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December 20, 2018

The Honorable Alex Azar
Secretary
Department of Health and Human Services
Attention: CMS-5528-ANPRM
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-5528-ANPRM – Medicare Program; International Pricing Model for Medicare Part B Drugs; Advance Notice of Proposed Rulemaking
83 Fed. Reg. 54546 (October 30, 2018)

Dear Secretary Azar:

The American Cancer Society Cancer Action Network (ACS CAN), appreciates the opportunity to comment on the International Pricing Model (IPI) for Medicare Part B Drugs advance notice of proposed rulemaking (APRM). ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

Approximately 1.7 million new cancer cases are expected to be diagnosed in 2018.[1] Age is one of the most important risk factors for cancer, with one half of cancer cases occurring in people over the age of 65.[2] Thus, cancer and the therapies used to fight the disease have an enormous impact on the Medicare program, given that almost half of all Part B spending on prescription drugs is related to cancer care.[3] Cancer patients and survivors rely on drug therapies for life-saving treatments. Thus, it is paramount that any new payment model must ensure that beneficiaries have access to medically necessary treatments in the setting that is best for them.

Both cancer patients and survivors rely on drug therapies to treat their disease, prevent recurrence and treat side effects. As more innovative therapies become available, we need to make sure that patients who are likely to benefit from these advances can also afford them so that we can achieve the national

[1] American Cancer Society, *Cancer Facts and Figures* 2018, https://www.cancer.org/research/cancer-factsstatistics/all-cancer-facts-figures/cancer-facts-figures-2018.html.
[2] National Cancer Institute, *Age and Cancer Risk*, April 29, 2015, https://www.cancer.gov/about-cancer/causesprevention/risk/age.
[3] Office of the Assistant Secretary for Planning and Evaluation (ASPE). (2016 December). Prescription Drugs: Innovation, Spending, and Patient Access. [Report to Congress]. *U.S. Department of Health and Human Services.*

goal of eliminating death and suffering from cancer. The inherent challenge will be balancing the need to incentivize continued development of new cancer drugs with greater affordability of these therapies.

We applaud the Administration for further examining new ways to tackle the problem of prescription drug affordability. While we understand the document under discussion is an APRM, we note that many of the concepts provided are broad and open to significant and divergent interpretation. We do not believe that the IPI Model, as described in the APRM, provides sufficient details to ensure that beneficiaries – particularly those in active cancer treatment – will have access to the medications needed for their cancer treatment.

We believe that the Model as written could actually make it harder for cancer patients, especially those living in rural areas, to find the right provider to treat their cancer with the right drug. We cannot sacrifice this patient access for program savings that may or may not materialize, based on price-setting processes that no American citizen can control.

Beyond these major issues we also have other concerns and questions highlighted below including:

- *Beneficiary cost-sharing*: We also note the APRM "expects" beneficiary cost-sharing to be the same or lower under the Model, but it is possible that beneficiary cost-sharing could be higher, as discussed in more detail below. We urge CMS to explicitly state that under no circumstances should beneficiary cost-sharing be higher for drugs reimbursed under the Model than under current policy.
- *Geographic considerations*: CMS intends to implement the Model in certain geographic areas. We also note that a beneficiary could experience different cost-sharing depending on whether they receive a drug within the Model or obtain health care outside the Model's geographic area. If contiguous geographic areas are randomly assigned to different payment models, it seemingly would be possible for Medicare beneficiaries to be directed to non-Model areas that offers the greater financial incentive to the provider. This diversionary practice could result in higher cost-sharing for the beneficiary depending on the reimbursement model being used. The beneficiary could also face transportation issues accessing the alternate site of care.
- *Included drugs*: We are concerned that a vast majority of drugs that would be included in the Model are used to treat various types of cancer. Should HHS decide to go forward with this Model, we strongly urge that oncology drugs not be included in the Model, at the very least, until significant guardrails are in place to ensure that beneficiaries maintain timely access to their oncology services. To achieve optimal results, cancer treatments must be provided according to a set schedule. Interruptions to that schedule can lead to negative health outcomes.
- *Beneficiary protections*: As a theoretical matter, a pharmaceutical manufacturer could choose to no longer sell a product in a foreign country included as one of the countries from which international price data is gathered under the IPI Model. If such an instance were to occur, it is unknown what actions CMS would take with regards to future reimbursement of the product. We urge CMS to ensure that beneficiaries have access to medically-appropriate medications if this hypothetical scenario were to materialize.

- *Oncology-specific evaluation*: Oncology drugs represent 42 percent of Part B spending.[4] If this Model were implemented, we strongly urge CMS in its evaluation to conduct specific analysis regarding beneficiary access to oncology care. Included in this analysis should be a determination of the extent to which the IPI Model has resulted in disruptions in beneficiary care and beneficiaries having to get care in higher-cost sites.

III. MODEL CONCEPT DESIGN

A. Model Vendors

1. Testing Alternative to CAP Requirements

The APRM suggests that under the IPI Model, physicians and hospitals would contract with vendors who would supply Medicare Part B drugs. Vendors would have "flexibility to offer a variety of delivery options, including beneficiary-specific prescriptions, pre-ordering approaches such as onsite inventory management solutions and other arrangements that would not require physicians and hospitals to purchase the drugs or face greater buying costs."[5]

The APRM is unclear as to the parameters of the vendors' flexibility in designing and implementing different payment designs. We strongly urge the Centers for Medicare and Medicaid Services (CMS) to promulgate clear requirements on these vendors and their ability to participate in the Model. For example, the APRM lacks clarity on the length of a vendor contract. To the extent that a vendor's contract with a given physician or hospital expires within the Model's evaluation, what mechanisms will be in place to ensure that impacted beneficiaries – especially those with serious conditions like cancer – are still able to access their medically-appropriate Part B covered drugs?

CMS as a party of interest in vendor contracts: The APRM seeks comment on whether CMS should be a party to and/or regulate contracts with vendors. Because of the potential impact on beneficiary access to medically appropriate therapies, ACS CAN strongly urges CMS to ensure that it is a party to contracts between vendors and physicians and hospitals. Absent CMS intervention, there is concern that beneficiaries may not receive their drugs on time and in a manner that ensures the safety of those products. If CMS chooses not to intervene directly in the contract, we strongly urge the Agency to develop detailed rules and regulations regarding these contracts, including clarity regarding the appeal rights of parties should a dispute arise.

2. Eligible Vendors

The APRM notes that in an effort to increase competition, the IPI Model would potentially allow a number of entities – including Group Purchasing Organizations, wholesalers, distributors, specialty pharmacies, individual or groups of physicians and hospitals, manufacturers, Part D sponsors, and/or other entities – to become a vendor provided they meet the qualifications.

While we appreciate CMS' interest in ensuring the IPI Model contains sufficient participation from vendors, we are concerned that allowing too many entities to become vendors may result in unintended

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[4] HHS Office of the Assistant Secretary for Planning and Evaluation, Medicare Part B Drugs: Pricing and Incentives, March 8, 2016, available at https://aspe.hhs.gov/sites/default/files/pdf/187581/PartBDrug.pdf.

[5] 83 Fed. Reg. at 54550.

consequences particularly as it relates to the vendor's ability to be able to refrain from contracting with other entities and/or other vendors. We also note that the APRM expects that all vendors would operate on a national basis, "that is, model vendors potentially would be required to serve all of the selected model geographic areas and supply all included drugs to the physicians and hospitals that enroll with the vendor."[6] While we see the merit in this approach, we question how it would be operationalized given the entities that could be considered vendors. For example, if a local hospital chooses to become a vendor, it is unclear how that hospital could operate as a national vendor. Further, it is unclear whether the hospital would be required to contract with all hospitals within the same geographic area including competitors.

The APRM also suggests that physicians and hospitals would not be required to use only one vendor. While we appreciate the need for flexibility, we note that contracting with multiple vendors would increase the administrative complexity for physicians and hospitals. This complexity may make it more challenging for beneficiaries who encounter problems that would necessitate an appeal.

3. Model Vendor Responsibilities

Possession versus title of drugs. The APRM would require the vendor to "take title to, but not necessarily physical possession of, included drugs."[7] ACS CAN questions how this arrangement will impact the beneficiary. For example, if a problem with the drug develops (i.e., the drug is missing in transit or the method of shipping has compromised the integrity of the drug in some manner), it is unclear whether the physician, vendor, or other party would bear responsibility. The physician and hospital would be handling a product that belongs to another party which raises significant concerns about which party would be at risk for wastage, spoilage or other reasons why the drugs cannot be administered (such as the patient being too ill to receive an infusion once the patient-specific dose is prepared that is unable to be used for another patient). We are concerned that the construct described in the APRM could lead to delayed care for the beneficiary as these issues are resolved between the parties.

Vendor-administered payment arrangements: The APRM would require the vendor to operate vendor-administered payment arrangements, including indication-based pricing. ACS CAN believes that indication-based pricing, if used appropriately, may be suitable in oncology care. Beneficiaries should be prescribed the drug that is expected to result in their best health outcomes. This determination can vary depending on the beneficiary's overall health status (e.g., her/his disease or condition, comorbidities, allergies, etc.) as well as non-health factors (e.g., availability of a caregiver, transportation to and from treatment, financial considerations, etc.). Such determinations are particularly important in oncology care given that potential side-effects of medication can be challenging to manage, and few treatment options may exist. This is why it is imperative that any treatment decision be made through informed decision making so the beneficiary – in consultation with her/his oncologist – can choose the treatment path that best meets her/his needs.

[6] 83 Fed. Reg. at 54551.
[7] Id.

However, the APRM does not define the term "indication-based pricing" and it is important to do so before allowing vendors the opportunity to use this tool. We are concerned when the term focuses too much on the cost of a given treatment and fails to accurately balance cost with the long-term health outcome benefits and quality associated with the treatment. Similarly, the APRM suggests the vendor may be required to operate outcomes-based arrangements. Any outcomes-based risk-sharing agreements would require clearly defined outcomes goals that include patient-desired outcomes.

To the extent that CMS would permit the use of such alternative payment arrangements, we urge CMS to promulgate regulations to establish parameters to not only define the terms, but also provide clarity regarding when such arrangements could – and could not – be used. The development and use of alternative payment arrangements may not be appropriate in all cases.

Discriminatory benefit design: We caution that allowing vendors to implement new payment arrangements – without proper CMS oversight – could potentially result in a discriminatory benefit design. For example, to the extent that CMS would permit the creation of a formulary for Part B drugs and that formulary placed all cancer drugs on the highest formulary tier, such a design could constitute a discriminatory benefit design.[8] We urge CMS to mandate that it have prior approval over any new payment design to ensure that it would not constitute a discriminatory benefit design prior to vendors being permitted to use such tools.

4. Model Vendor Payment

The APRM envisions that physicians and hospitals would pay the vendor for distribution costs and would collect beneficiary cost-sharing, including billing supplemental insurers. The vendor would be responsible for submitting claims to Medicare.

ACS CAN recognizes the benefit of having the point-of-service provider bear responsibility for the beneficiary's cost-sharing, for no other reason than that this is the entity with which the beneficiary has a relationship. However, we are concerned that if there are discrepancies with respect to billing issues, it is unclear from whom the beneficiary would seek clarification (other than to the Medicare Ombudsman, which is discussed in more detail below). Under the Model as envisioned in the APRM, the physician or hospital would likely not have title to the drugs and thus may not be in a position to render assistance to the beneficiary. Requiring the beneficiary to pose billing questions directly to the vendor could lead to confusion for the beneficiary, who more likely than not would be unfamiliar with the role of the vendor.

5. Model Vendor Selection

CMS notes that it does not intend to establish a Model vendor agreement with an entity. CMS is considering imposing conflict of interest requirements and reasons to terminate a Model vendor.

Number of vendors: The APRM envisions that CMS intends to select three or more vendors to participate in each geographic area. The APRM envisions vendors being required to provide all Part B drugs and physicians and hospitals being permitted to contract with one vendor or multiple-vendors.

[8] See Letter from Christopher W. Hansen, President, American Cancer Society Cancer Action Network, to Sylvia Burwell, Secretary, Department of Health and Human Services (Nov. 9, 2015).

If physicians and hospitals contract with only one vendor, then physicians and hospitals would be entering into contracts based on the totality of the contracted services – which means that payment rates for some drugs may be better than for others. This has direct implications for beneficiaries whose cost-sharing for Part B services is set at 20 percent of the total cost of the drug and service.

Geographic issues: While we appreciate CMS' intent to award approximately three vendor contracts per geographic area, it is less clear what happens if there is insufficient participation in an area. If CMS chooses a given geographic area and no vendors are able to fulfill their required obligations under the Model, it is unclear what mechanisms exist to ensure that beneficiaries are able to obtain their drugs in a timely manner.

Termination: Similarly, we are pleased that CMS has given thought to the fact that it may be possible for CMS to terminate a vendor contract. However, we are concerned about how a beneficiary's access to medically necessary treatments are protected in such an eventuality. According to the standard of care, chemotherapy agents must be administered in accordance with a set schedule, and any disruption to that schedule may result in negative health outcomes.

Conflict of interest: We are pleased that CMS is considering including conflict of interest requirements "to ensure that selected model vendors would be able to perform their responsibilities under the model vendor agreement without influence from parties that have a financial interest related to included drugs or participating health care providers."[9] We believe that conflict of interest standards are important to ensure the integrity of the program. The APRM suggests that physicians, hospitals, and pharmaceutical manufacturers would be eligible to participate as a vendor. We note that the conflict of interest requirements may need to be amended to allow these entities to participate, while at the same time ensuring program integrity.

6. Request for Feedback and Information

Bad debt: The APRM requests input on whether physicians and hospitals should receive bad debt payments if beneficiaries fail to satisfy their cost-sharing obligations. Under current policy, only hospitals are partially reimbursed for bad debt.[10] There is no mechanism for physicians to be compensated for bad debt. We urge CMS to provide full or partial compensation for beneficiary's non-payment of cost-sharing as bad debt. However, we are uncertain as to whether the bad debt for drugs would be to the Model vendor or the physician and hospital. Under the Model, physicians and hospitals do not take title to the drug. However, they do collect beneficiary coinsurance. Not stated but implied is that physicians and hospitals would provide that beneficiary coinsurance to the Model vendor (after all, hospitals and physicians could not keep coinsurance payments that do not belong to them). Bad debt reimbursements should be made to the entity that incurs the cost of the bad debt whether it be the physician, hospital or model vendor.

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[9] 83 Fed. Reg. at 54552.

[10] Under Medicare policy, in order to claim a bad debt the provider must establish that the debt is uncollectable and there is no likelihood of recovery anytime in the future. Centers for Medicare and Medicaid Services. Clarification of Medicare bad debt policy related to accounts at a collection agency. MLN Matters No. SE0824 revised.

B. Model Participants, Compensation and Selected Geographic Areas

1. Model Participants

The APRM states that physicians and hospitals within the given geographic area would be mandated to participate in the Model. However, the APRM is silent on how CMS intends to identify providers for purposes of the Model. One option would be to identify providers based on their National Provider Identifier (NPI). While all solo physicians are required to have their own NPI, physicians who are part of a large group practice may use the NPI of the large group practice to bill for the service.

However, to the extent that multiple beneficiaries are receiving care from the same provider, it is possible that a given provider (or group practice) may have locations at one or more sites that could be chosen to participate in the demonstration. If so, it is possible that the provider could divert beneficiaries to different sites of care based on which is more financially advantageous to the provider, which could result in beneficiaries having to drive to further distances to obtain their care. If such instances were to occur, we urge CMS to make clear to the provider that diversionary tactics are not permitted.

2. Model Geographic Areas

The APRM states that the Model would require mandatory participation of physicians and hospital outpatient departments (and potentially other providers and suppliers) in select geographic areas across the U.S. and its territories.

IPI Model Impact: While the APRM does specify which geographic areas would be selected for the IPI Model, the preamble notes that CMS anticipates the selected geographic areas would comprise 50 percent of Medicare Part B spending on separately payable Part B Drugs.[11] We are concerned that the scope of the Model is overly broad, which would impede CMS' ability to respond quickly to any beneficiary access concerns that may arise. If CMS decides to go forward with the Model, we urge that its scope be significantly curtailed.

Contiguous Geographic Areas: The APRM does not specify which geographic areas would be selected for the IPI Model. If contiguous geographic areas are randomly assigned to different payment models, it seemingly would be possible for Medicare beneficiaries to be directed to non-Model areas that offers the greater financial incentive to the provider. This diversionary practice could result in higher cost-sharing for the beneficiary depending on the reimbursement model being used. The beneficiary could also face transportation issues accessing the alternate site of care. We note that some providers operate in multiple states and thus this potential diversionary practice could occur regardless of geographic area chosen.

3. Potential Drug Add-on Payment

The APRM seeks to change the current Part B reimbursement structure from Average Sales Price (ASP) plus 6 percent[12] to a new structure that intends to incentivize physicians "to seek out lower cost drugs

[11] 83 Fed. Reg. at 54553.
[12] The preamble notes that given the impact of sequestration, the actual payment amount to providers is ASP plus 4.3 percent.

for their beneficiaries, reduce inappropriate utilization [and] continue to pay for certain distribution costs."[13] While this goal is laudable, we have some concerns with the proposal, as discussed below.

b. Description of Alternative Add-on Payment Amount

Set payment amount: Currently hospitals and physicians are reimbursed for Part B drugs based on the price of the drug being administered. The APRM states that physicians and hospitals "would be paid a set payment amount per encounter or per month (based on beneficiary panel size) for an administered drug, which would not vary based on the model payment for the drug itself."[14] The APRM's switch to a set payment amount per encounter or per month could pose a significant hardship to oncology practices, particularly small practices who may be more likely to close as a result of this policy.

The APRM suggests that set payment amounts could be based on (1) the class in which the administered drug resides; (2) the physician's specialty; or (3) the physician's practice. We caution that each of these potential options could create unintended consequences. For example, setting payment amount based on the class of drug could result in significant over- or under-reimbursement if there are many drugs within a given class. Tying reimbursement to physician's specialty (or subspecialty) unfairly advantages highly specialized physicians, especially specialties using expensive drugs without alternatives. ACS CAN believes that any payment model should incentivize beneficiaries to receive the right care, at the right time, and in the right setting.

The add-on payment could be further confusing to the beneficiary. Under current policy, the beneficiary pays coinsurance for the drug based on the ASP+6 percent pricing methodology. Under the Model, there would be two separate coinsurances where now there is one. The beneficiary would pay coinsurance on the Part B drug and separately for the add-on payment. It may be unclear to the beneficiary what service is being furnished for the add-on payment as it is a payment solely for the administrative overhead of the physician or hospital. We can think of no other circumstance where the beneficiary would be charged a fee solely for the administrative overhead associated with maintaining a pharmacy within a hospital or physician office.

Bonus pool: To incentivize reduced utilization, the APRM is considering creating a "bonus pool" which is envisioned to be available to prescribers who prescribe lower-cost drugs or practice evidence-based utilization. While we are supportive of the use of lower-cost drugs, where appropriate, and evidence-based utilization, where appropriate, we are concerned that a beneficiary's medical needs must be the first priority for choice of Part B drug and that policies incenting physicians based on financial considerations could result in significant unintended consequences.

It is unclear whether the bonus pool would be available to physicians who engage in both the prescribing of lower-cost drugs and who practice evidence-based utilization. We note that these are two different objectives. A lower-cost drug may not be the most appropriate drug for an individual using evidence-based prescribing. We also note that in cancer care, it can be medically-appropriate for providers to veer from an evidence-based guideline if warranted by the individual's cancer type and stage. Additionally, as cancer treatment becomes more personalized based on gene mutations and

[13] 83 Fed. Reg. at 54552.
[14] 83 Fed. Reg. at 54553.

other factors, patients and doctors may not have the ability to choose between drug regimens. If there is only one drug that will properly treat the patient, and that drug is disincentivized through this policy, will the provider be similarly disincentivized to treat that patient? And what access barriers will this cause?

C. Included Drugs

2. Potential Included Drugs

According to the preamble, in Years 1 and 2 of the potential IPI Model, CMS would include single source drugs, biologics, biosimilars, and multiple source drugs with a single manufacturer that they identify from reliable sources of international pricing data. In Years 3, 4, and 5 CMS would broaden the scope to include more single source and biologic drugs as more sources of international data become known.

We are concerned that a vast majority of the drugs that would be subject to the Model are used to treat various types of cancer. The Department of Health and Human Services (HHS) report[15] cited in the APRM overwhelmingly contains cancer drugs or cancer supportive drugs.

Should HHS decide to go forward with this Model, we strongly urge that oncology drugs not be included in the Model, at the very least, until significant guardrails are in place to ensure that beneficiaries maintain timely access to their oncology services. To achieve optimal results, cancer treatments must be provided according to a set schedule. Interruptions to that schedule can lead to negative health outcomes. Additionally, as discussed above, we have concerns about how this Model will impact physician practices. It is possible that implementation of this Model could result in some physician practices closing and/or further consolidation among existing practices. Such outcomes would be onerous on cancer patients – particularly those living in rural areas – because they would likely have to drive further distances to access their cancer care. Transportation issues already represent a significant barrier for cancer patients.

3. Potential Excluded Drugs

The APRM would exclude drugs that are identified by the Food and Drug Administration (FDA) to be in short supply. ACS CAN is pleased that CMS has chosen to exempt drugs that are in short supply and recognized the need to provide a safeguard to preserve access to these drugs. We note, however, that there are many different factors that cause drugs to be in short supply and encourage CMS and FDA to closely monitor any potential effects of the demonstration project on drug supplies. We encourage CMS to work with the FDA and other stakeholders to develop a policy to address any potential supply shortages and develop a mechanism to exclude drugs if they appear to be coming short supply.

4. Requests for Feedback and Information

Drug labeling: The APRM seeks feedback on whether to determine the inclusion of drugs based on FDA-approved indications (on-label) only or whether CMS should consider off-label and on-label use (if supported by clinical guidelines and/or compendia). We strongly urge CMS to consider both the on-label

[15] Assistant Secretary for Planning and Evaluation (ASPE). Comparison of U.S. and international prices for top Medicare Part B drugs by total expenditures. Oct. 25, 2018. Available at https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures.

and off-label use of drugs. Some cancer patients are appropriately prescribed off-label use drugs to treat their disease, a practice that is especially common with rarer cancers, or with older generic drugs whose labels have become out of date.

D. Model Payment Methodology for Vendor Supplied Drugs

1. Calculating the Model's Medicare Part B Drug Payment

The APRM is considering an alternative payment for included drugs, based on an index of international prices. This target price would be phased in over time, as follows:

Year	Percentage of ASP	Percentage of Target Price
1	80%	20%
2	60%	40%
3	40%	60%
4	20%	80%
5	0%	100%

We are concerned that the phased-in approach may be too ambitious, particularly in light of the Model's potential negative impact on oncology care. Cancer patients have no control over what a foreign government or other entity pays for the drug they need, yet their access to life-saving treatments may be impacted by a process that they are unaware of and powerless in.

Also, the ANPRM suggests an aggressive timeline for implementation. CMS suggests a proposed rule in the Spring of 2019 with implementation by April 2020. Such an aggressive timeline does not seem viable given that CMS must allow 60 days for public comment, time to do a final rule, solicitation of vendors, enrollment of vendors, enrollment of physicians and hospitals, negotiating and renegotiating of contracts (both between hospitals, physicians and vendors and hospitals, physicians and their current drug suppliers) and all of the systems, claims processing and other changes required to make payment under the Model.

5. Establishing Model Payments for New Drugs Entering the Market

The APRM acknowledges that there could be some time lag in capturing international sales information for newly approved and marketed Part B drugs. In the some cases, the FDA approves drugs at a faster rate compared to approval rates in other countries.[16] We would also note that cancer mortality rates in the United Kingdom are higher relative to the U.S., in part due to limited access to state-of-the-art

[16] Zeukeng MJ, Seoane-Vazquez E, Bonnabry P. A comparison of new drugs approved by the FDA, the EMA, and Swissmedic: an assessment of the international harmonization of drugs. Eur J Clin Pharmacol 2018 Jun;74(6):811-818. doi: 10:1007/s00228-018-2431-7. Epub 2018 Fed 22 (finding that of the drugs studies 66.4 percent were first approved by the FDA).

treatments.[17] If CMS were to proceed with implementing this proposal, we would urge policies to be enacted to ensure that beneficiaries have timely access to medically-appropriate drugs, without having to incur significant waiting periods while foreign regulators complete their analysis. Given the rapid pace of innovation in cancer drugs, we are concerned that such lag times would harm cancer patients.

E. Potential Foreign Market Considerations

International labeling: We note that while prescription drugs may be approved in different countries, the labeled indication may differ depending upon the regulatory pathway under which the sponsor sought approval. A drug's approved indication has a bearing on the price under which the product will be reimbursed. Comparing a drug's reimbursement from one country to another fails to take this into account. If CMS decides to proceed with this Model, it should thoroughly examine the extent to which a drug's indicated label may impact a foreign price of the drug and how to account for such discrepancies within the Model.

Beneficiary protections: As a theoretical matter, a pharmaceutical manufacturer could choose to no longer sell a product in a foreign country included as one of the countries from which international price data is gathered under the IPI Model. If such an instance were to occur, it is unknown what actions CMS would take with regards to future reimbursement of the product. We urge CMS to ensure that beneficiaries have access to medically-appropriate medications if this hypothetical scenario were to materialize.

F. Beneficiary Impact and Model Monitoring

1. Impact on beneficiary cost-sharing

The APRM states that CMS would expect beneficiary cost-sharing for included drugs under the Model to be the same or lower than non-Model cost-sharing. Beneficiary cost-sharing would remain at 20 percent.

It is unclear whether beneficiary cost-sharing would continue to be pegged to the CMS reimbursement rate, or to the Model vendor's negotiated price. If beneficiary cost-sharing is tied to the CMS reimbursement rate, the beneficiary cost-sharing would be artificially high given that CMS anticipates greater savings to be realized through the use of Model vendors. If the beneficiary cost-sharing is tied to the Model vendor's negotiated price, then this amount can vary significantly depending on the vendor used by the physician or hospital at the time of administration of the drug.

We also note the APRM's wording related to beneficiary cost-sharing, notably that it "would expect" beneficiary cost-sharing to be the same or lower.[18] This raises the possibility that beneficiary cost-sharing could be higher under the Model. If the stated goal of the Model is "to lower drug costs for Medicare beneficiaries,"[19] then CMS should explicitly state that under no circumstances should beneficiary cost-sharing be higher for drugs reimbursed under the Model than under current policy. We

[17] UK falling behind on cancer care. The Lancet. Editorial. July 4, 2009. Doi:https://doi.org/10.1016/s0140-6736(09)61214-9.
[18] 83 Fed. Reg. at 54558.
[19] 83 Fed. Reg. at 54547.

also note that a beneficiary could experience different cost-sharing for a drug when they receive a drug within the Model and obtain health care outside the Model's geographic area.

2. Medicare Ombudsman

The APRM indicated its intention to coordinate with the Medicare Beneficiary Ombudsman to ensure that any Model-related beneficiary complaints would be responded to in a timely manner.

While we support the Medicare Ombudsman's role, we are concerned that simply coordinating with that office will serve as insufficient beneficiary protection, particularly given the Ombudsman's existing charges and limited resources. New payment models often bring unintended consequences, and while these consequences are not always known, CMS should expect that issues may arise and plan accordingly. If CMS intends to utilize the Medicare Ombudsman as the point of contact for managing complaints, the office will need significantly more resources to respond to beneficiaries in a timely manner.

We are disappointed that the APRM does not contain information regarding any beneficiary education and outreach – or really beneficiary-focused information of any kind – regarding the existence of the Model and potential beneficiary implications. We strongly urge that if CMS decides to proceed with this Model, that it devote significant resources in the development and implementation of beneficiary educational materials. Given the complexity of the issues, we urge that any communication to beneficiaries be field tested – both with beneficiaries as well as beneficiary advocate groups – to determine the most appropriate way to communicate information to beneficiaries.

3. Monitoring

The APRM notes that CMS intends to "implement a monitoring program for the IPI Model to ensure the model is meeting the needs of Medicare beneficiaries, health care providers, and the Medicare program."[20] Other than noting its intention to use real-time data to identify problems, the APRM lacks specific information on how CMS intends to monitor this new Model.

Oncology-specific evaluation: Oncology drugs represent 42 percent of Part B spending.[21] If this Model were implemented, we strongly urge CMS in its evaluation to conduct specific analysis regarding beneficiary access to oncology care. Included in this analysis should be a determination of the extent to which the IPI Model has resulted in disruptions in beneficiary care and beneficiaries having to get care in higher-cost sites.

Additional beneficiary safeguards: As discussed in more detail above, ACS CAN is deeply concerned that the IPI Model could hinder beneficiary access to medically necessary cancer treatments. We note that CMS has indicated it has the ability to access in real time claims data to evaluate a new payment model. We strongly urge CMS to engage this evaluation tool to ensure that beneficiaries' access to oncology medications is not hindered – including monitoring the extent to which beneficiaries are unable to access their oncology services in a timely manner. Prior to the launch of any new payment model CMS should develop a contingency plan to be triggered in the event that the real-time evaluation reveals

[20] 83 Fed. Reg. at 54558.

[21] HHS Office of the Assistant Secretary for Planning and Evaluation, Medicare Part B Drugs: Pricing and Incentives, March 8, 2016, available at https://aspe.hhs.gov/sites/default/files/pdf/187581/PartBDrug.pdf.

beneficiary access problems. Such a plan must clearly identify the action steps CMS will implement in the event that access problems are identified. We strongly urge CMS to develop this plan and solicit stakeholder comments through an open and transparent comment process.

Periodic evaluations: As part of its evaluation process, we urge CMS to conduct evaluations of the IPI Model on a yearly basis. The results of these evaluations should be publicly available shortly after their completion so that interested parties can obtain a better understanding of any concerns or problems that may arise. Releasing an evaluation at the conclusion of the Model – particularly given the Model's five-year scope – would be too long of a delay.

Ensuring quality of care: We also note that the APRM provides scant information on how CMS intends to ensure that the quality of care for Medicare beneficiaries is preserved or enhanced. Improving quality should be one of the basic outcomes of a Center for Medicare and Medicaid Innovation (CMMI demonstration. In fact, CMMI was created to "test innovative payment and service delivery models to reduce program expenditures … while preserving or enhancing the quality of care furnished to individuals"[22] who receive Medicare, Medicaid, or Children's Health Insurance benefits. We believe improved quality for the patient is as important as program savings. Therefore, if this Model goes forward we urge CMS to clarify how it will ensure that the quality of care provided to beneficiaries is maintained or improved under the IPI Model.

G. Interactions with Other Models

Currently, CMMI has a number of other models currently being implemented. One of them is the Oncology Care Model (OCM). Implementation of the IPI Model would have a significant impact on participants in the OCM. According to recent analysis, 21 percent of cancer patients enrolled in fee-for-service Medicare were treated by an oncology practice that was participating in the OCM.[23] Implementing a new payment structure – particularly one as profound as that contemplated in the IPI – would significantly impact the evaluation of the OCM. We would urge CMS to strongly consider allowing the OCM to continue as originally proposed and CMS evaluate how the OCM model would be affected where a physician be a participant in both models.

In addition, CMS should consider that there could be unintended consequences within the U.S. based on the proposed Model. The reduced prices within the Model could be potentially offset by increases in drug prices outside of the Model for both Medicare and non-Medicare payers. The Model also has the potential to increase international prices and does not account for differences in drug coverage policies in these countries that result from payment changes.

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[22] 42 U.S.C. § 1315a(a)(1).

[23] Macher D, Kane R, Brow M. More than 1 in 5 Medicare cancer patient receive care from Oncology Care Model doctors. Avalere Health. May 30, 2018. Available at https://avalere.com/press-releases/more-than-1-in-5-medicare-cancer-patients-receive-care-from-doctors-participating-in-the-oncology-care-model.

CONCLUSION

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the International Pricing Model (IPI) for Medicare Part B Drugs advance notice of proposed rulemaking. Ultimately, a number of major questions remain regarding the operationalization of the IPI Model.

As discussed previously, we have significant concerns with the IPI Model as outlined in the APRM, which as written could actually make it harder for cancer patients to access the right provider to treat their cancer with the right drug. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org or 202-585-3261.

Sincerely,

Christopher W. Hansen
President
American Cancer Society Cancer Action Network