

December 31, 2018

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

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
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Attn: CMS-5528-ANORM

Re: Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Secretary Azar and Administrator Verma,

On behalf of the Cancer Support Community (CSC) and friends of the Cancer Policy Institute, a coalition of professional and patient advocacy organizations, we appreciate the opportunity to provide comments on the advance notice of proposed rulemaking (ANPRM) International Pricing Index Model for Medicare Part B Drugs (the model).

As noted in our comments regarding the HHS Blueprint to Lower Drug Prices and Out-of-Pocket Costs, we believe that a health care system which is not affordable is not accessible. At a time when patients should be able to focus on their health and wellbeing, many are more concerned with 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). Financial problems associated with cancer treatment have an impact on quality of life (Fenn et al., 2014) and for many families, render our health care system unaffordable.

The Model

As noted in this ANPRM, the model seeks to achieve the following:

1. Reduce expenditures while preserving or enhancing the quality of care for beneficiaries;

2. Ensure the United States (U.S.) is paying comparable prices for Part B drugs relative to other countries by phasing in reduced Medicare payment for selected drugs based on a composite of international prices;
3. Reduce out-of-pocket cost for included drugs for Medicare beneficiaries, and thereby increase access and adherence due to decreased drug costs;
4. Maintain relative stability in provider revenue through an alternative drug add-on payment for furnishing drugs that removes the current percentage-based drug add-on payments, which creates incentives for higher list prices and to prescribe higher cost drugs;
5. Reduce participating health care providers' burden and financial risk associated with furnishing included drugs by using private-sector vendors to purchase and take title to included drugs; and
6. Introduce greater competition into the acquisition process for separately payable Part B drugs.

Cancer drugs will be included in the model because they are one class of drugs that make up the majority of Part B spending. With 1.7 million new diagnoses of cancer each year and 15.5 million cancer survivors in the United States, we understand the impact of cancer care costs on society as well as on individual patients. For many of these patients, cancer poses serious limitations to their lives including physical, mental, emotional, and financial health and wellbeing.

As such, it is *critical* that should CMS choose to move forward with the IPI, it does so with the best interests of patients at the forefront of the model. Patients living with cancer cannot afford a model that takes away choice, creates higher out-of-pocket costs, interferes with their patient provider relationship, and/or delays or negatively impacts access to treatment.

Further, we know that many Medicare beneficiaries already struggle to understand their benefits and it is critical that the model not introduce additional confusion or complexity. Changes to beneficiary processes, access, or financial obligations must be clearly outlined in understandable language. Beneficiaries must have opportunities to ask questions, seek clarification, and determine treatment choices that fit their values, needs, and preferences.

It is with this in mind that we respectfully submit the following comments. We would like to start by reiterating the guiding principles we submitted with our comments on the Blueprint.

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 extensive input from patients and caregivers, evaluated on an ongoing basis by patients and caregivers, and updated as necessary when new information becomes available

Voluntary Model

According to Section 1115 of the Social Security Act, opportunities to test such models may occur when there is “evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title.” The proposed IPI model is so large that its sheer size violates the spirit of “testing” an idea. We are not only concerned about feasibility of implementation and meaningful evaluation but more importantly, about the ability of patients to choose their care, opt out of the test and find care elsewhere.

As we noted in our November 2017 letter to the Centers for Medicare and Medicaid Innovation (CMMI) regarding the new direction request for information, CSC supports voluntary, small scale testing that is specific to targeted populations. We do not believe that a voluntary model should involve mandatory participation that would include 50 percent of Medicare Part B spending on separately payable Part B drugs. Importantly, the impact of a test model will also be felt outside of the practices included directly within the model, potentially causing confusion and compromising access to life saving therapies.

Safeguards

Broadly speaking, there must be appropriate guardrails in place before any CMMI model is implemented to ensure that CMMI demonstrations first and foremost protect patient access and affordability. Safeguards should also ensure transparent implementation and evaluation of the model. CMS should create, implement, and ultimately spread models in a stepwise approach. All findings should be disseminated and commented upon publicly, and widespread implementation

should only occur when stakeholders have had ample time to understand, comment, and meaningfully engage in the process and when consequences of the model are well understood. There should be no unanticipated, mandatory demonstrations and Congress should advise when it determines that a model is mandatory since it will have a significant impact on the lives of millions of patients nationwide.

In terms of this model, there are no clear safeguards in place to ensure that the model does not negatively impact patients. The IPI notes that “agreements between vendors and physicians/hospitals would establish the terms of their arrangements and would include appropriate guardrails to protect all parties, including beneficiaries and the Medicare program.” What would these guardrails entail?

CMS requests feedback on whether CMS should be a party to and/or regulate these agreements, and whether the agreements should specify obligations to ensure the physical safety and integrity of the included drugs until they are administered to an included beneficiary, how drug disposition would be handled, and data sharing methods, confidentiality requirements, and potentially other requirements. We believe that CMS has a responsibility to ensure that all aspects of the model do no harm to patients and therefore, must be involved in these agreements to ensure beneficiary out-of-pocket costs do not rise, safety and confidentiality are protected, and access is facilitated.

CMS also requests feedback regarding guardrails to be put in place to prevent perverse incentives that could be introduced by the inclusion of a competitive acquisition program (CAP). We believe that such incentives should be in place before any model moves forward and continuously monitored. If they are harmful to beneficiaries in any way, CMS must revise the plan and/or implement additional patient protections.

In general, patients must be alerted, in language they can understand and process, of their provider’s enrollment in the IPI. Patients should be given ample opportunities to understand the goals of the IPI, ask questions about what it will mean to them, and determine if they would like to continue to seek care with their provider. Patients deserve access to transparent information regarding all aspects of the IPI including how Part B drugs are currently reimbursed and how the IPI will change this. In fact, we urge CMS to work closely with leading advocates for patients to develop culturally competent and patient-friendly language about the model and all its aspects..

If patients do not agree with their provider’s recommended course of treatment, they should be able to make personal decisions that fit their unique needs and if necessary, engage in a rapid appeals process. However, due to the broad nature of the model, it will be virtually impossible for a patient who does not wish to be included in the model to seek care elsewhere. We strongly oppose the fact that patients will be placed into the model with no realistic alternatives for care.

If the model proceeds, outcomes and evaluation data must be made available as quickly as possible and on an ongoing quarterly basis. This should include not only practice-generated data but also patient experience feedback. Providers must be allowed to make choices that work best for them and produce positive outcomes in the best interest of their patients.

Finally, we understand the limitations of an ANPRM, however the limited information available at this time, including the lack of the proposed geographic areas and practices that will be forced to participate in the model, makes it challenging to provide detailed comments on the specifics of the proposed model.

Patient Access

CSC is on the record with concerns dating back to 2016 when the Obama Administration released a Part B payment demonstration regarding the potential impact of such demonstrations on the ability of patients to access care. We have similar concerns about the implications of the ANPRM on patient access.

Cost as the Driving Factor

This ANPRM outlines the proposed structure of the model “such that physicians and hospitals would be incentivized to seek out lower cost drugs for their beneficiaries, reduce inappropriate utilization, continue to pay for certain distribution costs, continue to bill Medicare for drug administration, albeit following model-specific instructions, and continue to collect beneficiary cost-sharing for included drugs.” We are concerned that the ultimate goal of the IPI is really to reduce Medicare costs by promoting lower cost drugs and reducing inappropriate utilization. If mere cost cutting to the system is the sole or ultimate goal of this model, patients will suffer the consequences.

How will this model influence the total cost of care including not only the impact of drug spending but the full range of cost drivers to the system, providers, and patients? How will the costs related to drug administration be incorporated into the model? The ANPRM states that providers will be made whole. There must be additional information to help providers understand how that is possible and how it will manifest within the context of their practices.

Who determines what inappropriate utilization is? What outcomes are being measured and do they include not only patients’ clinical outcomes but also their quality of life outcomes? Will the patient and provider be able to engage in a shared decision-making process to ensure that the most appropriate medication is selected, even when that medication is not the lowest cost option? How will the model impact clinical decision making when a provider determines that a patient will benefit from a treatment that is off label? How will genetic and genomic testing be built into the model to help ensure that patients have access to the best and most appropriate treatments for them?

We agree with the need to reduce beneficiary cost sharing. However, patients should be placed on the optimal treatment regimen based on their stated needs, preferences, and values.

Bonus Payments

Further, CMS is considering a bonus payment to model participants who prescribe lower-cost drugs or practice evidence-based utilization. Cost must not be the primary factor driving provider prescribing behaviors. Further, CMS must define exactly what evidence-based utilization means (certain guidelines and/or pathways) and how they will be incentivized. Provider behaviors must be driven by shared decision making with patients. If these factors are incorporated into the model, patients need access to transparent information regarding clinical pathways and financial

incentives and the potential for those incentives to drive clinical decision making. If a patient does not agree with their provider's recommended course of treatment, they should be able to make personal decisions that meet their unique needs and engage in a rapid and efficient appeals process, when necessary.

Utilization Management

Will utilization management tactics be employed in the model? If so, what are the tactics and in what circumstances are they to be used? Will the model include formularies? If so, what evidence will be used to drive the drug selections and tiers? Will there be an appeals process that patients can understand and navigate quickly? Implementation of this model must not impede patient access or negatively impact patient care.

Provider Decision Making

Will providers be able to utilize sound clinical decision making in an individual patient context? For example, what will happen if a treatment plan must be changed during a patient's visit? What will happen if a patient's weight fluctuates and dosage must be altered? How will the CAP system be flexible enough to ensure uninterrupted and optimized patient access?

Competitive Acquisition Program

The model would include a component previously known as the Competitive Acquisition Program (CAP). This ANPRM outlines a list of model vendor responsibilities. Top among these responsibilities must include patient access to safe, timely medications. Vendors must ensure that they can successfully work with providers/hospitals to provide patients with the appropriate medications and dosages and guarantee safety and quality.

CMS states concern regarding "issues such as the lag time resulting from the provider having to obtain drugs from regular channels before the drug is available from the vendor, the lead time for the development of vendors' acquisition arrangements, and the potential unavailability of pricing benchmarks for new drugs immediately after a drug is marketed." In the case of cancer therapies, these challenges must be addressed before launch. Patients seeking treatment for cancer do not have the luxury of waiting for medications. Beneficiaries should see no change in the availability of or access to therapies and in fact, should be able to more quickly access appropriate treatments. If vendors are unable to fulfill their responsibilities, there must be policies in place for providers to file emergency requests for medications from other reliable sources. Such requests should be attended to immediately, so that patients do not suffer a lapse in care.

Vendor Selection

CMS outlined Model Vendor Selection and it is vital that if vendors fail to meet patient or provider/hospital needs, the vendor be terminated. It is unacceptable for patient access to appropriate therapies be sacrificed due to vendor inability to meet contract obligations. Further, vendor conflicts of interest should be analyzed by CMS to determine appropriateness of fit for this important role.

Practice Integration

CMS must ensure that the model will not negatively affect patients through its potential impact on health care practices, such as closure of physician offices, private practice integration into

healthcare systems, and early physician retirement. As we noted in 2016, patients and families will bear the additional burden of relocating to new sites of care delivery if their providers cannot afford to keep their doors open.

Further, will providers be appropriately reimbursed for the administration of treatment? While the model focuses on drug costs, how will providers cover the costs of chemotherapy administration and other overhead required to maintain a safe and effective health care practice?

Model Overlap

The ANPRM includes a section on the potential overlap of various models, particularly the Oncology Care Model (OCM) which is a five-year model with an anticipated end date of 2021. We are concerned about the impact of such overlap on patients as well as the ability of CMMI to determine model impact if the research methods are flawed by the use of dual models. The goal of such models is to determine best practices for broader implementation and the introduction of the model has the potential to interfere with such evaluation.

International Reference Pricing

The ANPRM inquires about the use of international reference pricing. Would reference pricing require patients to pay a surcharge for specific medications? Would patients and providers be able to file for a timely waiver or appeal if they believe that a medication outside of the reference price is necessary for a specific reason? How will the implementation of reference pricing address inequities in the health care system without exacerbating existing and driving future health disparities?

Cost Effectiveness Measures

The model would utilize reference prices from 16 foreign countries in order to set payment rates. Cost effectiveness assessments drive health care decision making in many of these countries. The Quality Adjusted Life Year (QALY) is central to many of these assessments, which we believe is a highly problematic and flawed metric. Multiple studies, including CSC's Cancer Experience Registry data, show that for patients with cancer and other long-term debilitating illnesses, there is a delicate balance between quality and quantity of life. In fact, patients have reported a desire for shorter overall survival in exchange for quality of life. The QALY framework assigns the exact same score to an individual who lives six months in perfect health and to an individual who lives a full year in a debilitated state. Many patients would assign a very different level of value to each of these scenarios. Further, the QALY discriminates against people living with disabilities, older people, or those living in other "less than desirable health states." The QALY makes assumptions at a population level that have a life defining negative impact on individual patients.

The Patient Protection and Affordable Care Act (ACA) prohibits the use of "dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended." Further, "the Secretary shall not utilize such an adjusted life year (or such similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII."

Beneficiary Cost Sharing

CMS states that there is an expectation that “beneficiary cost-sharing for included drugs under the potential IPI Model would either be the same or lower than the non-model cost-sharing. Medicare payment policy for beneficiary cost sharing would remain the same but since the IPI Model should reduce Medicare payment for some Part B drugs, the 20 percent beneficiary coinsurance would be similarly proportionately reduced. For those beneficiaries dually eligible for Medicare and Medicaid, the coinsurance paid for by the beneficiary or state would similarly be reduced.” There is a dearth of data regarding the expected impact on beneficiary cost-sharing should the model move forward. In order to fully comment, there must be thorough analyses of the impact of the model on patient out-of-pocket costs. Beneficiaries should not see their out-of-pocket spending increase, nor should they be confronted with unpredictable bills. This includes premiums, copayments, co-insurance, and all applicable costs that will be the obligation of the patient. Will there be instances in which patients will experience little to no cost sharing?

Patient Inclusion and Feedback

We also believe that competition among treatment options based on quality, outcomes, and costs does not go far enough in supporting and integrating patients as equal partners in their care. There are many factors patients consider when making treatment decisions that include not only financial, but also emotional, social, logistical, and legal considerations, among others. It is vital that this model be routinely informed by patient input from development to implementation to evaluation. The model must meet the needs of patients—and those needs must be defined by patients.

CMS should incorporate a patient, family, and advocate advisory panel for the model to help guide processes, interventions, and policies that impact patients and their care. We would be pleased to provide suggestions for members and serve as a resource to such a panel. Further, the public should be provided with routine updates on the model and be given ample opportunity to regularly engage and comment.

The ANPRM outlined a process to coordinate with the Medicare Beneficiary Ombudsman “to ensure that any Model-related complaints, grievances, or requests for information submitted would be responded to in a timely manner.” There should be a clear, understandable, and official process for interacting with the ombudsman including a timeline for when beneficiaries can expect a response and their options for appeals and other remediation. The monitoring system should ensure close evaluation of beneficiary access and affordability. We applaud the inclusion of real-time data in monitoring efforts. We also appreciate the inclusion of beneficiary surveys to obtain this information and encourage CMS to work with patients and patient advocates on the design and piloting of such surveys.

Quality Measures

The ANPRM states that there will be consideration of quality measures, specifically “patient experience measures, medication management measures, medication adherence, and measures related to access and utilization.” We applaud the inclusion of measures that will identify the full range of impacts on patients affected by the model. Such measures must be objective, comprehensive, and patient-centered.

Conclusion

In conclusion, we appreciate the opportunity to provide comments on this ANPRM. We respect the purpose of ANPRM however, the potential impacts of implementing the IPI model are concerning. There is very limited information regarding the impact on the finances and access to care for patients. A proposed change of this magnitude to our health care and economic systems should include far more detailed and much smaller scale modeling.

We believe that when patients have access to affordable treatments, services, and resources in the health care system, their health and wellbeing will improve. As our comments reflect, any actions taken by HHS and CMS should put the patient at the forefront, protecting and promoting their access to affordable, timely, high-quality, comprehensive health care. Please feel free to call upon us if we can serve as a resource in this pursuit. Elizabeth Franklin, Executive Director of CSC's Cancer Policy Institute can be reached at efranklin@cancersupportcommunity.org or 202.650.5369.

Sincerely,

Cancer Support Community and Friends of the Cancer Policy Institute
Colorectal Cancer Alliance
Academy of Oncology Nurse and Patient Navigators
Association of Oncology Social Work
CancerCare
Fight Colorectal Cancer
FORCE: Facing our Risk of Cancer Empowered
Lungevity Foundation

References

Cancer Support Community. (2017). *CSC letter on HHS blueprint to lower drug prices and reduce out-of-pocket costs*. Retrieved from

https://d2gyb6a32rq744.cloudfront.net/sites/default/files/uploads/policy-and-advocacy/letters-submitted/csc_drug_pricing_comments_final_july_2018_0.pdf

Cancer Support Community. (2016). *CSC on Medicare part B proposed rule*. Retrieved from

https://www.cancersupportcommunity.org/sites/default/files/uploads/policy-and-advocacy/letters-submitted/cms_part_b_proposed_rule_csc_comments_final.pdf

Delgado-Guay, M. O., Ferrer, J., Rieber, A. G., Rhondall, W., Tayjasanant,

S., Ochoa, J...& Bruera, E. (2015). Financial distress and its association

with physical and emotional symptoms and quality of life among advanced cancer patients. *The Oncologist*, 20 (9), 1092-1098.

Fenn, K. M., Evans, S. B., McCorkle, R., DiGiovanna, M. P., Puztai, L.

Sanft, T.,...& Chagpar, A.B. (2014). Impact of financial burden of cancer on survivors' quality of life. *Journal of Oncology Practice*, 10(5), 332-338.

Young, R. C. (2015). Value-based cancer care. *New England Journal of Medicine*, 373, 2593-2595. DOI: 10.1056/NEJMp1508387.

Zafar, S. Y., Peppercorn, J. M., Schrag, D., Taylor, D. H., Goetzinger, A. M.,

Zhong, X., & Abertnethy, A. P. (2013). The financial toxicity of cancer treatment: A pilot study assessing out of pocket expenses and the insured cancer patient's experience. *The Oncologist*, (4), 381-390.