The International Pricing Index Model's Far-Reaching Economic Costs Must be Fully Considered by the Centers for Medicare & Medicaid Services

Under Executive Order (EO) 12866, federal agencies must carefully assess costs and benefits of regulations and alternative approaches.[i] For "significant regulatory actions," agencies must provide the Office of Management and Budget (OMB) with more detailed information including an assessment and underlying analysis of the full range of potential benefits and costs of a regulation. This includes costs imposed on individuals and organizations in order to comply with a regulation, and any adverse effects on the "efficient functioning" of the economy and private markets.[ii] The International Pricing Index (IPI) model, as described in the Advance Notice of Proposed Rulemaking (ANPRM) published by Centers for Medicare & Medicaid Services (CMS), is a significant regulatory action that would have far-reaching and potentially unintended effects across a number of key stakeholders in health care.[iii] These include imposing significant new operational, administrative, financial, and infrastructure burdens on providers, reduced incentives for biopharmaceutical innovation, and reduced market competitiveness and increased health care costs. OMB should ensure that CMS has accurately assessed the full range of impacts of the IPI before moving forward with a proposed rule.

1) CMS must provide an assessment that considers the financial impact and burden on providers and other stakeholders in complying with the IPI model.[iv]

By establishing a mandatory requirement for providers to rely on new third-party vendors to obtain physician-administered drugs, rather than purchasing them directly, the IPI model as described in the ANPRM would impose significant compliance burdens on providers and holds potential for creating significant new costs to the health system. OMB should ensure that CMS has identified and provided estimates of the full range of these substantial new costs under the IPI model.

Additional supply chain and provider costs under IPI are so substantial that some key stakeholders have expressed concern that these costs would outweigh potential savings:

> "These administrative costs are not currently a part of the system for accessing Part B-covered drugs and will reduce the impact of reductions in price from the current reimbursement amount of the ASP+6. The IPI model could result in higher net drug costs overall due to increased drug distribution costs and higher administrative costs for providers and payers."[v]
>
> - Cigna, December 21, 2018, Comments on IPI ANPRM

> "…We believe the investments required to comply with the proposed updated [CAP] program design would likely eliminate any potential savings to the Medicare program and make distributor participation highly unlikely."[vi]
>
> - AmerisourceBergen, December 20, 2018, Comments on IPI ANPRM

A range of added costs to providers and the health system have been identified in stakeholder comments to CMS on the ANPRM, and include:

a) The cost to providers of managing a separate, bifurcated inventory of drugs for use on patients with Medicare versus those with other forms of insurance

Under the current "buy and bill" supply chain for physician-administered drugs, physicians negotiate purchase of their entire inventory of physician-administered drugs from manufacturers or wholesalers and these purchases do not distinguish between the type of insurance the physician will bill when the drug is administered. By requiring physicians to use vendors just for acquisition of drugs that will be billed only to Medicare, it will require physicians to invest in significant new administrative and IT capacity to manage and track drugs to be used on Medicare patients versus medicines used for patients with other types of insurance. Physicians will also face substantially increased regulatory uncertainty in making these investments because the IPI is a demonstration and providers have no way of knowing whether the policy will be discontinued, making useless the large new administrative and IT investments required to comply with IPI.

> "Hospitals are concerned that the IPI model could greatly increase their regulatory and operational burden and costs."[vii]
>
> - American Hospital Association, December 27, 2018, Comments on IPI ANPRM

> "We are concerned the potential payment model will increase physician and hospital operating costs." This includes costs related to: "tracking separate inventory, billing compliance, vendor negotiations, managing patient privacy concerns"[viii]
>
> - Mayo Clinic, December 31, 2018, Comments on IPI ANPRM

> "This proposal also raises significant concerns related to operational feasibility and administrative burden. The vendor-led model has the potential to significantly disrupt provider distribution systems, which, at best, would be expensive and time consuming and, at worst, could cause delay in getting drugs to patients if the vendor also serves as the distributor."[ix]
>
> - Alliance of Dedicated Cancer Centers, December 31, 2018, Comments on IPI ANPRM

> "The addition of the "model vendor" would come with added billing requirements, a need to restructure a large portion of each hospital's drug distribution workflow and less control for hospitals over their own drug inventory. To decrease diversion risk, hospitals would also have to separately store multiple inventories, a task that would be especially costly and difficult for the small, rural members of our system."[x]
>
> - MaineHealth, December 31, 2018, Comments on IPI ANPRM

b) <u>Additional cost burdens and inefficiencies created by IPI</u>

Stakeholders have identified a range of other costs and inefficiencies for the providers, patients, Medicare contractors, and the health system overall, as a result of the IPI model as described in the ANPRM. These include new fees imposed on providers, increased drug wastage, and new claims adjudication and appeals burdens.

> "KHA is also concerned that CMS' proposed model could create incentives for vendors to add distribution or other fees to hospitals, effectively raising the cost of drugs to providers. We encourage CMS to establish guardrails to protect hospitals from fees or restrictive utilization management policies that could be created through this new model."[xi]
>
> – Kansas Hospital Association, December 27, 2019, Comments on IPI ANPRM

> IPI vendors "would have incomplete information for [Medicare contractors] to adjudicate Medicare Part B claims in accordance with federal law" because the "vendors do not diagnose

or treat patients and would not be privy to patients' diagnosis codes. Systems would need to be put in place to flow such patient diagnoses from treating providers to" IPI vendors and/or Medicare contractors. "Again, such systems do not exist today in any context."[xii]

-Healthcare Distribution Alliance, December 31, 2018, Comments on IPI ANPRM

"We caution CMS that the way in which drug inventory is managed and changed by this model could substantially increase the amount of drug wasted and cost of overhead management…This possible unintended consequence must be factors into costs and/or reimbursements to model participants."[xiii]

– American College of Rheumatology, (no date provided), Comments on IPI ANPRM

"Greater waste: if multi-packs and multi-dose vials are used by [IPI vendors], it would increase drug wastage because physicians would not be able to use the vials for other patients."[xiv]

-Amerisource Bergen, December 20, 2018, Comments on IPI ANPRM

2) CMS must provide an assessment of the IPI model's potential costs to smaller providers, and costs due to increased provider consolidation and reduced market competition.[xv]

The IPI model as described in the ANPRM could impact providers across the entire U.S. (within and outside of the "model").[xvi] As noted by many stakeholders, these burdens would be substantial. Providers who are not able to absorb these burdens and reimbursement changes (e.g., smaller physician practices and smaller rural health providers) would likely close or shift services to higher-cost hospital settings. By driving provider consolidation and shifts to more costly sites of service, the IPI model has the potential to increase costs for patients and payers. CMS must assess these likely costs before moving forward with a proposed rule.

a) <u>Other stakeholders also expressed serious concerns about how the model has the potential to impact small and rural practices and potential for shifts to higher-cost care settings</u>

"Faced with the prospect of financial loss, many physician practices will shift infusion volume and other drug administration services to the hospital setting."[xvii]

- Trinity Health, December 31, 2018, Comments on IPI ANPRM

"We are concerned that the administrative difficulties that would be associated with utilizing vendors could lead some practices to lose the ability to provide infusion services."[xviii]

- American College of Rheumatology, Comments on IPI ANPRM

"The AAN is concerned that this model as proposed will have a disproportionate and unreasonable impact on neurology practices with infusion centers…If Part B reimbursement for these medications is further reduced, providers will no longer be able to sustain their infusion centers for Medicare patients and will have no choice but to refer them to their nearest available hospital, greatly increasing costs and further burdening hospital facilities."[xix]

- American Academy of Neurology, December 5, 2018, Comments on IPI ANPRM

"Mandatory participation in a demonstration may jeopardize the sustainability of physician practices…"[xx]

- National Infusion Center Association, December 28, 2018, Comments on IPI ANPRM

3) CMS must provide an accurate assessment of potential costs and negative impacts in the private-market areas of innovation and research & development (R&D).[xxi]

HHS has publicly stated that the IPI would cut Medicare Part B payments for drugs by $50 billion over 8 years and appears to be basing its estimates of a relatively small impact on biopharmaceutical research and development on this number. [xxii]

However, this estimate overlooks the financial impact of IPI on Medicare spending outside the model, as well as the financial impact on other federal programs and the commercial market.

Recently released analysis reinforces this point and indicates that the impact is likely to be much larger, with some manufacturers essentially forced to cut R&D by up to 23%,[xxiii] particularly for manufacturers engaged in research on cutting-edge physician-administered medicines. The U.S. Department of Commerce has found that international reference pricing and other price controls in foreign countries already suppress worldwide private R&D investment by 11-16% annually, leading to fewer new medicines launched each year.[xxiv]

Further, the IPI targets deep cuts to a very small segment of high-risk research and development, sending a strong negative signal for additional investment in this area. The effects of the IPI Model for individual future products will be highly variable and difficult to predict, particularly for newly launched products, creating uncertainty that could further chill R&D in the area of physician-administered medicines.

This potentially large impact on R&D will have downstream effects in the R&D ecosystem, most notably potentially impacting U.S. jobs and creating uncertainty in the venture capital and investment space. In a survey of PhRMA members, 66 percent of companies expressed concern about near-term job cuts and potential closure of facilities and abandonment of expansion plans if the model were to be implemented.

a) <u>Stakeholders have expressed serious concerns about the impact on R&D in public comments submitted on the ANPRM</u>

"Importing price controls will undermine this system by basing U.S. prices on the prices of socialized foreign healthcare systems. This will inevitably suppress innovation and harm American competitiveness."[xxv]

- Americans for Tax Reform, November 28, 2018, Comments on IPI ANPRM

"With more than half of the world's future medicines in development here in the United States, a Part B shift to the proposed IPI sends a strong signal that future treatments should be more limited for patients and controlled by the government, thereby curtailing the incentive for the development of new cures."[xxvi]

- National Association of Manufacturers, December 31, 2018, Comments on IPI ANPRM

"Finally, an additional, longer-term concern is the model's potential impact on pharmaceutical research and development (R&D). We depend on drug discovery to drive improved therapies and generate cures. This is where hope lives. We are concerned that investment in drug research will diminish in the wake of financial cuts to the pharmaceutical industry - cuts that

may stifle their investment in complicated and risky drug trials, with potentially fewer drug discoveries in the future."[xxvii]

- Hackensack Meridian Health, December 21, 2018, Comments on IPI ANPRM

"In addition to impeding competition, the program's costs to America's research and development of lifesaving treatments and cures far outweigh any potential benefits. At a time when the U.S. biopharmaceutical industry leads the world in the development of innovative medicines, adopting foreign price controls would discourage investment in R&D and hurt America's intellectual property system."[xxviii]

- Hispanic Leadership Fund, December 21, 2018, Comments on IPI ANPRM

"Because of this essential link between drug prices, industry revenues, and industry R&D, drug price controls contribute to lessened levels of less life-sciences innovation. In fact, one reason why Europe has produced fewer biopharmaceutical innovations than the United States is because European Union (EU) price controls mean its biopharmaceutical firms have not generated as much profit (which can be reinvested in R&D) as U.S. ones."[xxix]

- Information Technology and Innovation Foundation, December 31, 2018, Comments on IPI ANPRM

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[i] Exec. Order No. 12866. 58 FR 51735 (1993).

[ii] Id. Required under Executive Order 12866, Section 6(a)(3)(C)(ii), a regulating agency must provide: "An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs."[ii]

[iii] Centers for Medicare & Medicaid Services, International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (Oct. 30, 2018).

[iv] Exec. Order No. 12866. 58 FR 51735 (1993) (Regulatory Principle 5: When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.)

[v] Cigna, Re: CMS-5528-ANPRM; Medicare Program; International Pricing Index Model for Medicare Part B Drugs https://www.regulations.gov/document?D=CMS-2018-0132-1247

[vi] AmerisourceBergen. Comments on IPI ANPRM. https://www.regulations.gov/document?D=CMS-2018-0132-2662

[vii] American Hospital Association. RE: CMS-5528-ANPRM, Medicare Program; International Pricing Index Model for Medicare Part B Drugs; Advance Notice of Proposed Rulemaking with Comment (Vol. 83, No. 210), October 30, 2018. https://www.regulations.gov/document?D=CMS-2018-0132-2674

[viii] Mayo Clinic. Re: File Code CMS-5528-ANPRM: Medicare Program; International Pricing Index Model for Medicare Part B Drugs (Federal Register Vol. 83, No. 210). https://www.regulations.gov/document?D=CMS-2018-0132-2678

[ix] Alliance of Dedicated Cancer Centers. Re: Medicare Program; International Pricing Index Model for Medicare Part B Drugs, CMS–5528–ANPRMhttps://www.regulations.gov/document?D=CMS-2018-0132-1197

[x] MaineHealth. RE: CMS-5528-ANPRM, Medicare Program; International Pricing Index Model for Medicare Part B Drugs; Advance Notice of Proposed Rulemaking with Comment (Vol. 83, No. 210), October 30, 2018. https://www.regulations.gov/document?D=CMS-2018-0132-0964

[xi] Kansas Hospital Association. RE: CMS-5528-ANPRM, Medicare Program; International Pricing Index Model for Medicare Part B Drugs; Advance Notice of Proposed Rulemaking with Comment (Vol. 83, No. 210), October 30, 2018. https://www.regulations.gov/document?D=CMS-2018-0132-1303

[xii] Healthcare Distribution Alliance. Re: Response to International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM). https://www.regulations.gov/document?D=CMS-2018-0132-1020
[xiii] American College of Rheumatology. Re: [CMS-5528-ANPRM] Medicare Programs: International Pricing Index Model for Medicare Part B Drugs https://www.regulations.gov/document?D=CMS-2018-0132-1254
[xiv] AmerisourceBergen. Comments on IPI ANPRM. https://www.regulations.gov/document?D=CMS-2018-0132-2662
[xv] Exec. Order No. 12866. 58 FR 51735 (1993) (Regulatory Principle 5: When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.)
[xvi] Centers for Medicare & Medicaid Services, International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (Oct. 30, 2018).
[xvii] Trinity Health. RE: CMS-5528-ANPRM – Medicare Program; International Pricing Index Model for Medicare Part B Drugs; https://www.regulations.gov/document?D=CMS-2018-0132-1317
[xviii] American College of Rheumatology. Re: [CMS-5528-ANPRM] Medicare Programs: International Pricing Index Model for Medicare Part B Drugs https://www.regulations.gov/document?D=CMS-2018-0132-1254
[xix] American Academy of Neurology. RE: Medicare Program; International Pricing Index Model for Medicare Part B Drugs [CMS-5528-ANPRM] https://www.regulations.gov/document?D=CMS-2018-0132-1838
[xx] National Infusion Center Association. RE: International Pricing Index Model (CMS-5528-ANPRM). https://www.regulations.gov/document?D=CMS-2018-0132-1313
[xxi] Exec. Order No. 12866. 58 FR 51735 (1993) (Regulatory Principle 5: When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.)
[xxii] Best, D. "Answering Your Questions about the IPI Drug Pricing Model." October 30, 2018. https://www.hhs.gov/blog/2018/10/30/answering-your-questions-about-the-ipi-drug-pricing-model.html
[xxiii] Vital Transformations. "International Pricing Index: What will be the Impact on Patients, Outcomes, and Innovation? http://vitaltransformation.com/wp-content/uploads/2019/06/IPI_June_5.pdf. June 5, 2019.
[xxiv] U.S. Dept of Commerce (2004). Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research & Development, & Innovation.
[xxv] 57 Conservative Groups & Activists Oppose HHS Advanced Notice of Proposed Rule Making: International Pricing Index Model for Medicare Part B Drugs [CMS-5528]. https://www.atr.org/sites/default/files/assets/11-27-18%20Conservative%20Coalition%20Letter%20Opposed%20to%20HHS%20Part%20B%20IPI%20Rule.pdf
[xxvi] National Association of Manufacturers. Re: International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM). https://www.regulations.gov/document?D=CMS-2018-0132-1603
[xxvii] Hackensack Meridian Health. RE: CMS-5528-ANPRM, International Pricing Index Model for Medicare Part 8 Drugs https://www.regulations.gov/document?D=CMS-2018-0132-1251
[xxviii] Hispanic Leadership Fund. RE: CMS-5528-ANPRM / CMS-2018-0132-0001. https://www.regulations.gov/document?D=CMS-2018-0132-2670
[xxix] Information Technology & Innovation Foundation. RE: Medicare Programs: International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM). https://www.regulations.gov/document?D=CMS-2018-0132-1060