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CMS Drug Price Proposal Would Harm Patients, Providers

By **Justin Linder** (November 1, 2018, 1:04 PM EDT)

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In a speech delivered at the U.S. Department of Health and Human Services on Oct. 25, President Donald Trump unveiled a proposal he touted as a "revolutionary" step to counter "global freeloading" by foreign nations.[1] The International Pricing Index Model, or IPI Model, referenced by the president and detailed in an advanced notice of proposed rule-making, or ANPR, published Oct. 30 by the Centers for Medicare & Medicaid Services[2], however, bears little resemblance to the president's soaring rhetoric and promptly came under intense fire from a diverse cross-section of industry stakeholders.

According to the ANPR, the model would be implemented under the authority conveyed to the CMS Center for Medicare and Medicaid Innovation to develop novel health care demonstration projects, pursuant to the Affordable Care Act.[3] The IPI Model would be limited to certain geographic areas and would operate from the Spring of 2020 to the Spring of 2025.[4]

Physicians and hospitals residing in target geographic areas would be mandated to participate in the IPI Model, which would supplant the current "buy and bill" structure for Medicare Part B administration and reimbursement by interposing a new middleman, referred to in the ANPR as the "model vendor," between pharmaceutical manufacturers and wholesalers, on the one hand, and hospitals and physicians that administer drugs in an outpatient setting, on the other.

Participating providers would be required under the proposal to obtain Part B medications from one or more model vendors. CMS contends that these new drug supply chain middlemen would "introduce greater competition into the acquisition process for separately payable Part B drugs."[5]

The model vendors, chosen by CMS under a competitive selection process, would negotiate with drug manufacturers for pricing concessions, purchase drugs from manufacturers, take title to the drugs and arrange for distribution of drugs to physicians and hospitals. Physicians and hospitals, in turn, "would pay the model vendor for distribution costs and would collect beneficiary cost sharing, including billing supplemental insurers."[6]

Under the IPI Model, model vendors would directly submit claims to Medicare for reimbursement of Part B drugs administered to a beneficiary. CMS proposes to utilize drug pricing data from foreign countries with socialized health programs to set the reimbursement payment for model vendors, which would be updated quarterly.[7]

Physicians and hospitals participating in the IPI Model would continue to receive a Part B payment for drug administration. However, the current average sales price, or ASP, plus 6 percent add-on reimbursement for separately payable Part B drugs would be eliminated and substituted with a substantially reduced payment.

CMS states in the ANPR that it is considering a variety of potential replacements to the ASP plus 6 percent add-on payment. One such alternative would be to base payments to physicians and hospitals on 6 percent of the Part B drug's ASP and pay "a set payment amount per encounter per month ... which would not vary based on the model payment for the drug itself."[8]

According to CMS, the goal of this new, fixed add-on payment to physicians and hospitals is to "create an incentive to encourage appropriate drug utilization; remove the incentive to prescribe higher-cost drugs; and create incentives to prescribe lower-cost drugs in order to reduce beneficiary cost sharing."[9]

The Community Oncology Alliance, representing oncologists that administer costly infused Part B drugs, took umbrage at CMS' rationale for flat add-on payments, countering that the "notion that physicians, and oncologists in particular, practice medicine driven by financial incentives is not only false, but also highly offensive."[10]

Though CMS characterizes the proposed model as an improvement over the "buy and bill" system, the addition of another middleman to the drug supply chain is likely to complicate logistical burdens related to billing, reimbursement and distribution.

The model would necessitate at least two distinct claim submissions to CMS, one from the model vendor for drug reimbursement and possibly an administrative fee and one claim from the provider for drug administration and an add-on payment. The provider also would retain responsibility for collecting drug cost sharing from the beneficiary, though there is little explanation in the ANPR as to how such a mechanism would be operationalized.

To ensure that model vendor claims for reimbursement are valid, it would be necessary for CMS to reconcile model vendor and provider claims[11], complicating program integrity efforts and elevating the potential for Medicare fraud.

It also bears emphasis that the proposed model would apply solely to drugs administered to Medicare Part B fee for service beneficiaries. Accordingly, it would have no direct impact on Medicare Advantage plans, the Medicare Part D program, Medicaid beneficiaries, commercially insured patients, or self-pay consumers.

However, the most consequential flaw undermining the IPI Model is the absence of any incentive for pharmaceutical manufacturers to align their prices with the reduced international index price used by CMS to benchmark reimbursement to model vendors. The entire proposal is premised on the entry into the market of model vendors, whose negotiation power supposedly would enable them to extract price concessions of a magnitude sufficient to generate a margin between the model vendors' cost and reimbursement by CMS under the reduced international pricing index. If model vendors are unable to secure from manufacturers the deep discounts necessary to ensure a profit for themselves, the IPI Model would fail, reducing access to critical medications and increasing burdens on beneficiaries, physicians and hospitals.

Rather than encouraging manufacturers to offer deeply discounted pricing to model vendors, the proposal's current incarnation would perversely disincentivize pharmaceutical companies from extending disproportionately lower prices to model vendors. As acknowledged by CMS, offering sizable concessions to the middlemen would result in reductions to Medicaid best price and average manufacturer price computations and consequently require manufacturers to extend lower prices (or higher rebates) in

connection with other governmental programs, such as 340B and Medicaid.[11]

Indeed, CMS in the ANPR implicitly acknowledges a number of shortcomings in the proposal, inviting commenters to respond to the following queries:

- "What would be the ability of the potential types of entities that could be model vendors to negotiate for drug prices that would be at or below the IPI Model payment?"[13]
- "Are there processes that model vendors could use to increase their price negotiation leverage with manufacturers and lower their potential loss exposure without increasing burdens on beneficiaries, physicians, and hospital?"[14]

Inherent within the two foregoing questions is CMS' recognition that success of the IPI Model depends almost entirely on model vendors' ability to negotiate a spread between the purchase cost of the drug and the IPI Model reimbursement. CMS implicitly concedes that the failure of model vendors to extract a profit could produce "increase[ed] burdens on beneficiaries, physicians and hospitals ..."[15]

CMS similarly acknowledges the logistical challenges imposed by the convoluted nature of the model, asking commenters: "Are there unsurmountable challenges related to physicians and hospitals paying for distribution costs and to continue to collect beneficiary cost-sharing, including billing supplemental insurers?"[16]

In an Oct. 25 statement condemning the proposal, the Pharmaceutical Research and Manufacturers of America, or PhRMA, succinctly articulated the harm the model would visit upon patients and physicians, observing: "The administration's proposal will ... hinder patient access by severely altering the market-based Medicare Part B program by reducing physician reimbursement and inserting middlemen between patients and their physicians."[17] PhRMA further objected that: "The administration is imposing foreign price controls from countries with socialized health care systems that deny their citizens access and discourage innovation."[18]

CMS is assured to receive a flood of comments from a range of stakeholders before the comment period for the ANPR closes on Dec. 31, 2018. In light of the deficiencies and ambiguities inherent in the IPI Model as currently constituted, coupled with the intense opposition among diverse stakeholders, there is a strong likelihood that the IPI Model will be extensively modified before proceeding to the next stage of the rule-making process, assuming it moves forward at all.

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[1] Paige Winfield Cunningham & Felicia Sonmez, Trump Says He's Taking 'Revolutionary' Action to Lower Drug Prices, Wash. Post, Oct. 25, 2018.

[2] Medicare Program; International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (Oct. 30, 2018).

[3] 83 Fed. Reg. at 54547.

[4] Id.

[5] Id.

[6] 83 Fed. Reg. at 54551.

[7] See 83 Fed. Reg. at 54557.

[8] 83 Fed. Reg. at 54553-54.

[9] 83 Fed. Reg. at 54553.

[10] Press Release, Community Oncology Alliance Statement on Trump Administration's Part B Payment Model Proposal (Oct. 25, 2018), available at https://globenewswire.com/news-release/2018/10/26/1627613/0/en/Community-Oncology-Alliance-Statement-on-Trump-Administration-s-Part-B-Payment-Model-Proposal.html.

[11] 83 Fed. Reg. at 54551.

[12] See 83 Fed. Reg. at 54558-59.

[13] 83 Fed. Reg. at 54552.

[14] Id.

[15] See id.

[16] Id.

[17] Press Release, PhRMA Statement on HHS Speech and Part B Proposal (Oct. 25, 2018), available at https://www.phrma.org/press-release/phrma-statement-on-hhs-speech-and-part-b-proposal.

[18] Id.