<u>OMB Review of CMS' proposed International Pricing Index Model:</u>
<u>Key Issues to Consider</u>

The Office of Management and Budget (OMB) currently has under review a Notice of Proposed Rulemaking for the Center for Medicare & Medicaid Services' (CMS) International Pricing Index (IPI) model, which has been designated as an "economically significant" regulatory action. As described in CMS' Advance Notice of Proposed Rulemaking (ANPRM), the IPI is an overhaul of Medicare payment policy in half of the country for Part B drugs tying reimbursement to an internationally-derived price control. Its design will result in far-reaching direct and indirect costs and impacts on many key stakeholders involved in the development and delivery of physician-administered medicines (including patients, physicians, hospitals, manufacturers, and distributors). It is essential for OMB to ensure CMS has adequately assessed the costs and impacts of this proposal. Four key issues to consider are highlighted below and described in more detail in accompanying background documents.

1. <u>Impact on international trade and alignment with U.S. trade priorities:</u> The IPI Model impacts foreign trade and appears to conflict with U.S. trade priorities. CMS must coordinate with relevant U.S. trade agencies and examine the likely impact on U.S. international trade priorities. CMS must also consider whether there are alternatives to IPI-based price controls (e.g., via trade policy) to address the Administration's stated goal of ending "foreign free-riding."

2. <u>Substantial direct and indirect cost burdens imposed by IPI:</u> The IPI Model will have broad and, in some cases, potentially unanticipated consequences for key stakeholders and market competition. These include eliminating the current buy and bill system in the estimated half of the country that would be subject to IPI and adding new operational, administrative, financial, and infrastructure burdens on providers, as well as potentially increasing costs in other parts of the healthcare system. Key stakeholders have expressed concern that CMS overlooked important costs in the ANPRM and questioned whether the costs under IPI would outweigh potential savings. Under Executive Order (EO) 12866, CMS must provide an assessment of the impacts of IPI and "propose and adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."[i]

3. <u>Presumption against price controls; preference for market alternatives:</u> As described in the ANPRM, in half the country the IPI model would replace a market-based policy with a new price control in Part B. OMB guidance under EO 12866 states a presumption against price controls and a preference for market-oriented alternatives.[ii] It is important for OMB to ensure that CMS has met the higher burden of demonstrating a need for the price controls described in IPI and has explained why more market-oriented, flexible approaches were not selected.

4. <u>Regulatory inconsistency and unpredictability due to IPI:</u> EO 12866 states a goal of ensuring "regulations that are effective, *consistent,* sensible and understandable," and directs agencies to ensure any new rule is not inconsistent with other regulations (emphasis added). However, as described in the ANPRM, the IPI model appears inconsistent with prior HHS policy statements on launching new models and with the Department of Health and Human Services' (HHS) "patients over paperwork" initiative. Additionally, IPI would significantly increase unpredictability for providers in the model. OMB should ensure that, before CMS moves forward with a proposed rule, IPI meets the standards of regulatory consistency and predictability.

[i] Sec 1(b)(b) of EO 12866.

[ii] Circular A-4. September 17, 2003. https://www.transportation.gov/sites/dot.gov/files/docs/OMB%20Circular%20No.%20A-4.pdf