ASRS American Society of Retina Specialists

Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

December 26, 2018

Re: Medicare Program; International Pricing Index Model for Medicare Part B Drugs; CMS-5528-ANPRM

To Whom It May Concern:

On behalf of the American Society of Retina Specialists (ASRS), The Retina Society and Macula Society (hereafter retina societies), its members and their patients, we submit the following comments on the Centers for Medicare and Medicaid Services (CMS) Program; International Pricing Index Model for Medicare Part B Drugs, Advance notice of proposed rulemaking with comment [CMS-5528-ANPRM]. Retina specialists are board-certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The retina societies serve as national advocates and primary sources of clinical and scientific information and education for their members. The societies seek to enhance the ability of its members to provide the highest quality of patient care. We accomplish this through soliciting feedback from our patients, leveraging all available treatment options, and personalizing our approach to providing healthcare. As such, our comments focus on the physician's perspective and their commitment to providing quality care to their patients.

Based on experience with the 2006-2008 Competitive Acquisition Program (CAP) model, a new International Pricing Index (IPI) model should be significantly redesigned to address concerns about patient care, administrative burdens, and healthcare costs that arose when CMS initially implemented the CAP program. The overarching principle that will lead to a successful IPI model is the acknowledgment that the workflow of retina specialists requires a suite of products available on-site for immediate use (office stock) for new and established patients. Inventory management should be managed by the model vendors at a provider site. Secondly, there should be clear separation of physicians from Part B drug billing and collection as well as inventory management tasks.

The societies define office stock as a supply of drugs that is needed for the potential treatment of new and established patients. The office stock is not associated with any specific patient, and the drugs can be used at the physician's discretion. This supply will be maintained by the model vendors and restocked as drugs are used for any patient in need of treatment at the physician's discretion. This supply will be maintained by the model vendors, restocked as drugs are used or found to be damaged, and replaced when drugs expire. This system has some similarities to the consignment methods used by surgical centers for intraocular lens usage. In this system the manufacturer provides a broad range of intraocular lens powers which are only billed when used in a patient.

The previous CAP model did not make use of this system, and we believe it was one of the major causes for its suspension. For example, the CAP's high rate of use of the emergency stocking provision (46%)[1] meant that physicians still needed to have drug on hand as CAP did not allow for stored drugs. By addressing up front the concern of an office stock, the new model can be effective in attaining its goals.

Summary of the Competitive Acquisition Program

As part of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), the Center for Medicare and Medicaid Services and the Department for Health and Human Services (HHS) set forth the CAP for outpatient drugs and biologics covered under Medicare Part B, published in the Federal Register on November 21, 2005[2]. The purpose of the CAP model centered around reducing Medicare Part B costs, improving access, and eliminating the financial drug liability for providers[1]. This was done by introducing vendors selected by the CMS who would furnish drugs for providers and facilitate claims and reimbursement, thus sharply reducing the administrative load for providers. Physician participation in the program was voluntary with opt-in occurring on an

[1] Evaluation of the CAP for Part B Drugs, December 2009
[2] Federal Register Vol. 70 No. 223, November 21, 2005

annual basis and requiring a year-long commitment. Once participating, physicians could only acquire approved drugs from the sole CAP vendor that accepted CMS' terms, BioScrip, Inc.[3]. The first round of physician election into the CAP commenced on May 8th, 2006 and ended on June 30th, 2006.

Providers found CAP requirements very challenging to integrate into their practice because the program lacked the prescribing flexibility required for optimal patient care. First, each drug was to be administered to a pre-determined patient at a pre-determined dose, meaning physicians were unable to make same-day treatment modifications based on evaluation and test results or changes to patient status. This resulted in treatment delays and sub-optimal care. Second, drugs were only allowed to be administered where they were delivered, limiting providers' ability to move stock to other locations, and therefore negatively impacted timely patient access to drugs. Furthermore, physicians were not allowed to keep a general/emergency stock, making it impossible for physicians to treat patients with urgent needs, or requiring providers to use their non-Medicare stock and then utilize the Emergency Restocking provision. Finally, opting in to the program made many physicians feel trapped due to the year-long commitment and the inability to revert back to the buy-and-bill structure.

Over the years the program was in place, drug cost increased 3% - 3.5% on average for drugs furnished through CAP as compared to the traditional "buy-and-bill" model[2]. The CAP ultimately did not meet its goals, and on September 10, 2008 the CMS announced that the CAP would be suspended starting the beginning of the 2009 calendar year.

CMS' Proposed International Pricing Index (IPI) Model

CMS' new proposed IPI model is designed to leverage and improve upon the CAP model. The CMS will contract with several private-sector vendors to supply providers. Vendors will also be given the freedom to offer innovative delivery solutions to encourage physicians to obtain drugs from them, compete with other vendors, and ultimately lower costs. Key differences of the IPI model from the original CAP model include the following:

- Medicare will reimburse vendors for the drugs based on pricing data from fourteen other countries, as an effort to rein in the rising drug prices
- The drug add-on reimbursement provided to physicians will no longer be based on individual drug's Average Sales Price
- Providers will be responsible for collection of patient out-of-pocket expenses, although vendors will still take on the financial risk of acquiring drugs and seeking drug reimbursement from Medicare

Comments and Recommendations

The retina societies appreciate the CMS soliciting public comment on key design considerations for the proposed IPI model, which is intended to reduce healthcare expenditures while improving patient access and reducing provider financial risk associated with furnishing drugs. We believe that any drug distribution model should be implemented in a way that minimizes disruptions to patient care. To that end, we would like to describe some of the unique characteristics of patient care in an ophthalmic setting to help CMS create a model that will allow for optimal patient care.

The societies stand by the principles outlined on September 24, 2018 in response to CMS-1695-P[4] and have since then further refined our principles. Any CMS proposal to change the payment and distribution for certain separately payable Part B drugs and biologics should adhere to the following principles:

- shift all responsibility for collecting payments for drugs, including beneficiary co-pays, to the CMS selected vendors and indemnify physicians from the risk of bad debt,
- prohibit model vendors from imposing fees on physicians to cover distribution costs,
- supply drugs in a manner that is not patient-specific such that physicians have an inventory of products (office stock) that are utilized across both new and established patients,

[3] Approved Cap Vendor, November 23, 2016
[4] ASRS Re: CMS-1695, September 24, 2018

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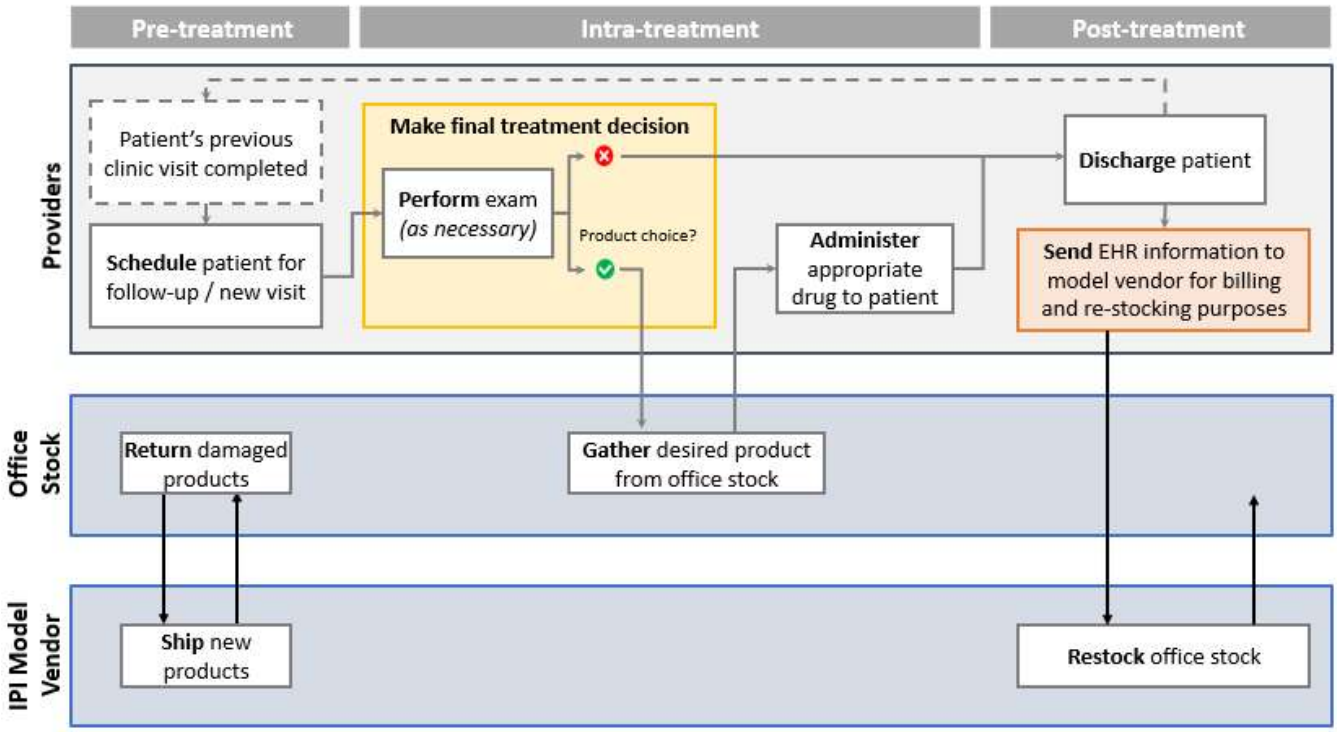
- prohibit model vendors from engaging in the corporate practice of medicine, utilization management, or medical review work,
- provide physicians with the option to remain in the current direct buy-and-bill system,
- ensure a minimum of three vendor options for all available products,
- allow physicians to easily switch among vendors or move back to direct buy-and-bill, and
- pay providers a reasonable fee to cover on-site product handling and product management

Ophthalmologists—retina specialists in particular—encounter highly variable and unpredictable treatment patterns when providing optimal patient care. In some other specialties of medicine, physicians may be able to *a priori* determine the appropriate treatment for a patient based on patient history, even before the patient reaches the physician's office. For "new" patients visiting a retina specialist practice for the first time, we are able to identify a list of *potential* treatment options based on patient history. However, it is only during the visit that we can fully evaluate the patient, reach a final diagnosis, and determine the best treatment option (Figure 1). Optimal patient care is often one where the patient is treated that same day. Therefore, retina specialists require an office stock of medicines to optimize treatment decisions and outcomes at the point of service. For established patients, the requirement is similar: in-person patient evaluation is needed to determine whether patient outcomes following the last visit necessitate changes to the treatment algorithm. Since retina patients are typically elderly and may have disabilities such as low vision, they often rely on family members to take time off of work to drive them to appointments making the delivery of care in the same day optimal. Furthermore, retina specialists serve these patients at multiple clinic locations including outreach clinics, so it is common for a physician to be at a specific location as infrequently as once a week, which is longer than would be reasonable to delay care. This adds complexity and has the potential to result in even longer treatment delays in the case that an office stock is not available. Any new distribution or payment model should provide appropriate inventory management to account for the patient care needs described above, and the vendors should not pose any hurdles to patient care and patient access to drugs.

Figure 1. Roles and responsibilities of the retina specialist vis-à-vis the IPI vendor require flexibility over time from pre-, intra-, and post-service



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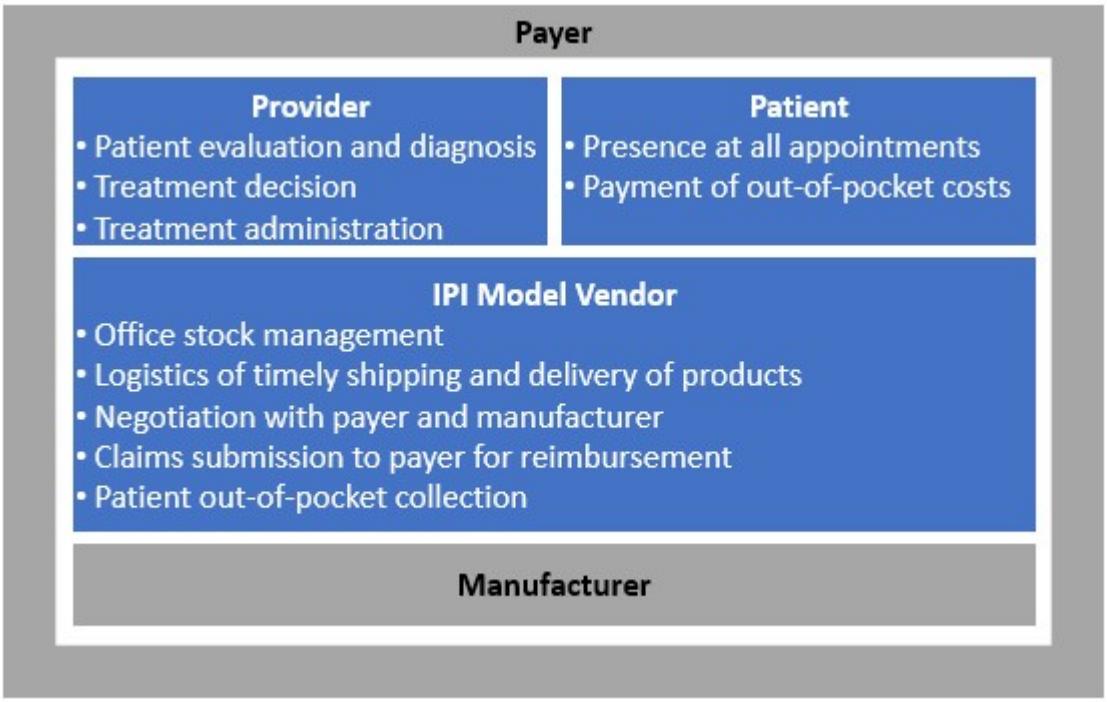
In addition, in order to reduce complexity for physicians related to using both the buy-and-bill model and the model vendor, products that are used off-label should be provided by the vendors if supported by clinical guidelines and/or compendia. For example, retina specialists often use repackaged Avastin (off-label) as a substitute for Lucentis and Eylea. It will be cumbersome for physicians to switch back and forth between using the new IPI model and the traditional buy-and-bill model, especially for such a high-volume drug.

The physicians' primary function is to diagnose patients and administer medically-appropriately treatments (Figure 2). Given this, we believe that the roles and responsibilities of the physicians should focus on this important function and that physicians should be protected from any financial risks associated with a new drug distribution model. To this end, physicians should not be concerned with any of the challenges arising from shipping and handling or any other logistical issues (e.g., broken vials, expired product, etc.). Physicians must also be exempt from any out-of-pocket collections from patients, such as co-pays. The cost of collecting payment and the associated bad debt risk is significant and should not be left with providers. Physicians should also be entirely separated from any financial discussions and contracts between payers, manufacturers, and vendors: they should not be responsible for anything related to drug pricing, and it is the responsibility of the aforementioned parties to come to an agreement without the need for physician input. Third-party vendors should be prohibited from charging physicians a fee to cover costs associated with distribution of Part B medicines. Finally, the physician must receive a reasonable fee to cover on-site product handling and product management for each procedure, independent of drug price.

Figure 2. Retinal specialists' key roles are to evaluate and treat patients, while other stakeholders will be responsible for product logistics and financials



All other roles and responsibilities associated with furnishing drugs fall on the vendors who manage their contractual and/or financial relationships with the manufacturer, the payer, and the patient. They are responsible for negotiating with the manufacturer and the payer, as well as billing the payer for used product and collecting patient out-of-pocket payments. Vendors should not play any role in medical decision making and patient care (e.g. utilization management under the guise of value-based payment arrangements). In addition, the vendors are responsible for the timely shipping and handling of all products a physician deems necessary to provide optimal patient care considering the unique retinal specialist considerations described above. This includes management and re-suppling of the office stock to a level that is adequate for the physician's historical need and expected

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demand. A physician's role is to determine the course of treatment and provide that treatment, not manage inventory.

Conclusion and Request for CMS

In conclusion, the ASRS, Macula Society, and Retina Society believe that any changes to the current buy-and-bill model should be implemented in a way that allows providers to continue uninterrupted, just-in-time patient care. Any changes to the current model should be for the benefit of the patient and cannot sacrifice the clinical benefit and convenience of being able to treat the patient on the same day they are examined in the office. This requires that providers have access to an office stock of drugs consisting of all possible treatment options for patients, that providers are not at any financial risk for Part B drugs, and that providers have the only say in treatment decisions. This is the only way to ensure patients continue to have access to the highest quality of care.

We would like to highlight that we analyzed the proposed IPI model strictly through a provider's perspective. As physician specialty societies, we believe that we have the best perspective on requirements of providing optimal patient care. As such, we at this point do not attempt to opine on areas outside of the provider's scope. We believe that other groups will be more qualified to provide feedback on those areas, while they would be less able to do so for provider-specific concerns. If we may provide any additional information, please contact Jill Blim, ASRS Executive Vice President, at jill.blim@asrs.org.

Sincerely,

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