- Assess the impact of such payment policies on low-income patients; and
- Implement a sufficiently transparent and adequate exceptions process to allow providers to prescribe more-expensive products when medically necessary.

Unfortunately, the current proposal falls short in not meeting: (1) the stated goals of the proposal itself, and (2) the standards set forth for MedPAC. As a result, the payment proposal has the potential to negatively impact patient care and outcomes when Medicare beneficiaries are treated with injectable drugs in the office setting.

[1] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-08.html

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IMPLICATIONS OF PAYMENT POLICY ON TREATMENT PATTERNS AND PRACTICE FINANCIALS

The proposal has several limitations due to the following:

- The existing ASP-based fee schedule payment methodology of 106% (104.3% after sequestration) does not yield profit for physicians and thereby does not provide an inappropriate incentive for them to choose high-cost treatment;

- Interchangeable treatment options are not necessarily available; therefore, less costly alternatives may not be an option to treat patients; and

- Across retinal diseases, we have no data demonstrating that changes in current treatment patterns would improve the quality of patient care.

What Do We Know About Physician Practice Expenses for Drug Acquisition and Other Overhead?

The House Ways and Means Committee has requested from the GAO a cost study to examine how Medicare's payment for drugs covered under Medicare Part B compares to actual acquisition and overhead costs. We feel that any proposal from CMS should be formulated after the GAO results are available.

ASRS membership, in response to the CMS proposal and to reply to requests from Deputy Administrator Conway, commissioned a study of 8 practices that were able to pull detailed cost accounting data for calendar year 2015 in the short time allotted in the comment period. The study found that drug acquisition and overhead expenses for injectable drugs that have their own unique HCPCS J codes was, on average, 98.9% (range 96.5% to 103.2%) of total payments across the 8 practices. (For more information, see appendix A.)

It is worth noting that given the limited time available to collect these data, only high volume practices with capable financial staffs were able to respond to the survey in this short period of time. Even under these circumstances, not all high volume practices generated net revenue from office administered drugs. In fact, our belief is that lower volume practices, which provide the majority of patient care in retina around the country, would have less purchasing power and higher overhead costs compared to the practices in the study from which we were able to collect data.

Based on the analysis of real retina practice data, we believe the ASP + 2.5% and a flat fee even without sequestration do not recognize the true costs of purchasing and handling the more complex biologics, and will limit the ability of some providers to administer essential sight-saving drugs. For physicians to be able to continue to purchase Part B drugs on behalf of their patients, the payment rate must at least cover all overhead costs. If not, patients will be forced to travel to the more expensive hospital outpatient departments to receive monthly treatments. Driving more care to an often less convenient, more costly setting will make it more challenging for beneficiaries to access needed care and will increase overall Medicare costs. This will lead to further consolidation and less choice for seniors.

Therefore, before proposing any payment policy that is not based on ASP+6% it would be helpful if CMS would explain why it has changed its position that "ASP+6% payment is an appropriate payment rate for separately payable drugs and biologicals."[2]

[2] 77 Fed. Reg. at 8,387.

Financial Incentives Do Not Influence Drug Choice

The ASRS takes issue with the assumption that physicians may choose their patients' drug therapy based on which drug provides them the highest reimbursement. MedPAC considered this issue and concluded that there is little evidence to support such a claim. Moreover, our research also suggests this is not the case. In the ASRS 2015 Preferences and Trends survey, 64% of respondents indicated that they currently use the least-costly alternative, Avastin®, as the first- line treatment for new patients with wet AMD. However, when asked which anti-VEGF agent they would choose if Avastin®, Lucentis® and Eylea® were the same price, respondents dropped Avastin® to the last choice. Avastin® was also the last choice of our members when asked "which anti-VEGF do you believe most effectively treats the broadest range of wet AMD patients." For those familiar with the results of recent clinical trials, these survey results are not surprising.

Treatment Options Are Not Interchangeable

In its June 2015 report, MedPAC recognized that a number of clinical factors, including variations in effectiveness of drugs in treating patients with specific conditions and comorbidities, potential side effects, on or off label use of a drug, as well as whether or not a drug is compounded, may influence a provider's choice among therapeutic alternatives. For retina specialists, all of these factors are in fact considered.

Currently, of the 3 utilized anti-VEGF agents, only Lucentis® and Eylea® have specific FDA approval for treatment of age-related macular degeneration, diabetic macular edema, and retinal vein occlusion. Avastin not only does not have FDA approval for the treatment of these retinal diseases, but it must also be used in a compounded form. Many patients are reluctant to choose a compounded drug being used off-label and should not be forced to do so when several FDA-approved options exist.

Clinical response varies among the 3 anti-VEGF agents in individual patients. While all 3 anti-VEGF agents have similar efficacy in many patients, various trials have demonstrated differences in subsets of patients. Retina specialists must evaluate each patient individually, and select the appropriate agent accordingly. Ultimately, the retina specialist utilizes clinical judgment and the patient's response to a particular drug to select the best course of therapy. As the recently released results of the National Eye Institute funded study Comparison of Age-related Macular Degeneration Treatments Trials (CATT) 5-year follow up found, patients often switch anti-VEGF agents and dosages. This ability of a physician to individualize treatment and select the most efficacious agent for each patient is critical to safely maximizing recovery and maintaining visual function in patients with blinding diseases of the retina.

Since anti-VEGF agents are not interchangeable, ASRS is seriously concerned that for many retina specialists the phase I new payment methodology will no longer cover the costs to deliver FDA-approved drugs to their patients. If retina specialists are unable to cover the costs of the medically necessary Part B drug, patients will be forced to go elsewhere (likely farther away and/or to a more costly care setting) to receive their injections.

THE RETINA COMMUNITY IS AND WILL CONTINUE TO BE VESTED IN IMPROVING PATIENT OUTCOMES AND BEING FINANCIALLY RESPONSIBLE

The ASRS is concerned that the CMS has not provided guidance on how it defines "most effective drugs." It is a physician's duty to base clinical decisions on clinical evidence, not just cost. Retina specialists work in a specialty that requires the administration of expensive Medicare Part B drugs – Lucentis® and Eylea® – to save vision, and the ASRS and its members have devoted tremendous resources to supporting efficacy, comparative effectiveness clinical research, and the dissemination of clinical trial results.

Through this research, cost savings have already been achieved. For example, the treat-and-extend protocol, now widely used in the treatment of macular degeneration and diabetic retinopathy, allows retina specialists to treat

less often than done in pivotal phase III clinical trials, yielding significant savings in terms of treatment burden and cost while maintaining excellent vision outcomes. In other cases, comparative effectiveness studies have found statistical differences in treatment options that support use of the more expensive treatment option.

Protocol T, for example, found that the relative benefit of Eylea® was clinically and statistically significant for the subset of eyes that had 20/50 or worse vision at baseline. If phase I moves forward unchanged, this subset of diabetic retinopathy patients may not be able to receive the most effective treatment. Given this, and the fact that more than 300 clinical trials are currently underway to explore additional ways to treat AMD and diabetic retinopathy with fewer injections and achieve even better outcomes, we believe CMS needs to establish a mechanism for defining "most effective drugs." Since the National Institutes of Health (NIH) fund many of the comparative effectiveness studies, we believe CMS should consider collaborating with NIH to develop this mechanism. Moreover, since some patients simply respond better to one treatment over another, ASRS recommends that CMS create a sufficiently transparent and adequate exceptions process to allow providers to prescribe medically necessary drugs irrespective of cost.

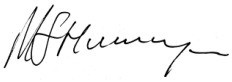
CONCLUSION AND RECOMMENDATIONS

Given the concerns expressed above, the ASRS recommends that CMS not continue with phase I of the demonstration project as written, and reevaluate the development of alternative payment models that can achieve the same goal without increasing risks for patient outcomes after real-world practice data is available to guide this process.

ASRS appreciates the opportunity to provide comments on the proposed Medicare Program Part B Drug Payment Model. If we may provide any additional information, please contact Jill Blim, ASRS Executive Vice President, at jill.blim@asrs.org.

Sincerely,

Tarek S. Hassan, MD
President



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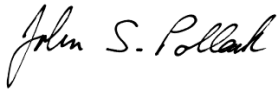

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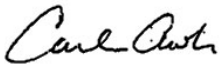

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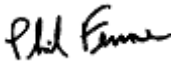

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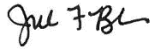

Jill F. Blim, MS
Executive Vice-President

APPENDIX A

ANALYSIS OF PRACTICE REVENUES AND EXPENSES FOR DRUGS ADMINISTERED IN RETINA PHYSICIAN OFFICES

BACKGROUND

On March 8, 2016, the Centers for Medicare & Medicaid Services (CMS) announced a proposed rule to test new models to improve how Medicare Part B pays for prescription drugs and supports physicians and other clinicians in delivering higher quality care.

Currently, Medicare Part B covers prescription drugs that are administered in a physician's office or hospital outpatient department, such as cancer medications, injectables like antibiotics, or eye care treatments. Drugs paid under Medicare Part B generally fall into three categories:

1) Drugs furnished incident to a physician's service in the office or hospital outpatient settings,
2) Drugs administered via a covered item of durable medical equipment, and
3) Other categories of drugs explicitly identified in the law.

PROPOSED RULE AND CHANGES IN PAYMENT THAT WOULD APPLY TO OPHTHALMIC DRUGS ADMINISTERED BY RETINA PHYSICIANS

Medicare Part B generally pays physicians and hospital outpatient departments the average sales price of a drug, plus a 6 percent add-on. The proposed model would test whether changing the add-on payment to 2.5 percent plus a flat fee payment of $16.80 per drug per day changes prescribing incentives and leads to improved quality and value. CMS goes on to say that:

> "CMS expects that the add-on payment of 2.5 percent plus a flat $16.80 fee will cover the cost of any drug paid under Medicare Part B. The flat fee is calculated such that it is budget neutral in aggregate."

While the proposal may be budget neutral in aggregate, the fact is that CMS does not know the impact of specific subspecialties based on provider financials, treatment mix, and so forth.

Therefore, the American Society of Retina Specialists (ASRS) commissioned an independent study by an economics and accounting firm, Quorum Consulting, Inc. (San Francisco, CA) to gather data from retina practices to: (1) determine revenue for injectable drugs; (2) account for direct and indirect costs associated with injectable drugs; in order to: (3) report profit or loss for physician administered drugs that may be affected by the proposed rule.

ABSTRACT OF STUDY METHODS AND RESULTS

Methods

We solicited members of the ASRS to provide detailed financial and cost accounting data. We requested data on revenues (total collections) and costs (expenses) for calendar year 2015. We obtained data on all injectable drugs administered retina physician practices offices (hospital and ASC facilities were not included). The scope of the analysis was specific to FDA approved drugs with product specific HCPCS "J" codes, which are addressed within the scope of the CMS proposal.

Cost Accounting Data Collection

For direct and indirect expenses, we obtained site-specific data on:

Drug Acquisition Costs (by HCPCS code)

a. Acquisition price per unit
b. Added costs
    a. Shipping and handling
    b. Sales tax
    c. Other cost increases
c. Cost offsets
    a. Discounts
    b. Chargebacks
    c. Rebates
    d. Other cost offsets

Other Practice Expenses

a. Practice Expenses
b. Staff Time
    - Salaries and benefits for staff time responsible for acquiring, storing, preparing, transporting, disposing of drugs and drug revenue collections * this differs from GAO allocated based on time spent on these activities
c. Other indirect expenses
    - Space - Physical space used for storing and preparing drugs
    - Equipment - Equipment used for storing, preparing, transporting, disposing of drugs and claims management (office equipment, PODIS, EHR, other IT, etc.)
    - Supplies - Supplies used for storing, preparing, transporting, and disposing of drugs
    - Support Contracts - Contracts for other organizations to provide services supporting acquiring, storing, preparing, transporting, and disposing of drugs (e.g. waste disposal)
    - State provider taxes

Results and Discussion

We obtained detailed revenue (collections) and expenses (direct and indirect costs) for calendar year 2015 from 8 retina practices from around the country. While sites were from regions throughout the country, participating sites all tended to be high volume practices. This is likely due to the fact that sites had to provide data in a short amount of time (to accommodate the CMS comment period), and only high volume sites had accounting and other administrative staff available to provide the requested information. Participating sites also varied in their payer mix and utilization of different types of drugs.

We found that drug acquisition and overhead expenses for injectable drugs included in the analysis were on average 98.9% (range 96.5% to 103.2%) of total collections across the 8 practices. In some cases, practices made a profit on injectable drugs while in other cases had a net loss. There was variation in drug profit or loss by drug and by practice.

It is worth noting that given the limited time available to collect these data, only high volume practices with capable financial staff were able to respond to the survey in this short period of time. Even under these circumstances, not all high volume practices generated profits on office administered drugs. In fact, our belief is

that lower volume practices, which provide the majority of patient care in retina around the country would have less purchasing power and higher overhead compared to the study for which we were able to collect data.