Oncology Nursing Society
125 Enterprise Drive • Pittsburgh, PA 15275-1214
Toll Free: 866-257-4ONS • Phone: 412-859-6100 • Fax: 412-859-6165
customer.service@ons.org • www.ons.org

May 9, 2016

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1670-P
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare Program; Part B Drug Payment Model; Proposed Rule

Dear Acting Administrator Slavitt:

The Oncology Nursing Society (ONS) is deeply concerned with CMS' proposed Part B Drug Model and its impact on access to quality cancer care. This is an important issue for oncology nurses as key members of the cancer care delivery and treatment team, and the patients we serve. We appreciate the opportunity to submit our concerns to the proposed rule.

Procedural Concerns

ONS is disappointed that CMS did not solicit comments from affected stakeholders during the development of this model and in advance of rulemaking. Executive Order 13563 (January 11, 2011) explains that, "Before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking." Apart from an erroneous posting of guidance for CMS' contractors regarding the Part B Drug Model, which alerted some stakeholders to the potential for rulemaking, CMS did not engage affected stakeholders in an open and transparent way.

Additionally, the Model is so expansive in scope and duration as to far exceed any reasonable definition of a demonstration program. With limited exceptions, CMS proposes to include all Part B drugs and require the participation of all providers and suppliers furnishing Part B drugs. While CMS has the authority to make participation mandatory, we believe the model can no longer be considered a "demonstration" when it is scaled nationwide (excluding Maryland).

A nationwide five-year Model that will incorporate all Part B medicines and affect the majority of Part B prescribers constitutes a program change.

Finally, the ACA explicitly states that no ACA provision, including the provision creating CMMI, can result in a reduction of guaranteed Medicare benefits. The Model will jeopardize beneficiary access – and thus may be a potential violation of ACA section 3601, which provides, in relevant part, that nothing contained in the ACA "shall result in a reduction of guaranteed benefits under title XVIII of the Social Security Act."

Substantive Concerns

The model may force providers to send patients to the hospital outpatient department for therapy because it will create sustainability challenges for practices. The current reimbursement level of ASP+6 already results in practices being "underwater" on some of the products they acquire because not all practices have the negotiating power to purchase at ASP or obtain rebates. A significant reduction to the add-on percentage will exacerbate this issue. Moreover, the actual reduction will be far greater than that proposed by CMS, since the agency failed to account for sequestration. Accounting for sequestration, **the current reimbursement level is actually ASP plus 4.4%. The 2.5% proposed by CMS does not appear to include sequestration**, thus, the actual add-on percentage will be smaller.

To manage the financial impact of this reduction, oncology practices may change their model of administering chemotherapy. They may choose to staff their infusion room with lower cost and less prepared, potentially unlicensed, health care workers which is a concern for safety or refer patients to hospital infusion centers. Hospital referrals will create financial challenges for patients who cannot afford the higher cost-sharing – for the exact same treatment. While many beneficiaries have wraparound coverage that prevents them from bearing the increased costs directly, traveling to the hospital outpatient department is inconvenient and can be challenging for cancer patients. It also runs counter to the goals of the Model, as **the cost to the Medicare program will be significantly higher when patients must receive therapy in the outpatient department** instead of the physician's office.

Similarly, and as outlined in our position statement on *Access to Quality Cancer Care*, it is the position of ONS that the provision of accessible and affordable healthcare coverage includes consumer and patient engagement in decision making regarding availability, cost, and efficacy of treatment options and supportive care. CMS' model is exclusively focused on the cost of medications; there is no mechanism by which the agency has proposed it would measure quality of care and shared decision making. It is also our position that registered nurses, properly prepared, administer chemotherapy and teach patients and their families about the treatments and how to manage side effects. The lack of focus on quality and patient engagement is alarming in light of ongoing reforms to our nation's health care delivery and payment systems that emphasize quality improvement and efficiency, as well as aim to promote meaningful dialogue between providers and patients about care and treatment options in a patient-centered, outcomes-focused manner.

The model also runs contrary to ONS' position that evidence-based conventional and integrative therapies, including regimens incorporating the use of off-label therapies approved by the U.S. Food and Drug Administration for other indications, comprehensive symptom management and palliative care, psychosocial care, and survivorship are options for every patient with cancer. We are sorely disappointed that CMS does not include any mention of how it will ensure access to new, innovative, and sometimes "off-label" therapies under its Value-Based Pricing strategies, or elsewhere in the model.

In the proposed rule, CMS explains that it expects to base many of its Part B drug policy analyses on secondary data sources such as Medicare FFS claims. With regard to the beneficiary experience, CMS states that it may consider a survey. ONS is disappointed that **CMS has placed little emphasis on the beneficiary experience** of care under this model. This approach to measuring the patient experience makes it clear that CMS' focus is purely focused on drug expenditures with minimal regard for whether or not it improves quality of care or quality of life.

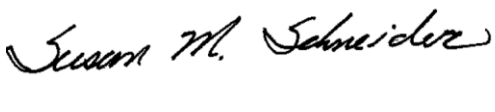
ONS also has concerns about the aggressive timeline contemplated by the Model. First, the anticipated Fall 2016 start date is ambitious given the number of concerns that must be addressed. Second, it is unclear how the agency can draw any meaningful conclusions from Phase 1 in a few short months before Phase 2 could begin in 2017.

Conclusion

Appropriate Medicare coverage of and reimbursement for treatments are critical for beneficiaries suffering from cancer. ONS believes that payment initiatives must be developed and implemented in a targeted, patient-centered, and transparent way that accounts for the unique needs of beneficiaries and input from affected stakeholders at the outset. The nationwide scope of the proposed model, and the unilateral way in which CMS has formulated it, render it unworkable to oncology providers who use Part B medications to treat our patients. Therefore, **ONS urges CMS to withdraw the Part B Drug Payment Model from consideration until stakeholder concerns are addressed.**

We appreciate the opportunity to comment on this proposed rule. ONS looks forward to continuing dialogue with CMS on these important issues.

Sincerely,



Susan Schneider, PhD, RN, AOCN®, FAAN
President

Brenda Nevidjon, MSN, RN, FAAN
Chief Executive Officer