

The Cancer Policy Institute *at the* 
CANCER SUPPORT COMMUNITY
Uniting The Wellness Community & Gilda's Club Worldwide

July 15, 2018

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

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar,

On behalf of the Cancer Support Community and Friends of the Cancer Policy Institute, a coalition of professional and patient advocacy organizations, we appreciate the opportunity to provide comments on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. We recognize the need for this blueprint and respectfully submit these comments in an effort to protect and promote the needs of patients.

Introduction

The United States health care system is the most expensive in the world (Institute of Medicine, 2010). The costs of cancer care are rising more quickly than other fields (American Society of Clinical Oncology, 2017) and account for five percent of total U.S. health care spending (Schnipper & Bastian, 2016). Over 15 million people are living with cancer in the United States today and that number is expected to grow to 20 million by 2020. At a time when patients should be able to focus on their health and wellbeing, many are more concerned about financial toxicity. The cost of copayments, out-of-pocket expenses, and rising insurance premiums may be beyond the reach of many cancer patients (Young, 2015). Patients report financial distress as more severe than other sources of distress associated with physical, social, and emotional functioning (Delgado-Guay et al., 2015). Findings from a research study on the impact of health care costs on wellbeing and treatment among cancer patients, suggest that insured patients undergoing cancer treatment experience substantial financial burden, and that health insurance coverage does not eliminate financial distress among cancer patients (Zafar et al., 2013).

In a 2016 Cancer Support Community (CSC) [study](#) on access to cancer care, we found that over 42% of participants experienced higher than expected out-of-pocket costs, 68% did not discuss health care costs prior to treatment, and 22% reported skipping recommended treatments to manage out-of-pocket costs. The majority of participants

(67%) reported cost as very important when they were selecting their health insurance coverage and their top concerns regarding their insurance included: 1) out-of-pocket costs for services (49%); 2) high deductibles (48%); high premiums (47%); and high copayments for medication (42%).

Simply put, financial problems associated with cancer treatment have an impact on quality of life (Fenn et al., 2014). As such, we appreciate the opportunity to provide the following comments on the components of the RFI, which we believe have the potential to most seriously impact patients.

Guiding Principles

The following principles guide our comments and we ask the Administration to utilize them as policy changes are made in an effort to curb drug pricing:

1. Policy changes should be considered in a broad context which places patients at the center. It is vital to understand the implications that each policy change will have on the health care system and in the lives of individual patients.
2. We urge HHS to pursue efforts to rein in drug pricing in concert with initiatives that address affordability and stability in the health care marketplace more broadly. We urge the Administration to revisit and halt any regulations and policies that are rolling back consumer protections under the ACA, including Medicaid, which were improving affordability and access for Americans.
3. Policy changes should be transparent to all stakeholders.
4. Policy changes should improve patient access to appropriate therapies.
5. Policy changes should improve affordability for patients.
6. Policy changes should be accompanied with information to help patients understand the potential impact to them. Such information should be provided in language they can understand and process.
7. Patients should be given ample opportunity and time to understand policy changes, ask questions, and seek assistance necessary to maintain access to care.
8. Decision support tools should be provided to patients. These tools should be created with tremendous input from patients and caregivers, evaluated on an ongoing basis by patients and caregivers, and updated as necessary when new information becomes available.

Medicare Part B to D

We have serious concerns about the potential negative impact (in terms of patient safety and out-of-pocket costs) of moving oncology and supportive drugs from Medicare Part B to Part D.

The President's Budget requested the authority to move some Medicare Part B drugs to Medicare Part D. We have serious concerns about this policy change which has the potential to not only increase out-of-pocket costs for patients but also could impact patient safety. The RFI specifically requests which drugs or classes would be good candidates for movement from Part B to Part D. Leavitt (2005) states that the "majority of categories of Part B drugs are not good candidates for shifting to Part B" (p. 13). According to the Centers for Medicare and Medicaid Services (CMS), Part B drugs include "drugs you get at a doctor's office or hospital outpatient setting" (n.d.). Oral anticancer and antiemetic drugs covered under Part B are currently administered by a physician as a part of cancer treatment, prescribed within 48 hours of cancer treatment, and are used as a replacement for intravenous chemotherapy (Marrero et al., 2011). Part D may currently cover oral medications that do not meet these conditions (Marrufo et al., 2011).

We strongly oppose the potential move of oncology treatments, such as chemotherapy, from the current structure of Part B to Part D. A move from Part B to Part D could result in "brown bagging" which occurs when a patient directly receives the medication and then takes it with them to the oncology practice for administration. This practice potentially increases room for error, could negatively impact timeliness of treatment, and can be dangerous as many medications must be kept in specific conditions. The American Medical Association (2016) notes that the integrity of the medications cannot be ensured when brown bagging occurs. Potency and efficacy can be impacted if the medications are not properly handled and stored (American Medical Association, 2016). Further, this method is inconvenient and has the potential to cause additional distress for patients as they must travel to procure the medication and maintain responsibility for proper storage conditions in order to ensure safety and efficacy. CMS (2008) has stated that it recognizes opposition to the practice of brown bagging by professional societies and encourages reinforcement of that message.

"The Part B benefit structure is significantly different from the benefit structure for defined standard coverage under Part D" (Leavitt, 2005, p. 3). In a 2018 report, Brow and Kane found that "Medicare patients' out-of-pocket costs for new cancer therapies can vary substantially based on whether a drug is covered by Part B or Part D, due to differing benefit designs and the use of supplemental health coverage" (p. 1). "Part B has a lower deductible, lower initial cost-sharing, and does not require 100 percent cost-sharing for a portion of spending" (Leavitt, 2005, p. 3). 2016 average out-of-pocket costs were approximately 33% higher for Part D-covered new cancer treatments than those covered in Part B (Brow & Kane, 2018). Additionally, while patient out-of-pocket costs are our primary concern, movement of certain drugs from Part B to Part D would also likely increase the overall Medicare program spending (Leavitt, 2005).

Part D coverage requires cost sharing for most patients. Part B coverage requires beneficiaries to pay a 20% coinsurance. Both Part B and Part D do not have a required out-of-pocket maximum for patients. Yet, many Part B patients have supplemental coverage such as Medigap to offset the cost. Notably, Medigap coverage is specifically

precluded for Part D patients. Thus, patients typically pay less out of pocket under Part B and shifting oncology medications into Part D could result into higher out-of-pocket costs for many cancer patients. Further, if costs are shifted from Part B to Part D, there is a potential for increased Part D premiums (Brow & Kane, 2018).

CSC encourages the Administration to create Maximum Out-of-Pocket (MOOP) limits for Part D and Part B beneficiaries similar to those that were created for non-government plans with the passage of the ACA. The out-of-pocket costs incurred by cancer patients are a major contributing factor to financial toxicity, putting beneficiaries at risk of skipping doses of life-saving medications, suffering from physical or emotional stress, or facing bankruptcy (Bach & Pearson, 2015). We also believe that the services patients often receive in their doctor's office, such as distress screening, navigation, and linkages to resources and community services are vitally important and could be lost in a transition from Part B to Part D.

Copayment Discount Cards

Many cancer patients rely on manufacturer and charitable copayment discount cards to access and afford their medications. Policy changes that impact these discount cards should not impact the ability of patients to access and afford their medications.

A new type of policy has been introduced that has the potential to put cancer patients at serious financial risk. Copayment accumulator or accumulator adjustment programs prohibit manufacturer copayment cards or other forms of manufacturer assistance from being used to pay down a patient's deductible or out-of-pocket maximum. The value of the card payments do not count towards the patient's deductible or out-of-pocket maximum. This means that patients will need to pay their full deductible or out-of-pocket maximum before cost sharing protections kick-in. The patient is responsible for significantly more money to cover the cost of their health care and prescriptions. Through the use of these policies, many patients will not be able to predict nor pay for their out-of-pocket costs. We are concerned that patients who cannot afford these expenses will forgo the appropriate treatment or make difficult financial choices regarding other expenses. We strongly oppose the use of copayment accumulator policies due to their negative impact on patients. While we understand why some payers may have originally created such policies—specifically where there were cheaper, alternative therapies patients could use, we believe these programs are inappropriate in oncology as therapies are carefully selected through a shared decision making process between patients and their health care team based on patient values, needs, and preferences. Many oncology therapies also do not have a generic alternative, making these policies not only financially untenable but simply poor policy.

Value Based Arrangements

Value based arrangements have the potential to improve quality while reducing costs in the health care system. However, it is critically important that patients are involved in the development of value based arrangements, experience the benefits of such arrangements, and do not see access impeded in any way.

Value based care has the potential in some instances to replace fee for service care, which has contributed to the expense of the United States' health care system. Yet, such arrangements must be appropriately designed and implemented for specific treatments. This includes testing any program to determine feasibility in specific therapies. Value based arrangements should be voluntary to ensure appropriate fit for particular therapies before widespread adoption. Such arrangements should also be transparent so that all stakeholders understand how they were created, what components are included, who will benefit and how, and how they will be evaluated and improved upon.

It is of utmost important that endpoints and outcomes that will be measured and considered as “valuable” are meaningfully informed by patients. Endpoints that are incorporated into an arrangement must be driven predominantly by what the patient values, not simply clinical endpoints such as overall or progression-free survival. In a 2015 CSC study of metastatic breast cancer patients, only five percent felt that value in care could be defined in an economic exchange context and nearly 40 percent felt that valuable care meant care of a personal value, including time with their physician, quality of life, and engagement in a shared decision making process. Patients should have access to information about value based arrangements and provided an opportunity to ask questions.

A sufficient number of diverse patients (who have experienced the disease state under consideration) should be meaningfully included in every step of the process to develop and implement value based arrangements. Patients should receive information regarding potential value based arrangements in a timely, transparent, and understandable manner. The National Health Council (2016) outlines “patient-centered data sources” as integral to a patient-centered value model. They note that value models should incorporate a variety of credible data sources that allow for timely information and account for the diversity of patient populations. This information should come from real-world settings and be reported by patients directly. Outcomes should be important to patients and capture their experiences. Finally, just as other stakeholders in the health care system benefit financially from value based arrangements, the ways in which patients are benefitting within these arrangements should be explored. For example, will patients experience reduced cost sharing? If the desired endpoint of a treatment is not achieved, will patients be reimbursed for the costs they have paid out-of-pocket for that treatment?

In order to successfully design and implement patient-centered value based arrangements, there are a number of regulatory barriers that must be addressed including Medicaid best price reporting and Anti-Kickback Statutes. It is also important to understand how the recently released FDA guidance on *Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities—Questions and Answers* will impact value based arrangements. As this guidance only covers communication from manufacturers to payors, it is important to understand implications for providers and patients. Policy makers must develop common sense approaches to allow for value based arrangements that improve the lives of patients through enhanced quality and overall reductions in health care costs.

Finally, if indication-based pricing is implemented, it is important for patients to be involved in the determination of value as it applies to treatment both on- and off-label. Such pricing should not negatively impact the ability of patients to access and afford the treatment that is appropriate for them based on their values, needs, and preferences.

340B

The 340B drug discount program is vital to ensuring that many patients in this country have access to lifesaving treatments. However, the evolution of the program over the past several decades has created cause for concern. We support policy changes to improve the transparency and accountability of the program to better support the needs of patients.

Neither the 340B statute, nor HRSA guidance, dictate how cost savings from the program are utilized by covered entities. This program was created to allow certain safety net providers to obtain discounted prices on covered outpatient drugs in order to help these entities stretch their scarce federal resources to meet the needs of vulnerable patient populations. Yet the government does not track how the cost savings are implemented. Some entities have been found to use savings to expand the number of patients served, such as federally qualified health centers, who may be required to use the revenue in ways consistent with grant requirements. Other entities may also use savings to invest in capital, cover administrative costs, or for any other purpose. Guidance is needed regarding the use of 340B cost savings. Although not a current requirement, we advocate that covered entities prove that these savings are directed back into direct patient care and support services.

In a 2016 CSC study on access to care, it was found that patients surveyed felt that although they needed specific services, they were not able to receive the following: general support services (45%), treatment for side effects (38.9%), eating and nutrition counseling (38.3%), financial counseling (28.9%), and mental health counseling (26.2%). Additionally, 71% of respondents indicated that they did not receive any social and emotional support services as part of their cancer care. Across all health insurance types, individuals identified availability, coverage, and high cost as the top reasons that they did not receive such services. These are precisely the types of services that should be supported by cost savings generated by the program. Guidance is needed to define what types of services (including psychosocial support services) covered entities should fund through program cost savings.

If covered entities are saving money through the program, it is imperative that those cost savings also be realized by all patients. Covered entities are permitted to use discounted 340B drugs for all individuals who meet the current definition of “patient,” not only those patients who are deemed low income, uninsured, or underinsured. As the Office of the Inspector General (OIG) (Bliss, 2017) reports, some covered entities take steps to ensure that 340B discounted prices are passed on to uninsured patients when they fill prescriptions at contract pharmacies (which are not a part of the entity and are allowable by the program) (Bliss, 2017). However, the OIG also found that this is not common practice with every covered entity and there are instances when uninsured patients pay

full price for drugs filled at contract pharmacies. Guidance is needed regarding how the program applies to uninsured patients. We advocate that uninsured patients at 340B entities also benefit from the program cost savings and are not charged full price for their medications.

The number of hospitals enrolled in the program has jumped from 583 in 2005 to 1,679 in 2014 (Conti & Bach, 2014). Stakeholders have questioned whether the 340B expansion underlies the “trend toward consolidation and affiliations between community-based oncology practices and 340B eligible hospitals” as well as a trend towards more expensive care (Conti & Bach, 2014). Such vertical integration has the potential to limit patient choice, reduce the quality of care, and increase prices (Alpert, His, & Jacobson, 2017). It is important for patients to be able to access and afford health care services in their community of choice. More information is needed regarding the role of the program in hospital consolidation and affiliation, the preservation of community practice, and the impact on access, cost, and quality to determine if the program is undermining patient goals, preferences, and needs.

Part D Formularies and Six Protected Classes

We strongly oppose changes to Part D formularies and the protected classes policy that will negatively impact patient access and affordability.

The RFI inquires about changing Part D plan formulary standards to require a minimum of one drug per category or class rather than two. We strongly oppose this change as we believe it will negatively impact patient options and access. We strongly oppose mid-year changes to formularies as well. This is particularly relevant for cancer patients and survivors who often take complex and/or combination therapies that carry with them various side effects. Patients and providers engage in shared decision making processes to determine the best medication for that particular patient based on their values, needs, and preferences. Patients have differing responses to treatments, and personalized medicine is offering more targeted options. It is critical that providers have the autonomy to exercise discretion in treatment recommendations, incorporating both clinical evidence as well as patient input through shared decision making. Medication substitutions can interfere with this process. If patients are stable on a certain therapy, changes to their medications can cause serious negative repercussions including declines in health outcomes, increased costs (if the patient must switch medications several times or if they are faced with higher out-of-pocket costs if they must be treated with the original medication), and increased distress. Finally, if patients are required to undergo substitutions, it is essential that they receive ample notification of any changes, that they are provided with timely and understandable information on ways to appeal such a decision, and that decisions in response to appeals are made within seven days.

The RFI also highlights the President’s Budget recommendation to create demonstrations for up to five states to test drug coverage and financing reforms that build on private sector best practices. Participating states could determine their own drug formularies, coupled with an appeals process to protect beneficiary access to non-covered drugs based on medical need, and negotiate drug prices directly with manufacturing. We have serious

reservations about the ability of such demonstrations to meet the needs of patients, particularly those with chronic diseases such as cancer. If such demonstrations do occur, it is essential that they are voluntary and small scale in nature. Data must be available as quickly as possible regarding the impact to patients, and ongoing adjustments based on this data should be made. An appeals process should be as simple as possible and take no more than 48 hours to complete.

The RFI did not include questions regarding the Medicare protected classes policy. We are taking this opportunity to strongly support the existing protected classes policy which has been vital to patients since its inception in 2006. According to the policy, Medicare Part D plans are required to cover at least two drugs in each therapeutic class. For the six protected classes, Part D is required to cover all or substantially all drugs. For many patients, including cancer patients utilizing antineoplastics, this policy has been critical to ensuring appropriate access to treatments. For many of the patients who utilize medications under the protected classes policy, their challenges are compounded by comorbidities. For example, many cancer patients experience mental health challenges making access to antidepressants important to their health and wellbeing.

Changes to the protected classes policy are unlikely to produce cost savings (Avalere, 2016). While formulary restrictions may temporarily reduce drug spending, the concomitant increases to inpatient and outpatient medical care outweigh the savings on prescription drugs (Avalere, 2016). Formulary restrictions may also lead to patients abandoning treatment or experiencing higher hospitalization rates with longer stays (Avalere, 2016).

In 2014, CMS proposed changes to the protected classes policy, keeping only antiretrovirals, antineoplastics, and anticonvulsants as protected classes. Immunosuppressants and antidepressants would have been removed from the classes of clinical concern and antipsychotics would be removed after one year. Facing extraordinary opposition from Congress, patients groups, and numerous other stakeholders, CMS did not finalize the rule stating that it “did not strike the balance among beneficiary access, quality assurance, cost containment, and patient welfare” (Federal Register, 2016).

Patient Access, Affordability, and Transparency

We support efforts by the Administration to protect and expand patient access to care, affordability of medications, and transparency to support informed decision making.

Beneficiary Cost Sharing

We strongly support efforts to limit beneficiary cost sharing. We encourage beneficiary cost sharing to be based on the negotiated price. We also support a portion of manufacturer rebates being shared with the patient. We ask the Administration to work to ensure that such changes do not create other incentives for plan sponsors to make up the difference through alternative cost sharing mechanisms, particularly if direct or indirect remuneration (DIR) received is above plan projections. We ask that sponsors be required to include all pharmacy price concessions received and ensure that patient cost sharing is

reflective of the lowest price. Beneficiaries should not only experience lower premiums, but also avoid high cost sharing whenever possible. We also support a standardized approach that is consistent and transparent across plans so that patients can consider cost sharing impacts as they make personal decisions. As Eaddy et al. (2012) found increased patient cost sharing has been associated with declines in medication adherence and poorer health outcomes. Further, we ask the Administration to explore avenues to identify and reward high performing pharmacies that go above and beyond to improve patient outcomes.

Pharmacy Gag Clauses

As noted in the RFI, some contracts between health plans and pharmacies do not allow the pharmacy to inform a patient that the same drug or a competitor could be purchased at a lower price off-insurance. Pharmacists should be able to freely share information with patients regarding their financial responsibility at the point of sale. Patients should be informed about cost-sharing and lower cost alternatives, as well as any differences in safety and efficacy in different drug options.

Site Neutrality

As noted in the RFI, the costs to administer care at different sites vary based on facility fees. It is important that any policies to create site neutral payments ensure that patients can access treatment at the site that is appropriate for them based on their treatment and care needs throughout the care continuum.

Biosimilars

New therapies that are safe and effective, as determined by the FDA, should be provided as an option to patients. Patients should be provided with information regarding all of their treatment options, including biosimilars when appropriate. The FDA should provide transparent and understandable information regarding biosimilars to interested patients and providers should be prepared to engage in a shared decision making process with patients so that they can make decisions that are right for them.

Competitive Acquisition Program

As noted in the RFI, HHS has the authority to operate a Competitive Acquisition Program for Part B drugs. CAP could change the ways in which oncology drugs are bought and billed in the United States. As such, we implore the Administration to consider the ways in which CAP would impact patients. We ask that no policies be put in place, including formularies, that would restrict access to the appropriate treatments for patients. We ask the Administration to consider how the implementation of CAP would potentially impact the ability of health care providers to provide services (both treatment and support) to patients.

Conclusion

In closing, we appreciate this opportunity to provide feedback on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. We are aware of the rising costs of treating cancer and other chronic illness, and we support efforts that contain costs while ensuring the provision of comprehensive, high quality, affordable, timely, patient-

centered care. Patients must be at the core of any policymaking that could impact their care.

We believe that a health care system based on quality, outcomes, and cost does not go far enough to fully support and integrate patients as equal partners in their care. Patients must be meaningfully engaged in all efforts to address any aspect of our health care system, including cost. Our health care system must be tailored to the unique values, goals, and preferences of patients. This should be evidenced through measures and metrics that are created, implemented, and evaluated with patients as equal partners as well as reimbursement systems that are flexible enough to reflect patient-defined outcomes. For example, some cancer patients may value a cure above all else—and our measures and funding mechanisms should reflect that choice. Meanwhile, other patients may value quality versus quantity of life, and in turn, measures and funding should meet the needs of that patient as well.

We would be pleased to serve as a resource to the Administration as next steps are taken to address drug pricing. Please contact Linda House, RN, BSN, MSM, President, Cancer Support Community at linda@cancersupportcommunity.org or 202.650.5382.

Sincerely,

Cancer Support Community & Friends of the Cancer Policy Institute
Academy of Oncology Nurse and Patient Navigators
Association of Oncology Social Work
CancerCare
Colorectal Cancer Alliance
Fight Colorectal Cancer
FORCE: Facing Our Risk of Cancer Empowered
Living Beyond Breast Cancer
Lung Cancer Alliance
LUNGeVity Foundation
Prevent Cancer Foundation

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