ASRS American Society of Retina Specialists

September 24, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Via online submission at www.regulations.gov

Re: CMS-1695-P –Request for Information on Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Administrator Verma:

The American Society of Retina Specialists, The Retina Society and Macula Society (hereafter retina societies) appreciate the opportunity to respond to the Centers for Medicare and Medicaid Services' (CMS) proposed rule (CMS-1678-P) Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model. Retina specialists are board-certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. As a specialty that uses Part B drugs to treat patients with age related macular degeneration, diabetic retinopathy and other retinal diseases, we want to ensure our patients continue to have timely access to sight saving drugs.

We appreciate the Center for Medicare and Medicaid Innovation (CMMI) soliciting public comment on key design considerations for developing a potential model that would test private market strategies and introduce competition to improve quality of care for beneficiaries. Specifically, CMMI is requesting public feedback on a potential model design that would build upon the Competitive Acquisition Program (CAP) and accelerate the move to a value-based health care system.

Based on experience with the 2006-2008 CAP, a new CAP program must be significantly redesigned to address concerns about patient care and administrative burdens that arose when CMS initially implemented the CAP program in 2006. The original CAP program was complex and problematic for both vendors and physicians. One sign of the CAP's logistical failure was the high rate of use of the emergency stocking provision (46%), which meant physicians still needed to have drug on hand as CAP did not allow for stored drugs. Ultimately, it was suspended by CMS due to lack of vendor competition, lack of physician participation and limited cost savings.

The retina societies provide the following principles to guide development of a new viable Part B CAP. The program must:

- provide physicians with the option to remain in the current direct buy-and-bill system,
- ensure a minimum of three vendor choices per physician,
- allow physicians to easily switch among vendors or move back to direct buy-and-bill,
- prohibit CAP vendors and carriers from engaging in any utilization management or medical review work,
- pay providers a reasonable fee to cover handling and storing products, and
- shift all responsibility for collecting payments for drugs, including beneficiary co-pays, to the CAP vendor and indemnify physicians from the risk of bad debt.

We note that CMS is "soliciting comments on how a model could be structured to advance the goals of the President's blueprint, namely to increase competition, strengthen negotiation, create incentives for lower list prices, and lower out-of-pocket costs."

Given physicians have no control over drug prices and limited market power, we believe that physicians should be protected from any financial risk associated with a new model. If CMS proceeds with a CAP demonstration, it must be voluntary. To ensure competition in the marketplace, we believe there must be multiple vendors. As we cannot predict its impact on patients and practices, physicians must be allowed to switch among vendors or move back to direct buy-and-bill. Moreover, it is a physician's duty to base clinical decisions on the patient's response and risks for a particular drug, not just cost. As such, CMS should prohibit CAP vendors from using utilization management tools that would block patients from getting the care they need.

CAP MODEL CONCEPT – Part B Drug Vending Machine

In response to CMS's request for specific public feedback on a potential CAP model design, the retina societies would like to offer a conceptual model that is designed to:

- allow physicians to focus on providing high quality patient care,
- reduce administrative hassles and costs associated with complying with utilization management, and
- shift the burden of drug acquisition and reimbursement to the CAP vendor.

The envisioned model can best be described as a Part B Drug Vending Machine. It would be designed to ensure inventory is rotated, drugs are kept at the appropriate temperature, and low stock/expiration date alerts are sent to the vendor. The CAP vendor would keep the machine stocked based on past practice patterns. While the machine is on the physician office premises, its contents are either owned or provided on consignment by the CAP vendor. This model addresses the past problems associated with physicians having to order specific treatments from the CAP vendor in advance of the patient's visit, limiting their ability to adjust therapies or dosages based on different patient needs they might identify during the visit.

To access drugs, the physician would send an electronic prescription to the vending machine and then insert the patient's "credit card" that contains insurance information and other necessary information. After the credit card is read, the machine would dispense the drug to the physician. Physicians would

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continue the standard practice of recording the lot number in the patient's record for market surveillance purposes.

Since physicians would have no financial incentive to use one treatment over another and CAP vendors have the ability to negotiate drug prices, patients would have full access to all FDA approved drugs covered by Original Medicare.

APPROPRIATE PATIENT PROTECTIONS

Robust and comprehensive patient protections must be included. Vendors must not interrupt patient access to medically necessary treatments due to delayed or delinquent co-pay issues. Vendors should be required to help patients find assistance or consider alternative payment arrangements if a patient cannot meet his or her cost-sharing responsibilities. The vendors should bear the risk of non-payment of patient copayments in a manner that does not penalize the treating physician and that does not interrupt patient care. Utilization management policies should not be tied to negotiated discounts.

VENDOR QUALIFICATIONS

Multiple CAP vendors must be available in any program, so that competition is created in the marketplace. Physician practices should be able to choose from multiple vendors to ensure competition exists for both pricing and service. The CAP vendors must deliver high-level service to ensure that patients receive timely access treatment. Vendor qualifications should include appropriate safety and quality standards.

CONCLUSION

The retina societies appreciate the work CMS/CMMI does and the opportunity to respond to this request for information. We look forward to being a resource to you and to working with the agency as a potential model is developed. 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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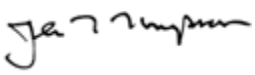

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