HHS' Proposed IPI Model Is Inconsistent with Other HHS Regulatory Actions and Increases Unpredictability for Stakeholders

Executive Order (EO) 12866 states a goal of ensuring "regulations that are effective, *consistent,* sensible and understandable."[i] In addition, one of its principles stipulates that the agency promulgating the rule should, in developing regulations, consider factors including "consistency" and "predictability."[ii] Finally, it directs that "each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies."[iii]

The International Pricing Index (IPI) model, as crafted in the Advance Notice of Proposed Rulemaking (ANPRM), fails to meet this standard, as it is inconsistent with prior policy pronouncements by the Centers for Medicare & Medicaid Services (CMS). The IPI model will also lead to a regulatory environment that is less predictable for affected stakeholders. Before moving forward with an IPI proposed rule, the Office of Management and Budget (OMB) and CMS should ensure it is structured in a way that is consistent with other Department of Health and Human Services (HHS) regulations and policy principles and avoids increased unpredictability for manufacturers and providers.

1) **IPI is inconsistent with principles for pursuing new demonstration projects that are described in HHS' "New Direction RFI"**

In 2017, CMS released a New Direction RFI, outlining principles for how the Centers for Medicare & Medicaid Innovation (CMMI) will approach model design. These principles included "voluntary models, with defined and reasonable control groups or comparison populations, to the extent possible, and reduce burdensome requirements and unnecessary regulations to allow physicians and other providers to focus on providing high-quality healthcare to their patients."[iv]

The IPI model is in direct conflict with these principles. The IPI model is a mandatory model that would include nearly half of the nation's providers, while also impacting reimbursement for providers not in the model and spilling over into the commercial market. As numerous stakeholders have pointed out, the demonstration is far larger than required to obtain scientifically valid results -- and in fact its size and scope will actually threaten the ability to obtain scientifically valid results, as CMS plans for manufacturer prices to IPI vendors to spill over into ASP and reduce the ASP-based payments to providers in the control group, thus making it more difficult to isolate the effects of IPI and understand how IPI affects the quality and costs of beneficiary care.

a) <u>Stakeholders have expressed concerns with this inconsistency in their comments on the IPI ANPRM</u>

"In its 'New Directions' Request for Information (RFI), the Innovation Center noted that it would 'focus on voluntary models' and 'smaller scale models.' A demonstration project covering half of Part B expenditures on separately payable drugs with mandatory participation for physician and hospitals does not meet those standards. The Alliance opposes mandatory physician participation and urges the Administration to allow physicians to opt out."[v]

- Alliance for Specialty Medicines, December 4, 2018, Comments on IPI ANPRM

"In the ANPRM, CMS indicates that model participation would be mandatory for physician practices, hospital outpatient departments, and potentially other providers and suppliers in each of the selected geographic areas. However, such mandatory participation is inconsistent

with guiding principles established for the Centers for Medicare and Medicaid Innovation Center (CMMI) in a September 2017 Request for Information (RFI)."[vi]

- Federation of American Hospitals, December 28, 2018, Comments on IPI ANPRM

2) IPI is inconsistent with HHS' ongoing "Patients Over Paperwork" initiative as it will establish substantial new administrative burdens for care providers

In 2017, CMS launched the Patients Over Paperwork Initiative, a plan that aims to reduce the administrative and operational burden facing many providers, allowing them to focus on delivering high-quality care to patients. In June of 2019, the CMS issued an RFI seeking new ideas on how to continue the progress of the 2017 initiative, stating: "In step with the Trump Administration's Cut the Red Tape initiative to reduce overly burdensome regulations across the federal government, Patients over Paperwork has made great inroads in clearing away needless complex, outdated, or duplicative requirements that drain clinicians time but contribute little to quality of care or patient health."[vii]

Again, the IPI model conflicts with these objectives. The IPI Model would insert a third-party vendor into the buy-and-bill system, creating additional burdens on providers, who apparently would have to pay distribution fees to these vendors. Given the use of foreign reference pricing to effectively set a ceiling price, IPI vendors are likely to use the same utilization management tools they use in other markets in order to drive increased profits. The ANPRM further opens the door to the use of these tools in the model, suggesting the potential to pay providers "bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization."[viii]

a) <u>Provider groups have expressed concern over the interaction with vendors and the potential for increased administrative and operational burden</u>

"If CMS finalizes this rule, nebulizer patients will need to face the burden of having two contacts, one for the medication and the other for the equipment and supplies. This goes against CMS' current efforts of Patients Over Paperwork. Increasing the complexity of healthcare delivery would decrease treatment adherence, which could ultimately lead to higher costs in other parts of Medicare."[ix]

- American Association for Homecare, December 23, 2018, Comments on IPI ANPRM

The IPI Model "will almost certainly create a process for distribution and billing that increases the need for physicians to spend more time in administration and less time treating patients."[x]

- Cardinal Health, December 26, 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. Specifically, we are concerned that the added administrative burden of proposed interactions with the vendors in the model exceeds any inherent benefits to practices."[xi]

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

"Second, providers would need a process to track drugs provided through the IPI and implement processes to submit informational claims to Medicare and billing information to the vendor. Both of these aspects create an additional layer of administrative complexity to the Medicare program which is contrary to CMS's Patients Over Paperwork initiative."[xii]

- Sanford Health, December 26, 2108, Comments on IPI ANPRM

Because the IPI model has the potential to increase provider burden in this manner, it is inconsistent with the Patients over Paperwork Initiative and RFI.

3) IPI will substantially increase regulatory unpredictability for manufacturers, providers and other stakeholders

Launching a regulatory "overhaul" that impacts a very large number of providers and patients under the auspices of a CMMI demo, in ways that conflict with previously articulated principles for demonstrations, creates substantial unpredictability for all health care stakeholders. Providers face unpredictable systems and new costs from vendors, and uncertainty as to whether the demo will be terminated in several years.

a) Stakeholders have expressed concerns in comments that the IPI model inherently creates an unpredictable environment for providers

"The disruptive elements of the IPI model pose excessive risk and unpredictability to community-based practices and could result in providers closing their doors, further pushing patients out of the community-setting and into less convenient, more costly settings of care."[xiii]

- The US Oncology Network, December 31, 2018, Comments on IPI ANPRM

"Additional operational barriers impacting IPI Model feasibility include but are not limited to: … Cash flow disruption and unpredictability as vendor supply sits on a provider's shelf and is unbillable to Medicare until it is used. The vendor must rely on the provider to declare when product is used, and also collect the patient cost-sharing."[xiv]

- McKesson, December 31, 2018, Comments on IPI ANPRM

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

[ii] Id. (Regulatory principle 5 states: 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.)

[iii] Id.

[iv] Centers for Medicare & Medicaid Services. Innovation Center New Direction. https://innovation.cms.gov/Files/x/newdirection-rfi.pdf.

[v] Alliance for Specialty Medicines. Re: Medicare Program; International Pricing Index Model for Medicare Part B Drugs; CMS-5528-ANPRM https://www.regulations.gov/document?D=CMS-2018-0132-1746

[vi] Federation of American Hospitals, Re: CMS–5528–ANPRM, Medicare Program; International Pricing Index Model for Medicare Part B Drugs. https://www.regulations.gov/document?D=CMS-2018-0132-1249

[vii] Centers for Medicare & Medicaid Services. CMS Seeks Public Input on Patients over Paper Initiative to Further Reduce Administrative, Regulatory Burden to Lower Healthcare Costs. https://www.cms.gov/newsroom/press-releases/cms-seeks-public-input-patients-over-paperwork-initiative-further-reduce-administrative-regulatory

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

[ix] American Association for Homecare. Re: Medicare Programs: International Pricing Index Model for Medicare Part B Drugs CMS-5528- ANPRM https://www.regulations.gov/document?D=CMS-2018-0132-1273

[x] Cardinal Health. Re: Advance Notice of Proposed Rulemaking with Comment: Medicare Program; International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM) https://www.regulations.gov/document?D=CMS-2018-0132-1285

[xi] 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

[xii] Sanford Health. Re: CMS File Code CMS-5528-ANPRM Medicare Program; International Pricing Index Model for Medicare Part B Drugs https://www.regulations.gov/document?D=CMS-2018-0132-1288

[xiii] The US Oncology Network. RE: International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM)https://www.regulations.gov/document?D=CMS-2018-0132-1199

[xiv] McKEsson. RE: Medicare Program; International Pricing Index Model for Medicare Part B Drugs [CMS–5528–ANPRM]. https://www.regulations.gov/document?D=CMS-2018-0132-1205