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December 31, 2018

**VIA ELECTRONIC FILING** – <http://www.regulations.gov/>

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
Washington, D.C. 20201

**Re: CMS-5528-ANPRM; Medicare Program; International Pricing Index Model for Medicare Part B Drugs**

Dear Administrator Verma:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments to the Center for Medicare & Medicaid Services (CMS) on the Advance Notice of Proposed Rule Making (ANPRM) International Pricing Index (IPI) Model for Medicare Part B Drugs published on October 25 in the *Federal Register*.<sup>1</sup> PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

PhRMA supports the Administration's goal of advancing value-based health care through reforms that strengthen market competition, improve incentives for organized care delivery and decision-making around improved outcomes, and equip and empower physicians, patients and consumers with the information they need to make high-value decisions.<sup>2</sup> We recognize the role the agency's Center for Medicare and Medicaid Innovation (CMMI) can play in conducting well-designed tests of new payment and delivery models to achieve these objectives. In comments submitted to CMS on November 20, 2017, responding to a Request for Information (RFI) on a potential "New Direction" for CMMI, PhRMA identified several such potential demonstrations, and expressed support for core patient safeguards and

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<sup>1</sup> Centers for Medicare & Medicaid Services, International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (Oct. 30, 2018).

<sup>2</sup> Department of Health and Human Services. HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. 83. Fed. Reg. 22692. (May 16, 2018).

policy principles articulated by the agency in the RFI announcement.<sup>3</sup> These included supporting provider choice through voluntary demonstrations; focusing on small scale tests of “defined populations” rather than broad, *de facto* policy changes; and ensuring demonstrations are designed and evaluated in a transparent manner with input from relevant stakeholders.<sup>4</sup>

PhRMA is deeply concerned that the IPI Model proposed by CMS abandons these core principles by suggesting new government price controls for medicines through international reference pricing. We are also deeply concerned that HHS is proposing to implement this sweeping policy change through a mandatory demonstration that would affect a substantial share of physicians and Medicare beneficiaries across the entire country, far exceeding CMMI’s authority. Requiring physicians in regions representing 50 percent of Part B drug spending to adopt an entirely new payment system that relies on third party vendors would significantly disrupt drug distribution and care management processes and have downstream impacts to physician reimbursement nationwide. It could also significantly harm physician care quality, patient access to physicians and treatment options, and the continued research and development of innovative medicines. **We urge the agency to abandon the International Price Index model and instead pursue reforms grounded in market competition and patient-centered care, as described in more detail below.**

Our comments address the following key concerns with the IPI Model:

- The IPI Model would replace the current market-based system for reimbursing drugs under Medicare Part B – which ensures that Medicare payment reflects discounts negotiated in the commercial market via an Average Sales Price (ASP) calculation – with government-dictated price controls tied to practices and prices set by foreign governments that do not value medical innovation for patients. HHS itself recognizes that prices in these countries are artificially suppressed by governments that run most or all of their countries’ health care systems and rely on flawed standards that impede or delay access to treatment.<sup>5</sup> Yet, by endorsing foreign price controls, the IPI Model would also endorse policies that lead to significant barriers and delays in patient access to clinically important treatments.
- Imposition of deep payment cuts in Medicare Part B via adoption of government price controls would chill continued biopharmaceutical progress at a time of significant scientific promise, as demonstrated by a substantial body of literature on the negative effects of price controls on innovation.
- The IPI Model would impose substantial policy changes on a national scale, disrupting care by forcing a large portion of providers – and their patients – into an entirely new reimbursement

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<sup>3</sup> PhRMA Comments Re: Request for Information: Center for Medicare and Medicaid Services – Innovation Center New Direction. Submitted November 20, 2017.

<sup>4</sup> Id.

<sup>5</sup> O’Brien, J “How the IPI Model Would Introduce New Market Competition to Medicare Drug Spending.” HHS.gov. December 6, 2018.

and distribution system. Additionally, providers outside the model would face declining reimbursement rates, potentially contributing to the closure of more small physician practices and accelerating costly provider consolidation.

- The IPI Model threatens patient access by opening the door to restrictive utilization management in Part B through the mandatory use of third-party vendors to purchase and seek reimbursement for Part B medicines based on a government-set Target Price. In addition, the vast majority of patients would not benefit from lower out-of-pocket costs.
- The IPI Model exceeds CMMI's statutory authority, imposing a *de facto* re-write of current Medicare statute rather than introducing an appropriately-scaled test of a new payment or delivery policy for a defined population with deficits in care.
- CMS should work with stakeholders on reforms that reinforce the Part B program's evolution towards value-based models of payment and delivery, rather than replacing the market with government price-setting.

Through the current market-based system, the Medicare Part B benefit provides access to medicines for vulnerable patients who suffer from a range of serious, complex disease and conditions, while at the same time ensuring that CMS benefits from discounts negotiated in the commercial market. However, as described in more detail below, the IPI Model threatens to disrupt the success the existing Part B program has achieved in supporting patient access and cost control. If pursued, the IPI Model could chill continued progress at a time of immense scientific promise, disrupt providers' ability to provide care, and increase barriers to patient access. We urge CMS not to move forward with the IPI Model and instead advance reforms that are patient-centric and grounded in the market competition that are hallmarks of the current system.

#### **I. THE IPI WOULD REPLACE THE CURRENT MARKET-BASED REIMBURSEMENT SYSTEM WITH ONE BASED ON PRICES SET BY FOREIGN GOVERNMENTS THAT UNDERVALUE MEDICAL INNOVATION AND ACCESS TO TREATMENT.**

A central feature of CMS' IPI Model is its reliance on foreign government price controls to determine Medicare payment for Part B medicines. In the ANPRM, CMS proposes to calculate an average international price for each Part B medicine to be included in the model, compare that to the ASP of the medicine, and develop an International Price Index. CMS would then establish a "Target Price" for each drug that would result in a roughly 30 percent reduction in spending on Part B medicines over time. The proposed calculation would have a varying impact on drugs included in the model. For example, the reimbursement rate of some drugs may not be impacted at all, while some may be reduced by up to 80 percent.<sup>6</sup>

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<sup>6</sup> PhRMA Analysis of ASPE Report; U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. October 25, 2018. <https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf>

CMS stated that it intends to include single-source drugs and biologics in the initial demonstration. For new drugs, in the absence of international pricing data, CMS is considering applying a standard factor, based on a ratio of the new drug compared to the international reference price, to the average volume-weighted payment amount across all Part B drugs included in the model.

The IPI Model would phase in the Target Price over 5 years.<sup>7</sup> CMS is considering using pricing data from the following countries: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom.

Under the IPI Model, CMS would rely on prices set by countries that artificially suppress reimbursement rates for medicines, including physician-administered drugs.<sup>8</sup> As discussed more below, foreign countries dictate these prices by relying on deeply flawed standards that ration care to their citizens and threatening manufacturers with the loss of intellectual property protections.

In many countries, including the 14 listed in the ANPRM, governments are the primary or only payer of health care and medicines and effectively dictate prices as a condition of market access. As a result, U.S. trading partners often fail to appropriately recognize the value of innovation in their pricing and reimbursement policies, instead engaging in actions that distort markets and artificially depress prices below what a competitive market would provide. Foreign governments employ a range of regulatory measures, which are often layered to exert maximum pressure on prices. As described below, these types of price control policies should be avoided in the United States because they reduce incentives for research and development, can undermine intellectual property protections, and harm patient access to clinically beneficial treatment options. Other countries deploy a variety of damaging tools to affect government price controls, including:

- **international reference pricing**, where developed markets reference prices in poorer countries or countries that undermine incentives for innovation;
- **therapeutic reference pricing**, where governments require innovative medicines to have similar prices to older medicines;
- **health technology assessment**, where governments apply arbitrarily low thresholds on the value of clinical improvements and human life gained from innovative medicines;

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and IQVIA Analytics Link and FDA, EMA and PMDA data on new active substances first launched globally between January 2011 and June 2018, November 2018.

<sup>7</sup> In the first year, payments would be comprised of 80 percent of the ASP and 20 percent of the target price. In the second year, payments would be comprised of 60 percent of the ASP and 40 percent of the target price, etc.

<sup>8</sup> See, e.g., White House Council of Economic Advisors. *The Opportunity Cost of Socialism*. October 23, 2018. "In a socialist system, the state decides the amount to be spent, how it is spent, and when and where the services are received by the consumer. A consumer who is unhappy with the state's choices has little recourse, especially if private businesses are prohibited from competing with the state (as they are under "Medicare for All")."

- **mandatory price cuts and clawbacks**, where governments unilaterally cut prices and take back revenue often to fund non-pharmaceutical care, and which act as perverse incentives against developing treatments for new indications and patient-centered formulations;
- **compulsory licensing**, where governments threaten to steal intellectual property as a price negotiating ploy; and
- **discriminatory practices**, by which U.S. companies are denied due process and a level playing field compared to companies based in that country.

All the above measures undermine incentives for innovation and destabilize competitive markets. While international reference pricing was once used informally by a small number of countries that lacked the resources to inform price negotiation, it is increasingly used as a blunt tool to exact the lowest possible price. International reference pricing has been shown to contribute to launch delays, reduce product availability, and reduce research and development of new treatments and cures.<sup>9</sup>

#### **A. As seen in other countries, when governments set prices, patient access suffers.**

The U.S. leads the world in medicine access because of our market-based system. In other countries, government bureaucracies not only set prices but the government, or government-led entities, often decide who gets access to new medicines and who does not. As a result, patients overseas have access to fewer new medicines and treatment options.

Nearly 90 percent of new medicines launched since 2011 are available in the United States, compared to just 60 percent in Germany and the United Kingdom, less than half in Canada and France, and only 48 percent across the 14 countries listed in the ANPRM, on average.<sup>10</sup> Even the medicines that do become available in these countries arrive an average of 16 months later. This international pattern of reduced availability and delays holds true for medicines currently covered by Part B. In marked contrast to the current standard of coverage for Part B beneficiaries, just half (51 percent) of new Part B medicines launched since 2011 are available in the 14 countries listed in the ANPRM, arriving 18 months later, on average. This finding is reinforced by HHS's own analysis showing that only 11 of the 27 medicines examined (41 percent) were available in all 16 comparator countries, nearly all of which have single payer health care systems.<sup>11</sup>

The United Kingdom in particular has implemented a government pricing and reimbursement system that rations care and leads to delays in access for its citizens. One key cause for the United Kingdom's

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<sup>9</sup> Danzon PM, et al. Effects of Regulation on Drug Launch and Pricing in Interdependent Markets. *Advances in Health Economics and Health Services Research* 23: 35-71, 2012.

<sup>10</sup> PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data on new active substances first launched globally between January 2011 and June 2018, November 2018.

<sup>11</sup> U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). *Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures*. October 25, 2018.

relatively limited levels of patient access is the high rate of rejections by the National Institute for Health and Care Excellence (NICE), the government body that makes national determinations about care using a cost-effectiveness threshold of between £20,000 and £30,000 per quality-adjusted life year, or QALY. Using QALYs to rigidly measure cost-effectiveness fails to recognize the full value of innovative medicines and has turned NICE into a blunt cost containment tool.

In this context, between March 2000 and December 2017, just 57 percent of all medicines undergoing technology appraisals were recommended by NICE for the full population included in the marketing authorization from the European Medicines Agency; while 23 percent were recommended in a restricted subset of patients, 4 percent for research purposes only, and 1 percent under the Cancer Drug Fund (CDF) which provides interim funding for certain medicines including those with managed access agreements. 15 percent were rejected altogether. Recommendations for cancer medicines were even more restrictive with just 37 percent of cancer appraisals recommended in-line with marketing authorization; while 32 percent were recommended in a restricted subset of patients, 3 percent in research only, 4 percent under the CDF – and 27 percent rejected altogether.<sup>12</sup>

In September 2018, NICE announced that it will not fund ocrelizumab for primary progressive multiple sclerosis (MS), even though the drug has been found to slow the progression of the disease and can delay the need for a wheelchair for seven years.<sup>13</sup> Because of this, thousands of patients have been denied access to ocrelizumab, even though the manufacturer has agreed to reduce the price of the treatment for that indication. NICE had already approved the coverage of ocrelizumab for relapsing and remitting MS after it determined the medication was a good value for those conditions. However, NICE cannot accept the lower price for the other indication because under bureaucratic Department of Health rules, drugs cannot be offered at different costs. A neurologist in the United Kingdom, Gavin Giovannoni, who was involved in conducting clinical trials on ocrelizumab was “left feeling powerless.” According to Giovannoni, “It is even more frustrating that an effective treatment that can help slow the disease has been developed and made available across the globe yet people in England and Wales will continue to suffer disability worsening because of an archaic and inflexible medicine assessment system.” This leaves patients with primary progressive MS with no treatment options. As Genevieve Edwards, Director of External Affairs at the MS Society, explains, “Right now bureaucracy is standing in the way of a better future for people with primary progressive MS.”<sup>14</sup>

In Canada, the Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial body created under the Canadian Patent Act.<sup>15</sup> The legislative mandate of the Board is to ensure that patented prices are not “excessive.” In the thirty years since the PMPRB was established, a variety of additional mechanisms have emerged in Canada for the government and industry to address medicine spending. These mechanisms include the Canadian Agency for Drugs and Technologies in Health (CADTH), the Common

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<sup>12</sup> National Institute for Health and Care Excellence (NICE), available at <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisalguidance/summary-of-decisions> (last visited Oct. 29, 2018).

<sup>13</sup> Knapton, S, “MS patients denied drug which could keep them out of wheelchair”, [The Telegraph](#), September 10, 2018.

<sup>14</sup> Knapton, S, “MS patients denied drug which could keep them out of wheelchair”, [The Telegraph](#), September 10, 2018.

<sup>15</sup> Patent Act, R.S.C. 1985, c.P-4, ss.79-103.

Drug Review, the pan-Canadian Pharmaceutical Alliance, and Product Listing Agreements, among others. Most recent (2016) data indicates that it takes an average of 449 days after Health Canada approval before a patient can access a new medicine through a Canadian public drug plan.<sup>16</sup>

The access restrictions in the countries the model would reference have led to lower survival rates for many of the world's deadliest diseases. The 5-year survival rate for all cancers is 42 percent higher for men and 15 percent higher for women in the United States than in Europe.<sup>17</sup> Implementing policies similar to those in reference countries could harm the health of Americans. Economists have found that implementing price setting policies in the United States would reduce life expectancy among Americans age 55 to 59 years old by 0.5 years in 2030 and 0.7 years in 2060.<sup>18</sup>

On October 23, 2018, just two days before the ANPRM was issued, CEA released a report titled "The Opportunity Costs of Socialism."<sup>19</sup> CEA highlighted research on the impact on medical innovation and associated health outcomes should the United States adopt "European-style" price controls. According to the research, such policies would reduce research and development of new medicines, resulting in significant increases in mortality for patients age 55 and older due to heart disease, hypertension, diabetes, cancer, lung disease, stroke, and mental illness.<sup>20</sup> CEA's analysis of existing research underscores that CMS should not proceed with a proposal that would set prices based on foreign government price controls.

Recent research by IHS Markit shows that patients in five other countries (United Kingdom, France, South Korea, Australia and Canada), on average, had access to 50 percent fewer medicines for non-small cell lung cancer (NSCLC) than patients in the U.S. In addition, these countries had an average delay of 589 days from approval to reimbursement, meaning that patients in the United States had access to medicines more than a year and a half sooner. Using a model to estimate the impact on patients if the United States were to adopt a health technology assessment framework similar to those found in countries like the United Kingdom and Canada, IHS found that American patients diagnosed with locally advanced and metastatic NSCLC between 2006 and 2017 would have lost half of the survival gains attributable to innovative medicines if the United States adopted a similar Health Technology Assessment scheme.<sup>21</sup>

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<sup>16</sup> Canadians Facing Delayed Access to New, Innovative Medicines: Report (May 24, 2016), available at <http://innovativemedicines.ca/canadians-facing-delayed-access-to-new-innovative-medicines-report/> (last visited Feb. 7, 2018).

<sup>17</sup> Allemani C, et al. Global surveillance of cancer survival 1995-2009: analysis of individual data for 25,676,887 patients from 279 population-based registries in 67 countries (CONCORD-2). *Lancet* 85(9972): 977-1010, 2015. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/25467588>

<sup>18</sup> Lakdawalla D, et al. U.S. Pharmaceutical Policy in a Global Marketplace. *Health Affairs* 28(1): w138-w150, 2019.

<sup>19</sup> Council of Economic Advisers. "The Opportunity Cost of Socialism." <https://www.whitehouse.gov/briefings-statements/cea-report-opportunity-costs-socialism/>. Accessed December 4, 2018.

<sup>20</sup> Id. P. 47

<sup>21</sup> Lockwood C and Su W. Population health outcomes of American patients under different drug access conditions. IHS Markit. December 28, 2018. <https://ihsmarkit.com/research-analysis/population-health-outcomes-american-patients.html>

**B. The IPI Model is based on a flawed premise of manufacturers’ ability to simply raise foreign prices and a flawed comparison of U.S. and foreign prices.**

American biopharmaceutical manufacturers face an un-level playing field in many overseas countries, with global trading partners implementing policies that discriminate against foreign competitors and inhibit the ability of innovators to secure value from their inventions. As stated above – and as recognized by the U.S. Department of Commerce, United States Trade Representative, Council of Economic Advisors and many others – these foreign government policies reduce investment in global biopharmaceutical research and development, which means fewer new treatments for patients and less competition in the marketplace to lower costs.<sup>22</sup>

The IPI Model ignores these challenges and is instead based on the concept that government-suppressed foreign prices provide a valid reference against which U.S. prices for health care should be gauged, and that private companies have latitude to “negotiate” higher prices in these countries. Because the overseas references are grounded in flawed policies, the reference itself – and resulting price and potential access restrictions – will also be flawed.

The IPI Model falsely assumes similarity between countries in the reference basket and the United States, implicitly applying the pricing and intellectual property policies of those countries without accounting for the circumstances that cause price differentiation. In the same way, the model implicitly applies the public health priorities of other countries without accounting for the health care agenda of the United States. The Administration has stated that bringing cures to market faster is a public health priority for the United States;<sup>23</sup> however, by using policies that inhibit this goal in other countries, the IPI Model effectively allows the public health priorities of other countries to supersede our own. American health care priorities diverge from other countries because of differences in systemic values. For example, American traditions and a preference for a transparent, de-centralized government have led to the U.S. not adopting government-run health technology assessment organizations (a tool popular in Europe).<sup>24</sup>

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<sup>22</sup> Office of the U.S. Trade Representative, 2018 Special 301 Report, April 2018, available at <https://ustr.gov/sites/default/files/files/Press/Reports/2018%20Special%20301.pdf>; Office of the U.S. Trade Representative, USTR Engagement on Pharmaceutical and Medical Device Issues, April 2018, available at <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2018/april/ustr-engagement-pharmaceutical-and>; U.S. Department of Commerce, International Trade Administration, Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation, December 2004, available at <https://2016.trade.gov/td/health/DrugPricingStudy.pdf>; The Council of Economic Advisors, *Reforming Biopharmaceutical Pricing at Home and Abroad*, February 2018, available at <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>; Schwartz TT, Ward AS, Xu XM, Sullivan J, The Impact of Lifting Government Price Controls on Global Pharmaceutical Innovation and Population Health, May 2018, available at [https://tools.ispor.org/research\\_pdfs/58/pdffiles/PHP216.pdf](https://tools.ispor.org/research_pdfs/58/pdffiles/PHP216.pdf); Goldman DG, Lakdawalla D, The Global Burden of Medical Innovation, Jan. 2018, available at [https://healthpolicy.usc.edu/wp-content/uploads/2018/01/01.2018\\_GlobalBurden20of20Medical20Innovation.pdf](https://healthpolicy.usc.edu/wp-content/uploads/2018/01/01.2018_GlobalBurden20of20Medical20Innovation.pdf).

<sup>23</sup> See e.g., The White House. Presidential Message on National Cancer Survivors Day. Outlines Trump Administrations renewed commitment to find a cure for cancer. <https://www.whitehouse.gov/briefings-statements/presidential-message-national-cancer-survivors-day/>; Also, the FDA has a number of policies that speed up and encourage the development of innovative therapies to treat serious diseases, including fast tracking, breakthrough therapy designation, and accelerated approval.

<sup>24</sup> Neumann PJ. Lessons for Health Technology Assessment: It Is Not Only about the Evidence. *Value in Health*. June 2009. 12(2) S45-S48. <https://www.sciencedirect.com/science/article/pii/S1098301510600617>



HHS itself recognized the harms of international reference pricing and aptly summarized them in the Administration's *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, which acknowledged that the problem stems not from a failure in private-sector negotiation, but from overseas systems that foreclose the possibility for such negotiation to occur. According to the Blueprint, "[e]very time one country demands a lower price, it leads to a lower reference price used by other countries. Such price controls, combined with the threat of market lockout or intellectual property infringement, prevent pharmaceutical manufacturers from charging market rates for their products, while delaying the availability of new cures to patients living in countries implementing these policies."<sup>25</sup> The answer is not to replicate these countries flawed policies, but to demand reforms to their systems so that manufacturers actually have an ability to negotiate in these countries.

Additionally, HHS is relying on a flawed analysis to justify a massive shift in Medicare reimbursement policy. On October 25<sup>th</sup>, ASPE released a report entitled "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures."<sup>26</sup> The report compares prices of 27 selected drugs in the U.S. to 16 other countries and finds that U.S. ex-manufacturer prices are the same or lower than international ex-manufacturer prices for 7 drugs and higher for the other 20 drugs. In the ANPRM, HHS references and relies on the ASPE report multiple times as a policy rationale for implementing international reference pricing. However, ASPE's analysis is compromised by several methodological limitations:

- By failing to adjust international drug prices for differences in income between countries, the ASPE report overstates the differences between U.S. drug prices and international prices. ASPE claims that the 16 countries used in its analysis are similar economically to the U.S., yet the GDP per capita in many of these reference countries is significantly less than in the U.S. In fact, in 2017 the GDP per capita in the U.S. averaged 1.4 times higher than the 16 reference countries chosen by ASPE, and U.S. per capita GDP was a full 2.1 times higher than the GDP per capita in Greece.<sup>27</sup>
- ASPE found that 20 medicines had higher prices in the U.S. compared to international settings. However, because ASPE does not provide a comprehensive country-by-country analysis for each drug, it is impossible to determine if the 16 medicines that are not universally covered comprised the majority of drugs with higher prices. It is possible that many of the drugs included in the analysis are only available in a few of the countries at steep discounts, skewing the results.

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<sup>25</sup> U.S. Department of Health and Human Services, *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, May 2018, available at <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.

<sup>26</sup> U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). *Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures*. October 25, 2018. <https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf>

<sup>27</sup> IMF and Central Bank of Ireland.

- ASPE included formulations of drugs not sold in the U.S., further skewing the analysis, and making direct pricing comparisons between countries difficult to interpret.
- ASPE limited the scope of its analysis to single-source drugs available in the U.S. As noted above, if a biologic drug already faced biosimilar competition in a foreign country, ASPE still included the price of the reference biologic in that foreign country, even though the reference biologic’s price would be influenced by the presence of the biosimilar. If a small molecule drug already faced generic competition in a foreign country, then ASPE included the prices for the generics. Including the prices of medicines with a generic form in a foreign country, but not in the U.S., creates a larger differential in price and makes direct comparison inappropriate.

**C. CMS should pursue reforms that recognize and build on the strengths of the current program instead of replacing it with government price-setting.**

Medicare Part B is a crucial benefit that provides vital medicines to seniors in a way that balances patient access and affordability. The broad coverage and structure of the Part B benefit provides the necessary flexibility for physicians to tailor treatment plans to optimize care for patients – and any reforms that CMS advances should recognize and build on the strengths of the current system instead of replacing them with price controls. Our specific recommendations for potential reforms are listed in section VI of this letter.

One of the stated goals of the model is to increase negotiation in the Part B program.<sup>28</sup> However, HHS ignores several unique features of Medicare Part B that already contribute to negotiation, stable prices, transparency, access to care, and predictable cost sharing for beneficiaries:

- **The Average Sales Price (ASP) reimbursement method reflects robust negotiation in the commercial market, resulting in savings for beneficiaries and the Medicare program.** Medicare Part B drug reimbursement generally is not based on manufacturer list price or Wholesale Acquisition Cost (WAC). Rather, for most drugs, reimbursement is based on ASP, which reflects the weighted average of all manufacturer sales prices subject to certain exceptions,<sup>29</sup> and includes rebates and discounts that are privately negotiated by health care providers and other payers. As a result, it serves as a mechanism for passing discounts negotiated in the commercial market on to Medicare beneficiaries and the Medicare program. Due to this market-based competition, ASP prices are often substantially lower than list prices. Looking at discounts for the 25 medicines with the highest spending under Part B, the ASP represents a weighted average discount of 21.2 percent off the list price.<sup>30</sup>

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<sup>28</sup> Centers for Medicare & Medicaid Services, International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (Oct. 30, 2018).

<sup>29</sup> Medicaid and certain other federal discounts and rebates are excluded from ASP. There are special rules for certain classes of drugs (e.g., DME infusion drugs, vaccines, and biosimilars).

<sup>30</sup> Estimates based on analysis by PhRMA using the July 2018 ASP Pricing File, 2018 Medispan files, and 2018 Medicare Part B Drug Spending Dashboard.

- **ASP moderates price growth.** CMS’ own analysis of the market-based ASP pricing mechanism found that in the first quarter of 2019, the ASP-based Part B payment amount for 30 of the top 50 drugs decreased and on average, there was no change in payment amount for the top 50 drugs. CMS notes, “In general, among the top drugs with a decrease, there are a number of competitive market factors at work – multiple manufacturers, alternative therapies, or market shifts to lower priced products.”<sup>31</sup> A long range analysis of the ASP system supports this finding: the volume weighted ASP for Part B medicines has remained steady year over year, and price growth for Medicare Part B drugs is below overall medical inflation.<sup>32</sup>
- **The ASP system was one of several market-based reforms enacted by Congress in 2003 to combat rising Part B drug spending.** Prior to implementing the ASP methodology, Part B medications were reimbursed based on the Average Wholesale Price (AWP) of a drug. In response to concerns about rising spending, Congress changed the Part B reimbursement system to a market-based system that more closely reflected providers’ actual acquisition and overhead costs. In the first year after implementation, spending on Part B drugs declined 8 percent.<sup>33</sup> Since the implementation of ASP, spending on Part B drugs has remained stable.<sup>34</sup>
- **ASP is a transparent metric that is not “set” by either a manufacturer or CMS.** Manufacturers report sales to CMS on a quarterly basis on an individual drug level. As explained above, these sales figures reflect discounts that providers and private payers negotiate with manufacturers. CMS then calculates the average sales price of all drugs in any given HCPCS code and posts the reimbursement rate in a public data file on the CMS website.
- **Part B offers a predictable cost-sharing structure and supplemental coverage offsets out-of-pocket costs for many beneficiaries.** Cost sharing for Part B medicines is set at 20 percent of the Medicare reimbursement rate. A majority of Medicare fee for service (FFS) beneficiaries (more than 87 percent) are already enrolled in supplemental coverage that helps to defray their out-of-pocket costs for Part B medicines, an option that is not available for Part D plans.<sup>35</sup> Recent analysis from Avalere found that, as a result of supplemental coverage, beneficiaries typically have lower out-of-pocket costs for oncology and rheumatoid arthritis medicines covered in Part B than in Part D.<sup>36</sup>

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<sup>31</sup> CMS, 2019 ASP Pricing Files. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2019ASPFiles.html>

<sup>32</sup> The Moran Company. Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2007-2017. December 2017.

<sup>33</sup> MedPAC. Report to the Congress: Impact of Changes in Medicare Payments for Part B Drugs. January 2007. p viii

<sup>34</sup> The Moran Company. Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2007-2017. December 2017.

<sup>35</sup> Kane R et al. International Price Index Model’s Impact on Patients and Providers. Avalere Health. December 27, 2018. <https://avalere.com/insights/international-price-index-models-impact-on-patients-and-providers>.

<sup>36</sup> Avalere Health. Moving Certain Part B Drugs to Part D, A Proposal Being Evaluated by The Trump Administration, Would Have Disparate Financial Impacts on Patients. May 2018.; Avalere Health. “Rheumatoid Arthritis Patients Could Face Access Barriers Under Proposal to Address Drug Prices.” October 18, 2018.

These dynamics successfully balance patient access with controlling costs, as evidenced by the fact that Part B medicines remain a small and stable share of Medicare spending. Spending on Part B medicines accounted for just 3 percent of total Medicare spending in 2015 (8 percent of all Part B spending),<sup>37</sup> even as patients gained access to important new treatment advances. HHS should not pursue policy changes to Part B, such as the IPI Model, that could reduce access to care or undermine the aspects of the program that have worked well to promote transparent, market-based reimbursement for physician-administered medicines.

## **II. ADOPTING INTERNATIONAL REFERENCE PRICING AS A PRICE CONTROL WOULD CHILL CONTINUED BIOPHARMACEUTICAL PROGRESS AT A TIME OF GREAT SCIENTIFIC PROMISE**

Today, the United States is the global leader in research and development (R&D) of lifesaving treatments and cures. There are nearly 7,000 medicines in development globally, more than half of which are in development in the United States, including hundreds for conditions like cancer and Alzheimer’s disease.<sup>38</sup> Physician-administered medicines like those covered by Medicare Part B are an area of some of the most exciting innovation. In the past 5 years, there have been major advances for patients living with lymphoma, lung cancer, and multiple sclerosis.<sup>39</sup> At a time when cutting-edge science and clinical progress is promising to transform treatment of many serious diseases, the IPI Model threatens to chill future R&D investment and jeopardize the economic support this leadership supplies.

Economists have concluded time and again that price controls suppress research and development by reducing the resources available to support it, and that removal of price controls will lead to increased innovation and better health outcomes.<sup>40</sup> Recent estimates suggest that lifting government price controls in other wealthy countries would increase the number of new treatments available by 9 percent in 2030, equivalent to 8 to 13 new medicines in that year.<sup>41</sup> Moreover, the U.S. Department of Commerce found that international reference pricing and other price controls in foreign countries already suppress worldwide private R&D investment by 11 to 16 percent annually, leading to fewer new medicines launched each year.<sup>42</sup> In fact, earlier this year, the Administration declared the need to address such foreign country practices: “...other countries are not paying an appropriate share of the

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<sup>37</sup> Analysis of 2017 Medicare Trustees Report and June 2017 MedPAC Databook conducted by Price Waterhouse Cooper for PhRMA.

<sup>38</sup> Adis R&D Insight Database. Accessed May 2018.

<sup>39</sup> U.S. Food & Drug Administration. New Drugs at FDA: CDER’s New Molecular Entities and New Therapeutic Biological Products. <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm>

<sup>40</sup> See e.g., Goldman, D and Lakdawalla, D (2018). The Global Burden of Medical Innovation; Blume-Kohout, ME and Sood N. 2013. “Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development.” *Journal of Public Economics* 97: 327–36; Acemoglu, D, and Linn J. 2004. “Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry.” *Quarterly Journal of Economics* 119 (3): 1049–90.

<sup>41</sup> Schwartz, T, Ward A, Xu X, and Sullivan J (2018). The Impact of Lifting Government Price Controls on Global Pharmaceutical Innovation and Population Health. *Value in Health* 21: S119.

<sup>42</sup> U.S. Dept of Commerce (2004). *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research & Development, & Innovation.*

necessary research and development to bring innovative drugs to the market and are instead freeriding off U.S. consumers and taxpayers.”<sup>43</sup> We applaud the Administration for recognizing this harm to Americans and support the continued efforts of the Department of Commerce, the U.S. Trade Representative, and the U.S. Intellectual Property Enforcement Coordinator to address this unfairness and welcome opportunities to assist them.

However, reducing reimbursement in the United States would not cause foreign countries to change their laws, regulations and other practices; instead it could harm research and development of new medicines that can lower total medical costs. For example, in a February 2018 report, the Council for Economic Advisers (CEA), an agency within the Executive Office of the President, warns that lowering reimbursement for medicines in the United States “makes better health costlier in the future by curtailing innovation.”<sup>44</sup> Evidence shows that every \$1-2 billion reduction in R&D investment leads to the development of one fewer new medicine per year.<sup>45</sup>

HHS has estimated its proposal would cut Medicare Part B payments for drugs by \$50 billion over 8 years, resulting in a reduction of biopharmaceutical industry revenues that represents just 1 percent of the industry’s R&D budget.<sup>46</sup> However, as described in more detail below, the IPI’s negative impact on research and development is likely to be much greater for several reasons. In particular, HHS only considers the government impact inside the model, and ignores the impact outside of the model, the impact on other federal programs, and the potential downward spiral effect of reference pricing. 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. Finally, the effects of the IPI Model for individual future products will be highly variable and difficult to predict, creating uncertainty that could further chill R&D in the area of physician-administered medicines.

The substantial, negative impact that the IPI Model could have on R&D was borne out in a survey of PhRMA members completed in December 2018. More than three quarters of respondents (77 percent) stated that if the IPI Model were to go into effect, it would affect their ability to pursue current or future research and development projects. In addition, nearly three quarters (73 percent) of companies saw risk of “significant” reductions in R&D investments into medicines likely covered under Part B. Not surprisingly, a large impact was predicted in research on cancer medicines, where 60 percent of companies reported that “significant” R&D cuts were “very likely.”

Many companies also predicted a negative effect on projects currently underway or being actively considered. Half of the companies stated that more than 20 percent of their current projects could be at

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<sup>43</sup> Department of Health and Human Services. HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. 83. Fed. Reg. at 22697. (May 16, 2018).

<sup>44</sup> The Council of Economic Advisors. February 2018. “Reforming Biopharmaceutical Pricing at Home and Abroad.” <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>

<sup>45</sup> Remarks, HHS Deputy Secretary Alex Azar, “Eating Today and Eating Tomorrow: Competition, Innovation, and Pricing for Modern Medicine,” November 9, 2005, The Policy Institute at Trinity College, Dublin, Ireland.

<sup>46</sup> 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>

risk for significant reductions or termination under this policy. Many companies also predicted negative downstream economic effects, with 45 percent expressing concern about near-term job cuts or the eventual closure of facilities.

The increased uncertainty associated with this significant cut to potential revenues could have a profound effect on the amount of venture capital and other forms of private capital available for R&D. Venture capital is especially important for the R&D-intensive biopharmaceutical industry where the vast majority of companies go over 20 years without a profit and cannot fund innovation on their own.<sup>47</sup>

The model also has the potential to stifle the development of biosimilars, an area where further development would increase competition in Part B. Recent studies project that biosimilars could reduce spending on biologics by between \$25 to \$150 billion over the next 10 years.<sup>48</sup> However, policies that would drastically reduce payment for physician-administered medicines could undermine incentives for development, deterring a marketplace that has not yet reached maturity. Further development and adoption of biosimilars is likely to lead to market-based cost savings grounded in the principles of competition, consistent with the Administration's goals.

Government-mandated prices and access restrictions in other countries have helped the United States become the global leader in biopharmaceutical innovation that it is today. For example, in 1986, biopharmaceutical R&D investment in Europe was 24 percent higher than in the United States. Today, after adopting international reference pricing and other government-mandated prices, Europe trails the United States by over 40 percent.<sup>49,50</sup> Adopting similar policies in the United States could take away America's competitive edge in medical research and development or reduce global development altogether.

These types of R&D cuts also threaten U.S. jobs. The biopharmaceutical sector serves as one of the biggest employers and investors in R&D sector in the United States. Biopharmaceutical companies employ 800,000 Americans directly and support 4.7 million jobs nationwide.<sup>51</sup> In 2016 alone, the biopharmaceutical industry invested an estimated \$90 billion in R&D.<sup>52</sup> In fact, the biopharmaceutical industry invests on average six times more in R&D as a percentage of sales than all other manufacturing industries.<sup>53</sup>

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<sup>47</sup> Fleming, J. (2014). "The Decline of Venture Capital Investment in Early-Stage Life Sciences Poses a Challenge to Continued Innovation." *Health Affairs*. 34(2):271-6.

<sup>48</sup> Mulcahy AW, Hlavka JP, Case SR. "Biosimilar Cost Savings in the United States: Initial Experience and Future Potential." RAND Corporation. 2017. Available at: <https://www.rand.org/pubs/perspectives/PE264.html>

<sup>49</sup> Golec, J and Vernon J, "European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending", NBER Working Paper No. 12676, National Bureau of Economic Research, November 2006, available at <http://www.nber.org/papers/w12676>.

<sup>50</sup> European Commission, "The 2016 EU Industrial R&D Investment Scoreboard", 2016, available at <http://iri.jrc.ec.europa.eu/scoreboard16.html> (last accessed August 2017).

<sup>51</sup> TEconomy Partners (2017). *The Economic Impact of the US Biopharmaceutical Industry*. Columbus, OH. July 2017.

<sup>52</sup> Research!America (2017). *U.S. Investments in Medical and Health Research and Development, 2013-2016*. Arlington, VA. Fall 2017.

<sup>53</sup> NDP Analytics (2018). *IP-Intensive Manufacturing Industries: Driving US Economic Growth*. Washington, DC.

In addition, the IPI proposal disproportionately targets treatments for complex conditions like cancer and rheumatoid arthritis that often must be administered by a physician. The IPI Model's implications for revenue and R&D creates a disincentive both to develop new physician-administered drugs that meet unmet needs for patients with serious diseases, and to develop competing drugs which help the market function effectively.

**A. The IPI Model would likely stifle innovation and disproportionately impact an area of R&D meeting critical unmet needs.**

Some of the most exciting advances in the pipeline, including the more than 1,100 cancer medicines in development, are physician-administered treatments that will often be covered by Medicare Part B, including:

- Gene therapies that use genetic material or DNA to manipulate a patient's cells for the treatment of an inherited or acquired disease including for many forms of cancer, metabolic disorders, neurologic conditions and many rare genetic disorders. While the first gene therapy was approved in 2017 for an inherited form of vision loss for children, more therapies to treat inherited disorders that affect Medicare patients, like hemophilia, are in development.
- Immunotherapy that uses the body's own immune system to attack cancer cells. Approved therapies include treatments for bladder, kidney, liver, and head and neck cancers, and immunotherapy is a potential treatment option for hard-to treat cancers of the brain and pancreas. Other forms of research into diseases outside cancer are underway.
- CAR T-cell therapy, where white blood cells are removed from patients, engineered to recognize and kill cancer cells, and then returned to the patient's body. The first of these was approved in 2017 for forms of blood cancer, and the technology holds enormous promise for other cancers. In remarks at a Washington Post event on cancer, the Commissioner of the Food and Drug Administration (FDA) Scott Gottlieb stated the importance of reimbursement in incentivizing innovation and that improper reimbursement for CAR-T could stifle an entire new industry.<sup>54</sup> Gottlieb stated: "If we don't get that right we have the potential to choke off a really exciting area of development."

**B. Intellectual property is the cornerstone of innovation and the IPI Model would undermine patents and intellectual property in the United States.**

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<sup>54</sup> Karlin-Smith, S. Gottlieb worries reimbursement hampering CAR-T cancer development. POLITICO Pro Health Care. November 13, 2018. "Gottlieb further said he worries if HHS mishandles reimbursement for CAR-T, which carries list prices of hundreds of thousands of dollars, the technology could go the way of radiopharmaceuticals last decade. Those drugs were just coming to market when Gottlieb was at CMS in the George W. Bush administration. At that time, he said, CMS made coverage decisions that "left hospitals underwater" for the effective medicines. This led hospitals to stop prescribing the drugs and destroyed that industry."

The IPI Model would undervalue U.S. innovation and the intellectual property (IP) underlying those inventions. IP protections are designed to afford a biopharmaceutical innovator a limited period during which they have the opportunity to recoup the significant investments they incur in developing a new medicine, as well as to earn the funds needed to invest in developing future cures and treatments. The development of new medicines is a complex process that requires significant investment, time, and risk. It takes about 10 years and \$2.6 billion, on average, to develop an FDA-approved treatment.<sup>55</sup>

One of the critical reasons the U.S. leads the world in developing innovative medicines is the IP protections that our country affords. Once those protections expire, other manufacturers are able to produce generic copies or biosimilar versions of the innovative products without incurring the same R&D costs. As a result, the prices for generic and biosimilar products are significantly lower than innovator products. While the innovative pharmaceutical industry supports this life-cycle, strong IP protection and enforcement are critical to its success.

The IP protections afforded in the United States cannot be assumed to exist overseas given the territorial nature of these protections. As a result, while a product may still have patent or other IP protections in the United States, those protections may have expired (or never been granted) in one or more of the proposed reference countries, such that generics or biosimilars may already be on the market. As an example of this, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) report cited by HHS in support of the IPI Model included biologic drugs already facing biosimilar competition in foreign countries but not in the U.S., even though the reference biologic's price would be influenced by the presence of the biosimilar.<sup>56</sup> Comparing the prices for innovative products in the United States with prices that include generic or biosimilar products in other countries is wholly inappropriate and undermines American IP protections.

Improper court decisions in foreign countries may result in the patents on certain products being revoked. For example, between 2005 and 2016, Canadian Courts impermissibly struck down patents on 24 innovative drugs under the so-called "promise utility doctrine," all so that Canadian generic companies could prematurely produce and launch their copies of these innovative products. This discriminatory doctrine, which was limited to pharmaceuticals, required U.S. pharmaceutical innovators to demonstrate not only that the invention had utility, but that each and every "promise" deemed by the Court to be made by the inventor in its patent application was in fact met by the invention. As such, this doctrine imposed impermissible, heightened patentability criteria beyond those set forth in the World Trade Organization Agreement on Trade-related Aspects of Intellectual Property Rights and the North American Free Trade Agreement. While the Canadian Supreme Court finally struck down the doctrine in 2017, this decision provided only prospective relief, not undoing harms that had already been suffered by companies.

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<sup>55</sup> DiMasi JA, Grabowski HG, Hansen RW (2016). Innovation in the pharmaceutical industry: new estimates of R&D costs. *J Health Economics* 47:20-33.

<sup>56</sup> U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. October 25, 2018. <https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf>



Inadequate IP protections such as these have routinely led to several of the proposed reference countries being included in the United States' annual Special 301 report, in which an interagency group led by the U.S. Trade Representative identifies those foreign trading partners where IP protection and enforcement have deteriorated or remained at unacceptable levels, and where market access for Americans who rely on IP protection has been unfairly compromised.

The IPI Model would amplify the impact of other countries' failure to uphold IP protection by referencing the lower prices obtained by those countries when they undermine strong IP. In short, the proposed IPI Model would import more than the bad pricing policies of other countries; it also would import bad IP policies that support these bad pricing policies. Setting prices for innovative products in the United States based on prices that include generic or biosimilar medicines available in other markets would not appropriately value and reward U.S. innovation and negates the very purpose of providing IP protections. Moreover, it would inappropriately cede U.S. sovereignty related to the IP protections it affords to the IP regimes, patent offices, and courts in each of the countries referenced.

### **III. THE IPI MODEL WOULD IMPOSE SUBSTANTIAL POLICY CHANGES ON A NATIONAL SCALE, THREATENING TO DISRUPT CARE FOR PROVIDERS AND THEIR PATIENTS ACROSS THE ENTIRE COUNTRY WITHOUT LOWERING OUT-OF-POCKET COSTS FOR THE VAST MAJORITY OF PATIENTS**

**A. The IPI Model is mandatory and forces providers and hospitals out of the current purchasing and reimbursement system for physician administered drugs (so-called "buy and bill"), while imposing on them new liabilities and uncertainty.**

With the IPI Model, HHS is contemplating a sweeping, mandatory policy change that would impact providers and patients across the entire nation, forcing doctors and hospitals in regions representing half of Part B medicine spending to participate in the demonstration. By extension, these providers' patients would be forced into the demonstration as well. HHS is planning to randomize model participants by geographic area and is considering Core Based Statistical Areas (CBSA), which are largely urban or include a population area of at least 10,000 people.

In prior comments to CMS, many provider organizations opposed making CMMI demonstrations mandatory in Phase I due to the disruptions such models would cause in care quality and access.<sup>57</sup> A poll conducted by the Medical Group Management Association earlier this year found that 72 percent of providers opposed mandatory demonstrations.<sup>58</sup> Providers have stated that mandatory models create concerns about patient safety, as many providers being forced into payment models may not be

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<sup>57</sup> See, e.g., Letter from 316 groups to Mitch McConnell, Paul Ryan, Harry Reid, and Nancy Pelosi about the Medicare Part B Payment Model. March 17, 2016.

<sup>58</sup> Gregory J, MGMA: Medical groups opposed to mandatory APMs. March 1, 2018. <https://www.healthexec.com/topics/healthcare-economics-policy/mgma-medical-groups-opposed-mandatory-apms>

equipped to handle administrative changes that may affect their ability to properly deliver quality care.<sup>59</sup>

PhRMA agrees that participation in demonstrations should be voluntary for all stakeholders. This is essential to ensure the demonstration program works not just for patients, but providers as well. Mandating participation in Phase I models could increase the risk that beneficiaries will experience problems with access to or quality of care, and that providers will be forced to abide by requirements that are unworkable from a clinical or operational standpoint. Voluntary models, by contrast, encourage approaches that fit with the clinical needs of patients and provider work flow. A voluntary model also increases the likelihood of success because the participants will be highly engaged, supportive of the demonstration concept, and motivated to help CMMI improve its design and achieve its goals. Approaches that encourage provider participation in a model by changing reimbursement for non-participating providers are not voluntary – because the non-participating providers did not choose the reimbursement change – and thus should also be avoided.

Forcing providers into a model that creates uncertainty about their reimbursement while imposing new costs is particularly concerning. For example, according to the ANPRM, providers in the demonstration “would continue to collect beneficiary cost sharing” despite no longer buying and being reimbursed for medicines. Today, many providers rely on the revenue from “buy and bill” to cover not only the cost of the medicines, but also debt they may incur from unpredictable patient payments. Thus, the IPI Model requires physicians to continue to incur the unpredictable liability of collecting patient cost-sharing, while not allowing them to manage revenue that accounts for variability in practice size and patient composition. CMS also considers reducing payment for other services to account for the copays being collected by physicians, raising important questions about the predictability of physician payments. The ANPRM would also require providers to pay model vendors for distribution costs. This is a new cost that doctors do not face today, resulting in additional financial burden for providers.

In addition, model participants would be prohibited from directly purchasing and billing for physician-administered medicines for their Medicare patients only. Removing physicians’ ability to “buy and bill” for Medicare patients can be expected to reduce their purchasing and negotiating power, likely forcing them to pay higher prices for medicines they use for non-Medicare patients. This would particularly affect providers with a large portion of Medicare patients forced to participate in the model.

**B. By reducing payment for providers outside of the model, the IPI Model threatens patient access to community and rural providers, which c shift patients to costlier sites of care.**

Reductions in ASP will lower payments to non-participating providers outside of the model area, while also reducing payments to participating providers who will no longer be purchasing Part B medicines. As CMS notes “as payments within the model are reduced, the average sales price Medicare pays will

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<sup>59</sup> LaPointe J, “72% of Medical Groups Oppose Mandatory Alternative Payment Models.” *Revcycle Intelligence*. <https://revcycleintelligence.com/news/72-of-medical-groups-oppose-mandatory-alternative-payment-models>

drop.”<sup>60</sup> This will reduce payment for providers who are not formal “participants” in the demonstration. A recent Avalere analysis found that these providers would experience a 7 percent reduction in ASP payment.<sup>61</sup>

The current ASP system accounts for the administration, storage and handling, and ongoing patient monitoring necessary for most Part B medicines, as well as variability in practice size and composition. The sequestration cuts mandated by the Budget Control Act of 2011 and implemented in Medicare in April 2013 have effectively lowered reimbursement for Part B drugs to ASP + 4.3 percent.<sup>62</sup> Additional cuts in the 2019 Hospital Outpatient Rule have further decreased physician reimbursement.<sup>63</sup> As seen with sequestration, and discussed further below, these types of mandatory reimbursement reductions disproportionately affect smaller rural and community practices.

The cuts to provider payment resulting from sequestration are already impacting physicians’ ability to recoup acquisition costs in some markets, and additional cuts could further jeopardize patient access.<sup>64</sup> Some physician offices, particularly smaller groups, are often “underwater,” such that reimbursement does not always cover the cost of providing Part B medicines under this current system. As the non-partisan Medicare Payment Advisory Commission (MedPAC) has noted: “there are some drugs that [physicians] cannot purchase at the [current] payment rate.”<sup>65</sup>

Reductions in reimbursement, such as those that would occur under the IPI Model, disproportionately impact smaller rural and community practices. Community physicians are already at a significant competitive disadvantage compared to hospitals, due to significant differences in the payments they receive from commercial insurers and differences in acquisition costs for medicines (e.g. because of the 340B program). For these reasons, community practices often cannot afford to stay in business and are then frequently acquired by hospitals. This consolidation leads to increased market power, which allows hospitals to charge more for the same care, driving up costs for patients with public and private insurance.<sup>66,67, 68</sup> For example, a recent analysis by the Moran Company found that nearly one in 5 hospitals marks up medicines to 700 percent of their acquisition cost.<sup>69</sup> This can increase costs for

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<sup>60</sup> Best D, “Answering Your Questions about the IPI Drug Pricing Model.” HHS.gov. October 30, 2018.

<sup>61</sup> Kane R et al. International Price Index Model’s Impact on Patients and Providers. Avalere Health. December 27, 2018. <https://avalere.com/insights/international-price-index-models-impact-on-patients-and-providers>.

<sup>62</sup> Sequestration affects only 80 percent of the reimbursement because a patient’s 20 percent copay is unaffected by the sequester. This yields a net effective reimbursement rate for Part B drugs of 104.3 percent of ASP.

<sup>63</sup> Centers for Medicare & Medicaid Services, *Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 83 Fed. Reg. 58818, 58955 (Nov. 21, 2018)

<sup>64</sup> Booth A, Primer: Medicare Part B Drug Payment System. *American Action Forum*. January 21, 2015.

<https://www.americanactionforum.org/research/primer-medicare-part-b-drug-payment-system/>

<sup>65</sup> MedPAC. Report to Congress: Impact of Changes in Medicare Payments for Part B Drugs, January 2007.

<sup>66</sup> Milliman. Cost Drivers of Cancer Care. April 2016. Available at: <http://www.milliman.com/insight/2016/Cost-drivers-of-cancer-care-A-retrospective-analysis-of-Medicare-and-commercially-insured-population-claim-data-2004-2014/>

<sup>67</sup> Baker LC, Bundorf MK, Kessler DP. Vertical integration: hospital ownership of physician practices is associated with higher prices and spending. *Health Affairs*. 2014;33(5):756-63.

<sup>68</sup> Bai G, Anderson GF. A more detailed understanding of factors associated with hospital profitability. *Health Affairs*. 2016;35(5):889-97.

<sup>69</sup> The Moran Company. Hospital Charges and Reimbursement for Drugs: Analysis of Cost-to-Charge Ratios. September 2018.

Medicare, particularly in the short run, because certain hospital payments, such as outliers, are based on hospital cost-to-charge ratios. It can also raise costs for other insurers that pay based on charges, including many commercial health, automobile, and disability insurers.<sup>70</sup>

HHS has also noted the negative impact that lack of competition in the provider market – which might be further exacerbated by the IPI Model – has on patients and the United States health care system. In *Reforming America’s Healthcare System Through Choice and Competition*, released in December 2018, HHS makes the following three points:

Hospitals without local competitors typically charge higher prices, which could add thousands of dollars to a hospital bill. One study estimates that the average prices at hospitals without local competitors are 12.5 percent higher than prices at hospitals with four or more competitors. For example, a 12.5 percent cost increase on an average admission would amount to almost \$1,800. Since healthcare expenses largely drive insurance premiums, these costs are mostly passed on to consumers or taxpayers.

[...] there is evidence that the lack of competition in provider markets leads to reduced quality of care. For example, a 2000 study of more than 500,000 Medicare beneficiaries found that those who experienced a heart attack had a statistically significant (1.5 percentage point) higher chance of dying within one year of treatment if they received care in a hospital with fewer potential competitors. To drive that point home, Americans have 790,000 heart attacks each year. Assuming that half the country lives in relatively noncompetitive hospital markets, we would expect from these findings that 5,925 premature deaths to be associated with a lack of competition. Of course, this calculation is just for heart attacks, just one of numerous diseases or conditions that kill Americans prematurely each year.

[...] Empirical evidence on the impact of mergers on competition in healthcare markets—based on studies by FTC staff and independent scholars—shows that healthcare consumers benefit from competitive markets and the associated lower prices and higher quality services.<sup>71</sup>

To address some of these concerns, in 2016 CMS finalized sections of the Bipartisan Budget Act of 2015 requiring that payments to certain entities for covered services, including physician-administered medicines, be site-neutral. Recognizing that a system where Medicare pays for the same service at a higher rate if it is provided in a hospital outpatient department versus a physician’s office creates perverse incentives for hospitals to acquire physician offices, CMS issued a regulation stating that particular services provided by certain off-campus hospital outpatient departments would no longer be

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<sup>70</sup> Bai G, Anderson GF. Market Power: Price Variation Among Commercial Insurers For Hospital Services. *Health Affairs*. 2018 Oct 1;37(10):1615-22.

<sup>71</sup> U.S. Department of Health and Human Services. *Reforming America’s Healthcare System Through Choice and Competition*. December 2018.

paid under the Hospital Outpatient Prospective Payment System (HOPPS).<sup>72</sup> The policy became effective in January 2017 but included some exceptions, most notably grandfathering in off-campus sites billing under HOPPS prior to November 2015, and some facilities with new or developing off-campus departments.<sup>73</sup> CMS has taken some important steps to correct policies that incentivize shifts to more expensive sites of care, but should be cautious of policy proposals – such as the IPI Model – that could restore these incentives, thereby increasing spending on both medicines and overall health care services.

Reductions in provider payments can also threaten access to rural providers. Rural cancer patients already face many challenges in receiving care, including limited availability of cancer treatments and cancer support providers, transportation barriers, financial issues, and limited access to clinical trials.<sup>74</sup> Many of these obstacles are not faced by patients in urban and suburban areas. Rural communities also have fewer physicians, pharmacies, nurses, specialists, and other health care workers. For example, in 2013, there were 31.2 physicians per 10,000 people in urban areas, compared to only 13.1 per 10,000 people in rural areas. This difference is starker among specialists, as the proportion of specialists was even more dramatically lower in rural areas (263 per 10,000 people vs. 30 per 10,000 people).<sup>75</sup>

Lower reimbursement rates are a key barrier to the recruitment and retention of healthcare professionals in rural areas. This is exacerbated by the growing exodus of healthcare providers from rural communities. Recent hospital closures highlight the challenges faced by rural providers. According to the American Hospital Association (AHA), nationally, hospitals have been closing at a rate of about 30 a year, with rural areas affected the most by such closures.<sup>76</sup> At present, more than 600 rural hospitals are vulnerable to closure,<sup>77</sup> primarily due to financial distress. Rural hospitals operate at significantly lower margins than those in urban settings and modest reductions in payment rates threaten rural hospitals' ability to meet their financial obligations.<sup>78</sup>

### **C. CMS' rationale for modifying the current ASP add-on payment formula in the IPI Model is not supported by the evidence.**

In the ANPRM, HHS references concerns that the ASP plus 6 percent payment formula incentivizes the prescribing of higher cost drugs, however, there is no conclusive evidence to support this claim. In fact, a

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<sup>72</sup> CMS. CMS Finalizes Hospital Outpatient Prospective Payment System Changes to Better Support Hospitals and Physicians and Improve Patient Care. 2016.

<sup>73</sup> CMS. CMS Clarifies Site-Neutral Medicare Reimbursement Exceptions. 2017.

<sup>74</sup> Charlton, M, Schlichting M, Chioreso C, et al. Challenges of rural cancer care in the United States, *Oncology*. September 15, 2015. <http://www.cancernetwork.com/oncology-journal/challenges-rural-cancer-care-united-states>

<sup>75</sup> Ratcliffe M, Burd C, Holder K, Fields A. American Community Survey and Geography Brief: Defining Rural at the U.S. Census Bureau. December 2016. <https://www.census.gov/content/dam/Census/library/publications/2016/acs/acsgeo-1.pdf> Accessed December 4, 2018.

<sup>76</sup> iVantage Health Analytics report. Rural Relevance - Vulnerability to Value: A Hospital Strength INDEX® Study. 2016. [https://www.chartis.com/resources/files/INDEX\\_2016\\_Rural\\_Relevance\\_Study\\_FINAL\\_Formatted\\_02\\_08\\_16.pdf](https://www.chartis.com/resources/files/INDEX_2016_Rural_Relevance_Study_FINAL_Formatted_02_08_16.pdf). Accessed December 4, 2018.

<sup>77</sup> Id.

<sup>78</sup> Kaufman BG, Thomas SR, Randolph RK, Perry JR, Thompson KW, Holmes GM, Pink GH.

The Rising Rate of Rural Hospital Closures. *J Rural Health*. 2016 Winter;32(1):35-43. doi: 10.1111/jrh.12128. Epub 2015 Jul 14.

recent report from Xcenda shows that there is no correlation between providers' prescribing habits and the cost of drugs.<sup>79</sup> In the study, Xcenda looked at claims data for fee-for-service beneficiaries in Medicare Part B taking physician-administered drugs for breast cancer, rheumatoid arthritis, and non-small cell lung cancer and found no meaningful correlation between utilization and drug payment.

Medicare utilization patterns also do not support the premise that the Part B drug payment rate creates an incentive to prescribe more expensive drugs. For example, if the payment rate did motivate use of higher-priced products, we would expect to see utilization rates of generic oncolytics to remain low over time (and use of existing branded medicines to remain high) after the generic is introduced. However, evidence shows that when a generic version of an injected medicine used to treat bone cancer came to market in 2013, utilization rapidly shifted away from the brand drug to the generic product.<sup>80</sup>

The Part B drug payment formula is intended to adequately cover the cost that providers incur to purchase and maintain an inventory of complex Part B medicines and to encourage providers to seek the best price for Part B products. Separately-payable Part B drugs are currently reimbursed at the rate of ASP plus 6 percent, or ASP plus 4.3 percent under sequestration. The formula was established in the Medicare Modernization Act as part of an effort to implement a market-based reimbursement system for Part B medicines. The 6 percent add-on to the ASP helps to capture overhead for the complex storage and handling of Part B drug products as well as variability in provider acquisition costs.

**D. By introducing new third-party vendors into Part B, the IPI Model opens the door to restrictive utilization management techniques that have the potential to interfere with patient access, worsen health outcomes, and hinder providers' ability to treat patients.**

Under the current system, physicians often rely on large Group Purchasing Organizations (GPOs) to negotiate discounts on the medicines they utilize. This system allows the physician to keep the drug on site to treat the patient directly and adjust dosing as is necessary for individual circumstances. For example, when Medicare Part B cancer patients go to their doctors' offices to receive their cancer treatment, they do not have to pick up their chemotherapy from the pharmacy counter first, as is required by some Pharmacy Benefit Managers (PBMs). In addition, physicians are able to adjust a medicine's dosing at the time of administration if a laboratory result or other biometric values suggest that the originally planned dosage would not be appropriate for the patient.

The IPI Model would introduce vendors into Medicare Part B that would be paid a Target Price for Part B medicines based on international prices. Vendors would negotiate prices with manufacturers and compete for business. HHS states that it intends to "allow entities such as GPOs, wholesalers, distributors, specialty pharmacies, individual or groups of physicians and hospitals, manufacturers, Part

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<sup>79</sup> Xcenda. "Medicare Physician-Administered Drugs: Do Providers Choose Treatment Based on Payment Amount?" September 19, 2018.

<sup>80</sup> ION Solutions, Navigating the Part B Drug Payment Model, (March 26, 2016) (webinar presentation)

D sponsors, and/or other entities to perform the role of model vendor.”<sup>81</sup> However, because model vendors are required to operate nationwide, and to comply with existing state and federal requirements, only existing entities such as PBMs and specialty pharmacies are likely to be equipped to meet vendor requirements by 2020, as they are already playing a similar role and meeting similar requirements in other markets.

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.”<sup>82</sup>

Current utilization management techniques in other markets are too often deployed simply as a method to control costs. When this happens, they can have adverse outcomes on patients’ overall health. Restrictive utilization management practices that cause access and adherence issues associated with poor health outcomes are increasingly used in the commercial market, particularly for complex conditions like the ones treated by Part B medicines.<sup>83</sup>

A 2016 survey from Cancer Support Community found that 1 in 7 patients were required to try an alternative cancer medication before they could receive the medication originally prescribed by their doctor. Half of respondents appealed this requirement, half of whom did not ultimately receive the original treatment. Of those who did receive the originally-prescribed treatment, more than half had to wait 7 to 30 days before doing so. Sixteen percent of patients chose not to start the treatment their insurance company recommended (potentially out of concerns about negative side effects with long-term consequences) and delayed any treatment until an exception was granted.<sup>84</sup> Given the increase in the commercial market of harmful utilization management techniques, policies that open the door to the use of these “tools” in Medicare have the potential to negatively impact seniors, and the Medicare program.

Cost-driven utilization management can reduce utilization of medicines, but many of these costs are offset by increased utilization and of medical services and associated costs, which reflects worse patient health outcomes.<sup>85</sup> More than half of the studies included in a literature review on the impact of formulary restrictions found a negative impact on patient and/or payer outcomes.<sup>86</sup> Formulary restrictions were associated with reduced medication adherence and negative clinical outcomes for

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<sup>81</sup> Centers for Medicare & Medicaid Services, International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (Oct. 30, 2018). – p. 18 in PDF

<sup>82</sup> Centers for Medicare & Medicaid Services, International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (Oct. 30, 2018)

<sup>83</sup> Park Y, Raza S, George A, Agrawal R, Ko J. (2017) The effect of formulary restrictions on patient and payer outcomes: a systematic literature review. *Journal of Managed Care & Specialty Pharmacy*, 23(8), 893-901

<sup>84</sup> Cancer Support Community. (2016). Access to Care in Cancer 2016L: Barriers and Challenges.

<sup>85</sup> Park Y, Raza S, George A, Agrawal R, Ko J. (2017). The effect of formulary restrictions on patient and payer outcomes: a systemic literature review. *Journal of Managed Care & Specialty Pharmacy*, 23(8), 893-901.

<sup>86</sup> Id.

patients.<sup>87</sup> A study on the impact of prior authorization on children with epilepsy found that over one-third of children with epilepsy experienced a delay of one week or longer in starting new antiepileptic agents due to prior authorization requirements, and 38 percent had a lapse in coverage resulting in missed doses.<sup>88</sup> Of those that missed doses, 64 percent experienced a worsening of seizures.<sup>89</sup> Subjecting seniors to purely cost-based utilization management has the potential to increase costs for Medicare in other areas and to harm beneficiaries' health.

Our concern over the potential introduction of harmful utilization management techniques in Part B via the IPI Model is reinforced by recent policy changes in Medicare Advantage and proposed changes in Medicare Part D. In August 2018, HHS announced that for the first time, it will allow Medicare Advantage plans to use step therapy, or "fail first" policies, for Part B medications. HHS made this announcement without implementing meaningful safeguards for patients or providers, such as ensuring that providers may override step therapy protocols that they find are contrary to a patient's clinical profile.<sup>90</sup> Shortly after this policy change was announced, research published in *Health Affairs* based on a review of step therapy protocols among commercial plans found substantial variation in how commercial plans implement step therapy for specialty medicines.<sup>91</sup> The authors stated that while some difference between policies is to be expected, the degree of variation in step therapy protocols "raises questions about whether they are grounded in sound clinical evidence."<sup>92</sup>

In November 2018, CMS proposed to allow Part D plans to use step therapy for patients currently stable on products used to treat complicated diseases like HIV, mental illness, cancer, and epilepsy.<sup>93</sup> This action clearly risks harming patients who are currently on effective treatments for these important conditions and shows CMS' willingness to undermine policies that protect patient health. When Medicare Part D was created, CMS recognized that access to the full range of products for these conditions would be essential for seniors and people living with disabilities to mitigate complications and risk often associated with disruptions in treatment, and established protections for the medicines used to treat these diseases (known as the "six protected classes").<sup>94</sup> When developing the policy, CMS stated that Part D plans had to provide access to all or substantially all drugs in those classes, but is now proposing to roll back those important patient protections.

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<sup>87</sup> Lu CY, Ross-Degnan D, Soumerai SB, Pearson SA. (2008) Interventions designed to improve the quality and efficiency of medication use in managed care: a critical review of the literature- 2001-2007. *BMC Health Services Research*, 8(1), 75

<sup>88</sup> Wirrell EX, Vanderwiel AJ, Nickels L, Vanderwiel SL, Nickles KC. (2018). Impact of Prior Authorization of Antiepileptic Drugs in Children with Epilepsy. *Pediatric Neurology*.

<sup>89</sup> Id.

<sup>90</sup> Center for Medicare and Medicaid Services. "Prior Authorization for Step Therapy for Part B Drugs in Medicare Advantage." Memo. August 7, 2018.

<sup>91</sup> Chambers JD, Panzer AD, Neumann PJ., Variations In The Use of Step Therapy Protocols Across US Health Plans, *Health Affairs*. <https://www.healthaffairs.org/doi/10.1377/hblog20180912.391231/full/>

<sup>92</sup> Id.

<sup>93</sup> Centers for Medicare & Medicaid Services, Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62152 (Nov. 30, 2018)

<sup>94</sup> Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual, Rev. 18, January, 15, 2016.

<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>



Providers have long recognized the challenges that utilization management creates for patient access and burden that it places on doctors. In a recent survey of physicians, 92 percent report that prior authorization has caused a delay in care for their patients.<sup>95</sup> In addition, more than 9 out of 10 physicians say prior authorization has a negative impact on patients' clinical outcomes.<sup>96</sup> In the same survey, 84 percent of physicians described the burden associated with prior authorization, an extremely common form of utilization management, as "high or extremely high."<sup>97</sup> On average, physicians estimated that a total of 14.6 hours (approximately two business days) are spent each week by the physician/staff in their practice to complete the workload related to prior authorization.<sup>98</sup> In response to the burden providers are increasingly facing from cost-focused utilization management, the American Medical Association (AMA) released 21 principles to "guide overdue reform of UM programs, including prior-authorization and step-therapy requirements."<sup>99</sup>

Utilization management can interfere with the doctor-patient relationship by preventing prescribers from being able to select the best drug for each patient's individual circumstances. These systems may discourage doctors from prescribing the most appropriate therapies. Due to the nature of many medicines in Part B and the diseases that they treat, patients often need to try multiple therapies before finding the appropriate treatment, and physicians and patients need maximum flexibility to tailor treatments to meet patients' needs, consistent with clinical evidence. Intermediaries, particularly the ones most likely to be vendors under the IPI Model, often interfere with this flexibility.

**E. Most patients taking medicines included in the IPI Model would not experience lower out-of-pocket costs.**

PhRMA strongly supports HHS' goal of improving patient affordability in Medicare and ensuring beneficiaries do not face financial hardship due to excessive out-of-pocket cost burdens. While we do not believe any patient should face such burdens, it also is important to recognize that less than 1 percent of seniors in Medicare Part B would have their out-of-pocket costs reduced by the IPI Model in a given year, if the model included the 27 drugs included in the ASPE analysis.<sup>100</sup> This is because the vast majority of patients in Medicare Part B have supplemental coverage, either through employer sponsored insurance, a Medigap plan, or Medicaid. According to a recent analysis, more than 87 percent of Medicare FFS beneficiaries have supplemental insurance that covers their cost-sharing for Part B medicines.<sup>101</sup>

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<sup>95</sup> American Medical Association. (2017). AMA Prior Authorization Physician Survey.

<sup>96</sup> Id.

<sup>97</sup> Id.

<sup>98</sup> Id.

<sup>99</sup> O'Reilly, KB. 21 principles to reform prior-authorization requirements. American Medical Association. January 25, 2017. <https://www.ama-assn.org/practice-management/sustainability/21-principles-reform-prior-authorization-requirements>. Accessed December 20, 2018/.

<sup>100</sup> Kane R et al. International Price Index Model's Impact on Patients and Providers. Avalere Health. December 27, 2018. <https://avalere.com/insights/international-price-index-models-impact-on-patients-and-providers>.

<sup>101</sup> Id.

Of the small share of beneficiaries who do not have supplemental insurance, the vast majority do not take any of the Part B medicines likely to be included in the model. Only 2 percent of beneficiaries without supplemental insurance take any of the 27 medicines listed in the ASPE report.<sup>102</sup> For this reason, the number of beneficiaries experiencing reductions in out of pocket costs from the IPI Model will likely be very limited.

## **V. THE IPI MODEL IS A BROAD OVERREACH OF CMMI'S STATUTORY AUTHORITY, IS NOT SUPPORTED BY THE CONSTITUTION, AND CONFLICTS WITH U.S. PATENT LAWS.**

CMS should not pursue the IPI Model because of its legal defects. As outlined below, the model exceeds several limits on CMMI models imposed by CMMI's enabling statute, Social Security Act § 1115A. This is clear both from the CMMI statute's text and from the principle that statutes must be interpreted to avoid raising constitutional questions, as the CMMI statute would raise serious constitutional separation of powers concerns if it allowed CMMI to cancel the Medicare statute and impose a new Part B drug pricing and distribution system based on foreign prices—which the CMMI statute plainly does not allow. In addition to the IPI Model's failure to conform to the CMMI statute and constitutional separation of powers and foreign commerce clause requirements, the model conflicts with our U.S. patent laws. These are laws that CMMI may not waive. Given the statutory and constitutional boundaries on CMMI models, the IPI Model has too many non-curable legal defects for CMS to proceed with its development

**A. The IPI Model would exceed the limits of the CMMI statute by not meeting the statutory criteria for Phase I models, not being a true “test”, not being tied to a research objective, and waiving laws outside of CMMI's authority to waive.**

### **1. The IPI Model does not meet the statutory criteria for a Phase I Model.**

Under the CMMI statute, Phase I testing models must be “models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.”<sup>103</sup> Despite this explicit statutory requirement, the IPI Model does not address a “defined population” with “deficits in care.” In fact, the model would require the participation of all physicians and hospital outpatient departments (HOPDs) in selected geographic areas accounting for 50% of Medicare spending on separately payable Part B drugs — thus sweeping in any beneficiaries in these geographic areas who are treated with separately payable Part B drugs. There is no reason to think that these beneficiaries have a “deficit in care”; nor does the ANPRM suggest they have any deficits in care, or even mention this issue. And apart from being Medicare beneficiaries receiving some type of Part B-covered drug treatment – which is not a “defined population” unless any group of beneficiaries CMS targets for inclusion in a CMMI model thereby becomes a “defined population,” thus making this Phase I selection criterion meaningless –

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<sup>102</sup> *Id.*

<sup>103</sup> SSA § 1115A(b)(2)(A) (emphasis added).

these beneficiaries have nothing in common and therefore do not even meet the requirement for a “defined population.”

Accordingly, the model would not be permitted by the CMMI statute, as it does not satisfy the statutory criteria for a Phase I model.

## **2. The IPI Model would be an overhaul of Part B rather than a true “test.”**

The CMMI statute divides CMMI models into two parts: (1) a test phase (Phase I) and (2) an expansion phase (Phase II). The IPI Model also does not comply with the CMMI statute because its scope goes beyond a “test,” which is the bedrock requirement for Phase I. The CMMI statute sets out a two-step procedure for testing and potentially expanding models. Payment or delivery reform ideas must first be “tested” on a small scale—according to specified evaluation criteria<sup>104</sup>—before, the Secretary, taking the Phase I evaluation into account, can expand their duration or scope.<sup>105</sup> Further, HHS must make three separate determinations before a model tested under Phase I may be expanded. An expansion to Phase II can only occur if—

- 1) the Secretary determines that such expansion is expected to—
  - (A) reduce spending under [Medicare or Medicaid] without reducing the quality of care; or
  - (B) improve the quality of patient care without increasing spending;
- 2) the Chief Actuary of [CMS] certifies that such expansion would reduce (or would not result in any increase in) net program spending under [Medicare or Medicaid]; and
- 3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under [Medicare or Medicaid] for [beneficiaries].<sup>106</sup>

As these requirements indicate, Phase I testing requires an actual test, with meaningful limits, before CMMI may expand the model. If CMMI could launch large-scale models without any testing, then there would be no need for statutory provisions on “expansion,” and the detailed statutory prerequisites for an expansion would become meaningless, as CMMI could just skip over those prerequisites.<sup>107</sup> This result is thus not permitted by the statutory language, and would not accord with Congress’ intention to ensure — before a model can be expanded—that the model does not reduce the quality of beneficiaries’ care, restrict their access to benefits, or increase Medicare spending. Permitting an expansion before these questions have been evaluated would create significant risks for Medicare and its beneficiaries. Congress drafted the CMMI statute in terms that explicitly foreclose those risks.

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<sup>104</sup> SSA § 1115A(b)(4).

<sup>105</sup> SSA § 1115A(c).

<sup>106</sup> SSA § 1115A(c)(1)-(3).

<sup>107</sup> Statutory language cannot be interpreted so that any provision in the statute is rendered superfluous, void, insignificant, or inoperative. See, e.g., *Hibbs v. Winn*, 542 U.S. 88, 101 (2004); *Astoria Federal Savings & Loan Ass’n v. Solimino*, 501 U.S. 104, 112 (1991); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2003); *Bailey v. U.S.*, 516 U.S. 137, 146 (1995).

Accordingly, a large-scale model may be adopted only after a meaningful Phase I test evaluating the model’s impact on quality of care, access, and Medicare spending on a small scale, and only after the requisite findings have been made based on the test results. The ANPRM describes the IPI Model as covering nearly all separately payable Part B drugs in geographic areas accounting for half of Medicare Part B drug spending -- meaning that Medicare beneficiaries treated with Part B drugs, and physicians and HOPDs that furnish these drugs in regions representing half of Part B drug spending, would be forced to participate in the model. That would not be a true “test” as required by the CMMI statute. As CMS Administrator Seema Verma observed: “There are no two ways about it -- the IPI Model is a significant change; it is an overhaul of Medicare Part B drug pricing.”<sup>108</sup>

The IPI Model would move well beyond a test to “an overhaul of Medicare Part B drug pricing.”<sup>109</sup> CMS does not yet know how the IPI Model would affect Medicare spending, or whether it would adversely affect beneficiaries’ quality of care or their access to benefits<sup>110</sup> — and the law does not permit CMMI to even expand a Phase I test, let alone “overhaul” part of Medicare, until these questions are answered. Precisely because these crucial questions are unknown in Phase I, Phase I models must be tested on a small scale to limit risk to Medicare and its beneficiaries before the law permits “expansion” to Phase II. A model requiring participation by all physician offices and HOPDs that furnish Part B drugs in geographic areas accounting for 50 percent of Medicare Part B drug spending represents an “overhaul” (in Administrator Verma’s terminology), rather than a true “test” to evaluate the model’s effects.

### **3. The IPI Model is not tied to a research objective.**

Another reason the IPI Model would not qualify as a Phase I test is that it would go beyond what is necessary to accomplish a research objective. To avoid needlessly exposing people to risk, studies posing potential risks to participants must be no larger than necessary to achieve the research objective.<sup>111</sup> Test models must be small and otherwise designed so that the model can be easily reversed if it proves unsuccessful. But the IPI Model has a substantial scope and could disrupt the existing drug distribution and pricing system in half of Part B drug spending – potentially making it difficult to put the existing distribution and pricing system back in place in areas covered by the IPI Model if the model fails.

In addition, CMS acknowledges that the IPI Model would affect physicians and hospitals operating outside the model, by reducing the Average Sales Prices (ASPs) that determine Part B drug payments

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<sup>108</sup> November 14, 2018 Remarks by Seema Verma at the Biopharma Congress (as prepared for delivery), <https://www.cms.gov/.../remarks-administrator-seema-verma-biopharma-congress>.

<sup>109</sup> Remarks by Seema Verma at the 2018 Biopharma Conference, supra (emphasis added).

<sup>110</sup> 83 Fed. Reg. at 54559 (stating that the “evaluation of the model would help inform the Secretary and policymakers whether this model, as designed, reduces program expenditures while maintaining or improving the quality of care furnished to Medicare beneficiaries”). This is exactly what the CMMI statute requires -- the effects of a particular model on beneficiary quality of care, access, and Medicare spending must be evaluated, not presumed.

<sup>111</sup> For example, “overpowered” studies (with a sample size larger than necessary to yield valid research results) are considered unethical. See e.g., Celik S, et al., Are sample sizes of randomized clinical trials in rheumatoid arthritis too large? 44 Eur J. Clinical Investigation 1034 (2014); Altman DG, Statistics and ethics in medical research III: How large a sample? 281 Brit Med J.1336 (1980); Horrobin DF, Are large clinical trials in rapidly lethal diseases unusually unethical? 361 The Lancet 695 (2003).

under current law.<sup>112</sup> As a result, the IPI Model would have no true control group. All of the physician offices and HOPDs outside the IPI Model would be affected by the Model reducing Part B drug payments, which in turn could affect beneficiary care in the geographic areas outside the model. Changes in the quality of care resulting from participation in the Model could thus be nearly impossible to isolate. The ANPRM acknowledges this problem:

We note that to the extent that model sales [sales by manufacturers to model vendors] affect the overall ASP calculations, we may experience evaluation challenges with the comparison group geographic areas not selected for the model.<sup>113</sup>

This is a serious methodological problem that could keep CMS from understanding the IPI Model's effects. A true small-scale test would alleviate this problem and help CMS to obtain valid results, as it would reduce manufacturers' sales to model vendors and thus reduce the risk of the model influencing patterns of care in the control group.

Thus, for all the reasons discussed above, the IPI Model would not be a test but an "overhaul" that the CMMI statute does not permit at Phase I.

#### **4. The waivers in the IPI Model are not authorized by the CMMI statute.**

Because the IPI Model would be an overhaul of Part B's drug pricing system rather than a Phase I "test," CMMI's waiver authority does not apply. The statute permits CMS to waive specified provisions of law (including any provisions of the Medicare statute) only during the Phase I testing conducted under SSA § 1115A(b). Specifically, the waiver authority applies "solely for purposes of carrying out this section [SSA § 1115A] with respect to testing models under subsection (b) [SSA § 1115A(b), 'Testing of Models (Phase I)']."<sup>114</sup> Expansion is addressed in SSA § 1115A(c), "Expansion of Models (Phase II)." The statute does not allow CMS to waive statutory requirements for Phase II expansion models authorized by § 1115A(c). And this makes sense, because Phase II expansion models may be nationwide<sup>115</sup>; permitting CMMI to cancel statutory requirements on a permanent nationwide basis would usurp Congress' lawmaking powers and raise constitutional separation of powers concerns.<sup>116</sup>

The IPI Model would waive key requirements in the Medicare statute concerning Part B drug payments and the Competitive Acquisition Program.<sup>117</sup> But because the model goes far beyond a Phase I test –

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<sup>112</sup> 83 Fed. Reg. at 54560 (noting that the IPI Model might affect overall ASP calculations).

<sup>113</sup> 83 Fed. Reg. at 54560.

<sup>114</sup> SSA § 1115A(d)(1) (emphasis added).

<sup>115</sup> SSA § 1115A(c).

<sup>116</sup> Statutes must be interpreted in a way that avoids constitutional concerns whenever possible. See, e.g., Gomez v. United States, 490 U.S. 858, 864 (1989) ("It is our settled policy to avoid an interpretation of a federal statute that engenders constitutional issues if a reasonable alternative interpretation poses no constitutional question"). Here, the plain language of SSA § 1115A(d)(1) does not permit waivers of statutory requirements in Phase II expansion models; therefore, the statute only raises constitutional concerns if interpreted in a way that contradicts its plain language. Accordingly, both the plain language of SSA § 1115A(d)(1) and the constitutional avoidance canon call for limiting CMMI's waiver authority to Phase I tests.

<sup>117</sup> 83 Fed. Reg. at 54559.

representing an “overhaul of the Part B drug pricing system,”<sup>118</sup> by CMS’ account – its waivers are not permitted by the CMMI statute.

**B. The IPI Model raises several constitutional concerns, including concerns about violating of separation of powers and the foreign commerce clause.**

**1. Separation of Powers Concerns**

As discussed above in section I.D., SSA § 1115A does not give CMMI the broad waiver authority envisioned by the ANPRM. And if it did, it would raise serious separation of powers concerns, by enabling CMMI to cancel any provisions of the Medicare statute without following the constitutional framework for repealing legislation.

The Constitution does not permit Congress to delegate its legislative powers to other bodies, including executive agencies.<sup>119</sup> Accordingly, when Congress assigns decision-making authority to an agency, Congress must delineate an “intelligible principle” to guide the agency’s decision-making.<sup>120</sup> How specific that principle must be in order to pass constitutional muster “varies according to the scope of the power congressionally conferred,” with more delegated power requiring more specific congressional guidance.<sup>121</sup> As one scholar has noted, “the statutes previously upheld by the Supreme Court can be divided into two categories: those that delegate broad authority upon relatively concrete principles, and those that delegate specific authority on relatively vague principles.”<sup>122</sup> If the CMMI statute permitted the IPI Model (which it does not), then it would fall outside both of these recognized categories, by combining an extremely broad delegation of authority with vague principles. If SSA § 1115A(d)(1) allowed CMMI to waive any provision of the Medicare statute (as well as other Social Security Act provisions) in a far-reaching mandatory model, then CMMI would have vast waiver authority unconstrained by an intelligible principle.

CMMI does not in fact have that nearly-boundless waiver authority. Instead, SSA § 1115A(d)(1) allows CMMI to waive specified statutory provisions (including the whole Medicare statute) “as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b).” This is the statute’s only intelligible principle: CMMI’s waiver authority is limited to Phase I testing models, and thus has a narrow field of operation confined to genuine tests.

The waivers planned under the IPI Model also raise constitutional concerns because CMMI would effectively be repealing statutory provisions outside the constitutional process for passing legislation. The Constitution requires that legislation be passed by both houses of Congress and signed by the

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<sup>118</sup> Remarks by Seema Verma at the 2018 Biopharma Conference, *supra*.

<sup>119</sup> U.S. Const., art. 1, § 1.

<sup>120</sup> *Whitman v. Am. Trucking Ass’ns.*, 531 U.S. 457, 472 (2001) (quotation marks omitted).

<sup>121</sup> *Whitman*, 531 U.S. at 475.

<sup>122</sup> Clark B., *Refining the Nondelegation Doctrine in Light of Real ID Act Section 102(2): Time to Stop Bulldozing Constitutional Barriers for a Border Fence*, 58 *Cath. U. L. Rev.* 851, 875-76 (2009).

President (unless the President’s veto is overridden, in which event the bill must be passed by supermajorities in both houses of Congress).<sup>123</sup> These constitutional requirements apply to the enactment of any statute, including statutes that repeal existing legislation.<sup>124</sup> Thus, the Supreme Court struck down the Line Item Veto Act, which purported to allow the President to cancel certain statutory provisions.<sup>125</sup>

If interpreted to permit the waivers described in the ANPRM, SSA § 1115A would have the same constitutional defects as the Line Item Veto Act. If CMMI could waive duly enacted statutory provisions on a sweeping basis, it would effectively wield a line item veto over much of the Social Security Act. But repealing laws is a power the Constitution assigns jointly to Congress and the President, rather than executive agencies.

CMMI’s statutory authority would stretch far beyond constitutional limits if it permitted CMMI to cancel the Medicare statute in areas of the country including a large portion of physicians. But SSA § 1115A does not grant CMMI such sweeping powers; instead, it confines CMMI’s waiver authority to small-scale tests limited to a defined population with deficits in care. This reading of the CMMI statute is dictated both by its plain language and by the rule that statutes must be construed so as to avoid raising constitutional questions.<sup>126</sup> Therefore, even if the language of the CMMI statute could otherwise allow a model that waived provisions of the Medicare statute for large portions of the country – which it does not – that interpretation would be rejected under the constitutional avoidance canon. As the Supreme Court has stated, where an agency’s interpretation of a statute “would make such a sweeping delegation of legislative power that it might be unconstitutional under [the non-delegation doctrine],” a “construction of the statute that avoids this kind of open-ended grant should certainly be favored.”<sup>127</sup>

## 2. Foreign Commerce Clause Concerns

The IPI Model also raises important separation of powers concerns under the Constitution’s Foreign Commerce Clause, which grants Congress alone the power “[t]o regulate Commerce with foreign Nations.”<sup>128</sup> Yet the Administration has made clear that a key goal of the IPI Model is ending “global freeloading” in drug pricing whereby “Americans pay more so other countries can pay less.”<sup>129</sup> PhRMA

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<sup>123</sup> U.S. Const., art. 1, § 7.

<sup>124</sup> INS v. Chadha, 462 U.S. 919, 954 (1983).

<sup>125</sup> Clinton v. New York, 524 U.S. 417 (1998).

<sup>126</sup> See e.g., Gomez v. U.S., 490 U.S. 858, 864 (1989) (“It is our settled policy to avoid an interpretation of a federal statute that engenders constitutional issues if a reasonable alternative interpretation poses no constitutional question.”); Commodity Futures Trading Com’n v. Schor, 478 U.S. 833, 841 (1986) (“[f]ederal statutes are to be so construed as to avoid serious doubt of their constitutionality”); Crowell v. Benson, 285 U.S. 22, 62 (1932) (“When the validity of an act of the Congress is drawn in question, and even if a serious doubt of constitutionality is raised, it is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided.”); Richmond Screw Anchor Co. v. U.S., 275 U.S. 331, 346 (1928) (the courts’ duty in interpreting federal statutes is “to reach a conclusion which will avoid serious doubt of their constitutionality”); Phelps v. U.S., 274 U.S. 341, 344 (1927) (“Acts of Congress are to be construed and applied in harmony with and not to thwart the purposes of the Constitution”).

<sup>127</sup> Industrial Union Dep’t, AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 641 (1980).

<sup>128</sup> U.S. Const. Art. I, Sec. 8, Cl. 3.

<sup>129</sup> <https://www.bostonglobe.com/news/nation/2018/10/25/trump-says-taking-action-lower-drug-costs-blames-foreign-freeloading-for-high-prices/rXZqPMHSsfeyCQiZuDFUxO/story.html>

shares the Administration’s concern that U.S. patients bear a disproportionate amount of the cost to develop medical advances. Fortunately, the Administration has powerful tools that it can use without raising constitutional concerns. As we wrote in our comments in response to the Administration’s *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, we encourage the Administration to take the following actions to end the most unfair and discriminatory trade practices faced by the U.S. innovative biopharmaceutical industry:

- (1) Securing strong commitments in global, regional and bilateral negotiations to drive and sustain 21st century biopharmaceutical innovation;
- (2) Enforcing and defending existing trade commitments (such as those negotiated with South Korea and Australia);
- (3) Ensuring that foreign government pricing and reimbursement policies are transparent, provide due process and appropriately value U.S. innovation; and
- (4) Leveraging all available trade tools to combat abuse of compulsory licensing.

Each of these powerful actions would move the U.S. closer to a more level playing field with our trading partners, and all of them are at the Administration’s immediate disposal and none raise concerns that they conflict with the Constitution.

The IPI Model, in contrast, would not serve as a proper exercise of the Administration’s authority. The Executive Branch cannot regulate foreign commerce absent an express congressional delegation of power. The case law holds that the power to regulate foreign commerce is far-reaching and belongs only to Congress, except to the extent that Congress chooses to delegate certain powers to the President. The Supreme Court has thus held that “[n]o sort of trade can be carried on between this country and any other, to which [the foreign commerce clause power] does not extend,”<sup>130</sup> and that Congress’ power over foreign commerce is “exclusive and plenary,”<sup>131</sup> although Congress may delegate specified powers over foreign commerce to the President.”<sup>132</sup>

The Administration has made clear that a key goal of the IPI Model is ending “global freeloading” in drug pricing whereby “Americans pay more so other countries can pay less.”<sup>133</sup> The President explained that “[f]or decades, other countries have rigged the system” but ... “[u]nder our new plan, the Department of Health and Human Services would allow Medicare to determine the price it pays for certain drugs based on the cheaper prices paid by other nations . . . . At long last ... foreign countries will be held accountable for how they rigged the system against American consumers.”<sup>134</sup> “The American middle class is effectively funding virtually all drug research and development for the entire planet,” the President stated, “[b]ut no longer.”<sup>135</sup> HHS released a set of questions and answers on the IPI Model similarly emphasizing that the model was partly designed to increase drug prices abroad:

[U]nder the IPI model— which uses other countries’ prices to calculate U.S. prices but does not aim to match them—all wealthy countries would now be using competitive models for pricing

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<sup>130</sup> Gibbons v. Ogden, 22 U.S. 1, 193 (1824).

<sup>131</sup> Bd. of Trustees of Univ. of Illinois v. United States, 289 U.S. 48, 56 (1933).

<sup>132</sup> Chicago & S. Air Lines v. Waterman S. S. Corp., 333 U.S. 103, 109 (1948).

<sup>133</sup> <https://www.bostonglobe.com/news/nation/2018/10/25/trump-says-taking-action-lower-drug-costs-blames-foreign-freeloading-for-high-prices/rXZqPMHSsfeyCQiZuDFUxO/story.html>.

<sup>134</sup> <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-prescription-drug-prices/>.

<sup>135</sup> <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-prescription-drug-prices/>.



this set of costly drugs. The pharmaceutical industry would finally be pressured to fairly allocate the burden of funding innovation across wealthy countries ....

The model would encourage manufacturers to cut down on foreign freeriding through higher prices abroad, because pushing up prices abroad will lessen the discounts that pharmaceutical companies will be forced to offer here in the U.S.<sup>136</sup>

These comments make plain that the IPI model is intended to affect foreign commerce by prompting American companies to increase prices in the foreign countries referenced in the IPI model, thus causing these countries to contribute a larger share of pharmaceutical research and development costs.<sup>137</sup>

Even if the model's impact on foreign commerce were indirect, it could still violate the Foreign Commerce Clause. The Supreme Court has affirmed that the Foreign Commerce Clause – an authority exclusive to Congress – extends to “every species of commercial intercourse between the United States and foreign nations.”<sup>138</sup> Therefore, without a clear statutory delegation for CMMI to increase drug prices American companies offer abroad, the IPI Model usurps powers the Constitution granted exclusively to Congress.

Nor does the CMMI statute delegate this power to the Executive Branch. The CMMI statute certainly may delegate some powers to the Executive Branch, but if the CMMI statute were so broad that it authorized models intended to affect drug pricing in foreign countries, it would lack any intelligible principle cabining the President's discretion and go beyond its stated purpose of testing models “to reduce program expenditures under [Medicare or Medicaid] while preserving or enhancing the quality of care furnished to [program beneficiaries].”<sup>139</sup> Moreover, Congress is not presumed to hide “an elephant in a mousehole”<sup>140</sup>; therefore, had Congress intended SSA § 1115A to delegate significant decisions concerning foreign commerce to CMMI, it would have had to do so explicitly. But § 1115A does not explicitly authorize CMMI to influence foreign drug prices, or even allude to such a goal.

Finally, Congress is also presumed to be concerned primarily with domestic conditions.<sup>141</sup> It is a “longstanding principle of American law” that statutes are “meant to apply only within the territorial jurisdiction of the United States” unless a contrary intent is apparent.<sup>142</sup> This canon of construction (called the “presumption against extraterritoriality”) applies “regardless of whether there is a risk of conflict between the American statute and a foreign law.”<sup>143</sup>

Over the past three decades, the Supreme Court has consistently emphasized the presumption against extraterritoriality. In E.E.O.C. v. Arabian Am. Oil Co., the Court noted that the presumption is only overcome if Congress “clearly expressed” an affirmative intention that a law apply abroad.<sup>144</sup> Two decades later, in Morrison v. Nat'l Australia Bank Ltd., the Court stated that “[w]hen a statute gives no

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<sup>136</sup> Answering Your Questions About the IPI Drug Pricing Model, Oct. 30, 2018, <https://www.hhs.gov/blog/2018/10/30/answering-your-questions-about-the-ipi-drug-pricing-model.html> (emphasis added).

<sup>137</sup> As highlighted above, the premise that manufacturers will be able to negotiate higher foreign prices is fatally flawed; nonetheless, this does not alter the intent of the IPI model.

<sup>138</sup> Gibbons v. Ogden, 22 U.S. 1, 193–94 (1824).

<sup>139</sup> SSA § 1115A(a)(1).

<sup>140</sup> Whitman v. American Trucking Ass'n, 531 U.S. at 468.

<sup>141</sup> Foley Bros., Inc. v. Filardo, 336 U.S. 281, 285 (1949).

<sup>142</sup> Foley Bros., Inc. v. Filardo, 336 U.S. at 285.

<sup>143</sup> Morrison v. Nat'l Australia Bank Ltd., 561 U.S. 247, 255 (2010).

<sup>144</sup> E.E.O.C. v. Arabian Am. Oil Co., 499 U.S. 244 (1991).

clear indication of an extraterritorial application, it has none.”<sup>145</sup> Most recently, in RJR Nabisco v. European Cmty., the Court held that “[t]he question is not whether ... ‘Congress would have wanted’ a statute to apply to foreign conduct ‘if it had thought of the situation before the court,’ but whether Congress has affirmatively and unmistakably instructed that the statute will do so.”<sup>146</sup>

As noted above, the stated purpose of the CMMI statute is to “test innovative payment and service delivery models” in Medicare and Medicaid.<sup>147</sup> The statute is exclusively domestic in nature and provides no indication of any Congressional intent to “push[] up [drug] prices abroad”. Therefore, applying the presumption against extraterritoriality, the CMMI statute’s reach is limited to domestic commerce – thus precluding the Executive Branch from using the statute to increase foreign drug prices and thus put an end to foreign “freeloading.”

Because the IPI model cannot be pursued under the authority granted to CMMI, we urge the Administration to use the many other tools it has available to it to address global freeloading.

### **C. The IPI Model conflicts with U.S. patent laws.**

The patent systems in the referenced countries differ in significant ways from the US patent system. Adopting a modified form of international reference pricing that reflects the varying patent protection standards in jurisdictions such as Canada, the European Union, Japan, and the United Kingdom effectively imports foreign regimes for patent protection into the United States, including the differing legal standards applicable to IP.<sup>148</sup> Because the U.S. Constitution assigns sole responsibility for defining the scope of patent rights to the Congress, not the executive branch,<sup>149</sup> importing prices derived from these foreign patent regimes raises constitutional separation of powers concerns. The Federal Circuit has previously struck down analogous attempts to effectively modify the U.S. patent system outside of Congressional action.<sup>150</sup> Because the standards applicable to patent prosecution and enforcement in the proposed referenced jurisdictions result in weaker patent protection compared to the protections available in the United States for the same inventions, the HHS proposal to adopt a reference pricing regime derived from these weaker patent systems without Congressional authorization raises particularly acute constitutional concerns. Below we highlight two of the major legal differences between the U.S. patent system and the patent systems in the referenced countries.<sup>151</sup>

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<sup>145</sup> Morrison v. Nat'l Australia Bank Ltd., 561 U.S. at 255.

<sup>146</sup> RJR Nabisco, Inc. v. European Cmty., 136 S. Ct. 2090, 2100, 2101 (2016) quoting Morrison v. Nat'l Australia Bank Ltd., 561 U.S. 247 (2010).

<sup>147</sup> SSA § 1115A(a)(1).

<sup>148</sup> Adopting this system would also have significant negative effects on innovation in the United States. See [IP Policy Section].

<sup>149</sup> Article I, Section 8, Clause 8 ([The Congress shall have power] “[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”)

<sup>150</sup> See Biotechnology Industry Org., et al. v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007).

<sup>151</sup> In addition to the Patent Act in general, in the context of pharmaceutical products, the Congress has exercised its constitutional authority through the Drug Price Competition and Patent Term Restoration Act (the “Hatch-Waxman Act”) as well as various other laws that strike a careful balance between the rights of a patent holder to recoup its innovation investment during a period of exclusivity and the interests of generic manufacturers to market a competing copy of the innovator product.

The first significant difference between U.S. patent law and foreign patent law relates to “grace periods.” Jurisdictions have different “grace periods” that apply to public disclosures made by the applicant before filing.<sup>152</sup> If an applicant files a patent application within a certain time after the invention covered by the application is disclosed to the public by the applicant, the earlier disclosure is not considered in the patent office’s determination of whether the claimed invention is new. The United States has a twelve-month grace period for such disclosures.<sup>153</sup> However, countries that are signatories to the European Patent Convention have either no grace period or extremely limited grace periods that rarely extend beyond six months.<sup>154</sup> Thus, the same invention could be patentable in the United States but not patentable in a country in Europe due to the different lengths of the grace periods.

A second significant difference between U.S. patent laws and foreign patent laws relates to patent term adjustments. Patent term adjustment is available in the United States for delays caused by the United States Patent and Trademark Office (the USPTO) during the process of working with the USPTO to obtain a patent (prosecution) of a U.S. patent application in any sector.<sup>155</sup> The USPTO adjusts a patent’s term by the number of days of delay in prosecution by the USPTO that are not caused by the applicant. Such patent term adjustments for patent office delays is not available in other countries or regions. As a result, the same invention could be subject to a later-expiring patent in the United States than in, e.g., Japan or many European countries, despite having spent the same amount of time under examination by the patent offices in the relevant jurisdictions.

The U.S. patent system differs in several significant ways from the patent systems in the referenced countries, including with respect to “grace periods” and patent term adjustments. The IPI Model would rely on prices derived from these foreign patent systems to develop payment rates for Medicare Part B drugs. In effect, therefore, the model would alter the balance that Congress struck through the patent laws.

The present patent system reflects the result of Congress’s deliberations. In the absence of clear Congressional authority, HHS does not have authority to pursue the IPI Model. And, because the HHS proposal would effectively import patent systems that differ significantly from the system set up by Congress, the HHS proposal raises substantial constitutional concerns.

## **VI. HHS SHOULD SEEK MARKET-BASED, VALUE-DRIVEN REFORMS OF MEDICARE PART B.**

Instead of pursuing the IPI Model, which would reduce innovation, harm patient access, and drive provider consolidation, HHS should seek concrete reforms that support improved affordability of care for patients in Medicare Part B while supporting continued patient access, such as:

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<sup>152</sup> To be patentable, inventions must be novel (among other things). In examining a patent application to determine the patent should be granted, patent offices consider evidence regarding whether the invention covered by the patent application has been disclosed or otherwise made available to the public. Typically, patent applications are filed at the patent office before the invention is disclosed to the public so that disclosure of the invention is not taken into account when the patent examiner considers whether the invention is new.

<sup>153</sup> 35 U.S.C. §102(b)(1); *see also* MPEP §2153.01(a).

<sup>154</sup> Euro. Patent Convention, Art. 55 and Patents Act 1977, s.2(4).

<sup>155</sup> 35 U.S.C. §154(b); *see also* 37 C.F.R. §1.705.

- *Outcomes-based and other value-based contracts:* These arrangements encourage manufacturers to assume more financial risk for the results that new medicines deliver in real-world use. A recent survey from Avalere found that 74 percent of health plans with outcomes-based contracts experienced cost savings.<sup>156</sup> While the number of publicly announced value-based contracts continues to increase (49 contracts were publicly announced from 2009 through Q2 2018<sup>157</sup>), HHS should support reforming obsolete regulations to expand the opportunity for manufacturers and payers to pursue even more of these arrangements.
- *Value-based payment models in Part B:* HHS should continue to pursue voluntary payment models that focus on increasing efficiency and providing higher quality care for patients, including demonstrations like the Oncology Care Model (OCM). Providers participating in OCM follow national guidelines for the treatment of cancer patients and provide enhanced services to Medicare beneficiaries, including care coordination.<sup>158</sup> OCM includes 178 practices and 13 payers.<sup>159</sup> Appropriate financial incentives make providers accountable for health outcomes, making OCM one of the highest-impact reform demonstrations for Medicare Part B drugs in recent years. This model includes practices that cover 25 percent of chemotherapy related cancer care in the U.S. and is having a significant impact on cancer drug spending.<sup>160</sup>
- *Better performance measures and incentives for Shared Decision Making:* HHS should seek reforms that expand the health care industry's ability to measure value in care, including work to increase the number and use of patient-reported outcomes measures, and investing in novel value assessment tools. An example is the development of the National Quality Forum's (NQF) Shared Decision Making Playbook, a tool developed through a multi-stakeholder collaboration, which highlights best practices of shared decision making to improve the process between patients and providers and ensure patient-centered outcomes.
- *Better data transparency for value:* HHS should pursue policies that strengthen market competition by making evidence on the benefits and costs of treatments more transparent to stakeholders. Many thought leaders and policymakers have called for steps to expand and encourage use of data on the relative comparative effectiveness of treatments as an important solution for controlling drug costs and ensuring spending aligns with value.<sup>161</sup> Done right, reforms can support patient and consumer choice and enhance market competition.

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<sup>156</sup> Avalere Health. Health Plan Interest in Outcomes-Based Contracts Increasing. July 12, 2018.

<sup>157</sup> PhRMA. Value-Based Contracts: 2009 – Q2 2018. August 7, 2018.

<sup>158</sup> Center for Medicare and Medicaid Services. "Oncology Care Model." <https://innovation.cms.gov/initiatives/oncology-care/>

<sup>159</sup> Id.

<sup>160</sup> Center for Medicare and Medicaid Services. "Oncology Care Model Overview." <https://innovation.cms.gov/Files/slides/ocm-overview-slides.pdf>.

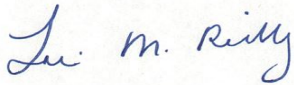
<sup>161</sup> National Quality Forum. National Quality Partners Playbook™: Shared Decision Making in Healthcare. [http://www.qualityforum.org/National\\_Quality\\_Partners\\_Shared\\_Decision\\_Making\\_Action\\_Team\\_.aspx](http://www.qualityforum.org/National_Quality_Partners_Shared_Decision_Making_Action_Team_.aspx)

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In summary, PhRMA opposes the IPI Model out of concerns about the impact it would have on patients, providers, and pharmaceutical innovation. For these reasons we urge CMS not to proceed with the model.

Please feel free to contact us if there is any further information we can provide or if you have any questions about our comments

Sincerely,



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