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July 16, 2018

The Honorable Alex Azar, Secretary
U.S Department of Health and Human Services (HHS)
Hubert H Humphrey Building
200 Independence Avenue SW, Room 600E
Washington DC 20201

Re: **ONS Comments on HHS Blueprint/RFI to Lower Drug Prices and Reduce Out of Pocket Costs**;
RIN: 0991-ZA49

Submitted electronically via www.regulations.gov

Dear Secretary Azar:

On behalf of the Oncology Nursing Society (ONS), we are pleased to provide comments on "American Patients First," the HHS Blueprint and RFI to lower drugs prices and reduce out of pocket costs for Americans.

Oncology nurses caring for patients with cancer witness first-hand the overwhelming financial stresses associated with paying for cancer treatments, including complex therapies and specialty prescription medications that can be prohibitively expensive. Research shows that "health insurance does not eliminate financial distress or health disparities among cancer patients" and that even insured patients who undergo cancer treatment seek copayment assistance and "experience considerable financial burden, and they may alter their care to defray out-of-pocket expenses." [1] ONS strongly advocates for patient access to affordable quality cancer care and is pleased the Administration is seeking input from nurses and other healthcare providers on meaningful solutions to make healthcare more affordable and improve outcomes.

<u>INCREASED COMPETITION</u>: ONS commends the Administration for seeking ways to increase competition and lower drug prices by providing greater access to affordable generics and biosimilars as opposed to more expensive brand biologics.

- **Biosimilars Development, Approval, Education and Access** - ONS supports the development of generics and biosimilars so that patients have access to affordable cancer medications. Although the price differentials between biosimilars and brands have not been as large as initially hoped, ONS still encourages accelerating their development and regulatory approval to increase drug competition and choice. ONS urges Congress and the FDA to uphold high safety standards while reducing barriers to market entry for generics and biosimilars, including those not marketed by the original patent holder.

[1] "The Financial Toxicity of Cancer Treatment: A Pilot Study Assessing Out-of-Pocket Expenses and the Insured Cancer Patient's Experience." The Oncologist 2013; 18:381-390.

- **Provider Education** - ONS supports efforts to better educate providers, including oncology nurses, on biosimilars in oncology and interchangeable products, so they better understand prescribing options for patients they treat, particularly if biosimilars are less expensive and achieve the same clinical outcomes. ONS appreciates that FDA has reached out to clinicians and welcomes the opportunity to work with FDA as it updates online materials on the website.

- **Interchangeability/Patient Safety -** With respect to interchangeability improvements, ONS wants to make sure that patients who are required to switch back and forth from a brand biologic to a biosimilar would have no adverse outcomes. We encourage FDA to work with CMS to inform insurers about the need for biosimilars to meet interchangeability requirements before requiring patients to use them, so they don't automatically require a non-interchangeable biosimilar just because it is less expensive.

BETTER NEGOTIATION – While ONS appreciates the HHS intent to promote better negotiation to lower drug prices, ONS has serious concerns about a CAP program for Part B drugs, moving Part B drugs to Part D, limiting Part D formularies, and any changes to the inclusion of cancer drugs in the Part D protected classes. The Administration has in the past signaled its openness to out-of-pocket caps in Part D, and we strongly urge HHS to move forward with such a policy.

- **Competitive Acquisition Program (CAP) for Part B Drugs**

ONS wants to make sure that any CAP program is voluntary for providers. It should be designed in a way that has adequate patient protections to ensure access to medications and adequate payment for providers administering medications. Providers should clearly have the option to leave the program if vendor performance is unsatisfactory.

- **Ensuring Competition**: ONS has reservations over the CAP, because the previous CAP program had only one vendor sign up to participate and a high attrition rate from its original 4,200 participating providers.[2] Any CAP program should be voluntary for providers, not mandatory. For providers who choose to be in CAP, CMS should offer at least three vendors to give patients and providers choice.

- **Provider Reimbursement:** ONS wants to ensure that providers are given sufficient reimbursement for administration of the drug if vendors are receiving the payment for the drug itself.

- **Ensuring Dosage Flexibility**: ONS supports a CAP program that allows for dosage flexibility so that dosage changes that occur over the course of treatment do not create treatment delays, especially if required medications are ordered in advance. ONS seeks more information and details on how HHS would address this need.

[2] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf.

- **Moving drugs from Part B to D**

ONS opposes moving Part B infused drugs, such as chemotherapy, and legacy oral cancer medications into Part D and proposes to exclude both of these from any move to Part D. We are not opposed to other non-cancer medications such as vaccines being moved if it reduces drug costs and does not harm beneficiary access.

- **Ensure Safe Handling:** Oncology nurses are specially trained to handle chemotherapy agents and ONS has a set recommendations for the safe handling of hazardous drugs that guides oncology nursing practice in this area.[3] ONS has concerns over the safe delivery and mailing of hazardous drugs and is willing to serve as a resource to CMS when considering safety concerns of the health care professionals, delivery personnel, and patient/caregivers receiving the drugs. .

- **Ensure Out of Pocket Costs Don't Increase**: ONS is troubled by an Acumen study commissioned by CMS that showed significant increases in out of pocket costs for patients using oral cancer drugs when they were moved to Part D:[4]

Table ES- 4: Change in Point-of-Sale Costs for Beneficiaries, Medicare, and Medicaid, by Cohort, 2007

Beneficiary Cohort	Number of Beneficiaries	Beneficiary	Medicare	Medicaid
B to D Cohort				
Anticancer/Antiemetic	68,082	$391	-$814	-$113
Pumped Insulin	12,269	$426	-$351	-$40
Nebulizer Inhalant	1,101,622	$287*	-$239*	-$95*
Immunosuppressant	74,136	$418	-$700	-$708
D to B Cohort				
Vaccines	353,158	-$10*	$107*	$4*
Parenteral Nutrition	3,587	$161	-$137	$820
Combined Cohort	1,600,053	$207*	-$230*	-$99*

The RFI should provide more details on guardrails that would protect these patients against increases in out of pocket costs. We are concerned about patients without Medicare prescription drug coverage in Part D and that some have supplemental benefits in Part B that could not be transferred for use in Part D. Any changes need to consider the complex coverage differences currently in the two programs.

- **Part D Formulary Restrictions and Six Protected Classes**

- ONS opposes changing the Part D drug formulary from two drugs per therapy class to only one drug per therapy class, as this would potentially be a hardship on patients with cancer who may have very limited options to treat their disease. If the one drug on the formulary is not one that is prescribed by their healthcare provider, the patient will be denied the treatment they need, potentially harming their health outcomes.

- ONS opposes mid-year changes to formularies as that could negatively impact the treatment regimen for patients with cancer. Patients with cancer cannot simply change medications in the middle of a treatment as these are often personalized to ensure the best outcomes for that patient's condition.

[3] https://ebooks.ons.org/book/safe-handling-hazardous-drugs-third-edition

[4] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Acumen_B_to_D_Final_Report_2011.pdf.

- Although not addressed in the RFI, ONS wants to ensure that cancer drugs remain in the Part D "protected classes" so that patients can continue to access them without restriction on Part D. We are concerned about the concept of "rewarding" manufacturers via leveraging the protected classes, as this could ultimately harm patients (see below).

- **Indication-based payment and assessing drug value**

While ONS sees merit in the concept of charging more for drugs that deliver the best patient outcomes, we request that HHS provide more detailed information on how drug value would be assessed and to make sure such assessments are supported by evidence-based research. Patients are more likely to agree to take a higher priced medication if they perceive it will have superior results over another, but the superior effectiveness must be clearly proven before increasing the price. Oncology nurses are aware of off-label prescribing and support flexibility to treat patients with the drug that will provide the best outcome for a specific disease. ONS urges caution if indication-based pricing restricts off-label uses by making it more cost prohibitive or not reimbursable. Already, some insurers raise barriers to reimbursement for off-label uses. Given the prevalence of off-label use in oncology, we would be concerned about any proposal that worsens this dynamic.

- **Long term Financing Models**

Since cancer medications are prohibitively expensive, offering long term financing models may help patients better afford their medications and adhere to treatment. Additionally, if cured, there are long-term societal savings. These models should be encouraged and explored, and we are eager to work with the Administration to do so.

- **Site neutrality for physician-administered drugs and between inpatient and outpatient settings**

ONS supports a site neutral payment to prevent misaligned incentives for prescribers. Oncology nurses practice and administer drugs in a variety of settings and so reimbursement should not be based on the setting where the cancer drug is administered.

CREATING INCENTIVES TO LOWER LIST PRICES

- **Incentives to lower (or not increase) list prices and impact protected classes of drugs**

While ONS sees value in incenting drug companies to offer discounts and not increase list prices, we are concerned that penalizing them by removing their drugs from the protected classes or rewarding them by including their drugs in the protected classes would do more harm to patients with cancer that require that specific medication. The protected classes were created out of access concerns for patients with certain conditions – they were not created to exert pricing pressure over manufacturers. Misaligned incentives ultimately hurt patients.

- **Passing along more rebate savings to patients**

While ONS supports giving more out of pocket savings from rebates to patients, we understand the drug supply chain is complicated and want to make sure that guardrails are in place to protect patients. As prescribers, oncology nurse practitioners would benefit from timely information on drug costs and efficacy to support their treatment decisions. ONS supports including the relative clinical benefits of alternative treatment regimens and the relative financial costs of treatment settings to both patients and payers.

REDUCING PATIENT OUT OF POCKET SPENDING

- **Copay discount cards**

ONS believes that patients who require a specific cancer treatment that is only offered as a brand without a generic alternative should be allowed to use manufacturer copay discount cards in Medicare to offset the cost sharing. On the other hand, patients accessing brand drugs that have a cheaper generic or biosimilar alternative should not be allowed to use copay cards, which incent the use of the more expensive brand drug.

ONS Is concerned that copay accumulator programs make it harder for patients to afford their treatments. Patients should be able to apply charitable assistance and manufacturer copay assistance cards toward their deductible. Research shows that patients who cannot afford cost-sharing are less likely to adhere to their treatment, which increases their risk of poor health outcomes. An NIH study found that survivors of cancer were "more likely to report that they could not afford medication, asked their physician for lower cost medication, and used alternative therapies in the previous year to save money."[5]

- **Pharmacy Gag Clauses**

ONS supports the removal of pharmacy gag clauses so that pharmacists can freely share information with patients about cost sharing and lower cost alternatives, including notifying patients if paying cash "off insurance" for a medication would be less expensive. Patients should be well informed of costs to make decisions about their medications and treatment. Oncology nurses and nurse navigators play an important role helping patients interpret and sort through information they receive from pharmacists. ONS understands that Pharmacy Benefit Managers (PBMs) want to avoid having patients pay cash for their medications "off-insurance" as that prevents them from capturing utilization data. However, ONS urges HHS to ban gag clauses and require that utilization information be captured in a way that does not require patients to incur unnecessary out-of-pocket costs.

We appreciate the opportunity to comment on issues and questions raised in this Blueprint and RFI. If you have any questions about our comments, please contact Dede Sweeney, ONS Director of Government Affairs, at dsweeney@ons.org.

Sincerely,

The Oncology Nursing Society

About ONS

The Oncology Nursing Society (ONS) is a professional organization of over 39,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of professional roles, practice settings, and subspecialty practice areas. Oncology nurses are leaders in the healthcare arena, committed to continuous learning and leading the transformation of cancer care by advocating for high-quality care for people with cancer.

[5] "Cost-related medication nonadherence among adolescent and young adult cancer survivors," 2017, http://dx.doi.org/10.1002/cncr.30648