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Jessica L. Bailey-Wheaton, Esq., Editor
Todd A. Zigrang MBA, MHA, ASA, FACHE, Publisher


## Drug Pricing Proposal Targets High Pharma Expenditures

On October 25, 2018, the Trump Administration released a proposed plan to modify the *Centers for Medicare & Medicaid Services* (CMS) Medicare Part B payment model in an effort to control pharmaceutical spending, employing an *International Pricing Index* (IPI) model in contrast to the current model (defined below).[1] Major concerns provoking the payment model adjustment include the considerable amount that Medicare spends on drugs, as well as the relatively low costs that other countries pay for the same drugs.[2] A CMS evaluation of Medicare spending from 2011 to 2016 indicated that *fee-for-service* (FFS) drug spending increased from $17.6 billion to $28 billion under Part B, a *compound annual growth rate* (CAGR) of 9.8%.[3] In addition, the *Department of Human and Health Services* (HHS) released a report that revealed drug prices to be approximately 80% higher in the U.S. compared to other nations for 27 of the most expensive physician-administered drugs.[4]

Due to these concerns, CMS released an *Advanced Notice of Proposed Rule Making* (ANPRM) regarding the details of the new model, with the goals of rebalancing the market power between the U.S. and other countries while encouraging manufacturers to cut down on "*foreign freeriding*."[5] This new model will be implemented through a five-year pilot program, projected to start in 2020, and will aim to:

1. "*Reduce the price Medicare pays for a set of costly drugs to closer to what other countries pay.*
2. *Remove perverse incentives that encourage the prescribing of more expensive drugs.*
3. *Reduce physician burden associated with 'buy and bill' by enabling private sector vendors to pay a larger role in the purchase and distribution of these drugs.*"[6]

This model will be mandatory for participants, incorporating 50% of eligible providers at the start of the pilot and gradually introducing other providers throughout the subsequent five years.[7] Mandatory model participants include physician practices and hospital outpatient departments (HOPDs); CMS is considering also incorporating *durable medical equipment* (DME) suppliers, *ambulatory surgery centers* (ASCs), and other Part B providers and suppliers in the future.[8] The five-year plan intends to test three new measures: the IPI model, a *Competitive Acquisition Program* (CAP), and *average sales price* (ASP) add-ons.[9]

The IPI model would create a Target Price that is 126% of the average price other countries pay for each drug, and this Target Price would be paid to providers that buy and bill for the drug, in contrast to the current payments for physician-administered drugs that are evaluated at the ASP in the U.S. market, with a price-based add-on fee.[10] This change is meant to reduce the high Part B spending compared to other countries and ensure that patients will receive fair deals on the discounts that pharmaceutical companies voluntarily give other countries.[11]

In addition, the new plan would integrate a CAP that enlists private vendors to buy Part B drugs and supply them to physicians and hospitals.[12] This program intends to eliminate the financial risk under the current system, wherein physicians and hospitals take on the risk associated with buying and supplying drugs themselves.[13] With this program, the contracted private sector vendors would bill Medicare for administered drugs; providers would be able to compete to be a vendor under the program.[14] The intention of this private vendor practice is to create new competition through the vendors seeking volume-based discounts and competing for provider business.[15]

Lastly, in the proposed plan's ASP add-on model, providers would receive a flat fee for provider costs associated with drugs covered by this model in order to remove the current model's financial incentive to administer more expensive drugs, allowing patients to benefit from lower drug costs.[16] Currently, Medicare Part B pays physicians 6% in addition to the ASP, but that percentage is subject to the 2013 Budget Sequestration, which effectively reduces the add-on to 4.3%;[17] the new flat fee would more accurately reflect the 6% mark-up.[18] With the initiation of these measures in the pilot program, the Administration projects a savings of $17.2 billion over five years, and $50 billion over eight years.[19]

However, there are concerns with the strength of this plan due to the lack of effectiveness of, and opposition to, similar programs and proposals. In the *Medicare Modernization Act of 2003*, a similar voluntary (rather than mandatory) CAP was enacted.[20] This program had only a few participating physicians and only one company approved to be a CAP vendor, causing the early cancelation of this program and apprehension toward utilizing the program again.[21] However, HHS believes


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that the new CAP system will provide more incentives for participation, flexibility, and choice of vendors, due to the previous CAP being a voluntary program.[22] Further, in 2016, the Obama Administration proposed changes to the Medicare Part B payment model, but the proposal did not move forward, and was formally withdrawn by the Trump Administration due to opposition from stakeholders (i.e., physicians, patients, and the pharmaceutical industry).[23] This proposal utilized the current purchasing framework, rather than through private vendors in the Trump Administration's plan, while cutting the ASP add-on from 6% to 2.5% and providing an additional flat fee.[24] Although different from the proposed model, it is unclear whether the new proposal will succeed due to opposition from various stakeholders, mainly pharmaceutical companies and physician advocacy groups,[25] with patient advocacy groups yet to respond.

In the proposed program, pharmaceutical companies would receive lower Medicare Part B drug payments compared to the current model.[26] Stephen Ubl, Pharmaceutical Research and Manufacturers of America (PhRMA) president and CEO, believes that this model will discourage innovation in the pharmaceutical industry (i.e., research and development) and will ultimately be detrimental to patients.[27] The new model will include the shifting of cancer drug and biologic payments (which take a considerable amount of time and financial resources to develop) to international prices.[28] In 2016, the biopharmaceutical industry invested $90 million in *research and development* (R&D), with biopharmaceutical drugs taking on average 10 to 15 years and $2.6 billion to develop.[29] Upon lowering Medicare prices paid in the U.S., profits for pharmaceutical companies would decrease, potentially reducing the incentive to invest in the considerable cost of R&D for innovative drugs. Despite this concern, R&D spending has stayed relatively the same while profits are continually increasing, suggesting that pharmaceutical companies will still profit even with reduced Part B spending.[30] In addition to reduction in innovation, Ubl also believes that reducing physician reimbursement and utilizing private vendors will limit patient access to medicines.[31]

In addition to concerns regarding the stifling of pharmaceutical innovation, there are also patient access concerns with this model. In the new model, pharmaceutical companies potentially may not sell their products to vendors at the new reference price, causing the drugs to be unavailable to consumers.[32] If pharmaceutical companies are unwilling to reduce prices, vendors may stop providing certain drugs, further exacerbating the access issue.[33] Although patient access could potentially be affected, patients will likely be benefited by reduced spending under this model. Medicare beneficiaries (without other coverage) pay a 20% coinsurance on physician-administered drugs; if drug prices were to be reduced, coinsurance payments will similarly decrease.[34] Consumers will save an estimated $3.4 billion in the first five years of this model through cost sharing.[35]

As mentioned above, the physicians and HOPDs that currently experience financial risk when purchasing, storing, and billing for drugs under Part B will be relieved of this duty and the associated risks in the new model. The current reimbursement (i.e., ASP add-on model) incentivizes physicians for using high cost drugs, contributing to out of control costs, while the new program will remove these incentives with a flat fee tied to storing and handling drugs rather than on drug prices.[36] However, the *Community Oncology Alliance* (COA) asserts that the incentive of reimbursement rates do not change oncologists' prescribing patterns.[37] In addition, the COA believes that the transition to private sector vendors will interfere with Medicare treatment in terms of quality, accuracy, and timeliness.[38] In contrast, the *American Hospital Association* (AHA) commends the model's focus on reducing drug prices that may be detrimental to both patient access and a physician's ability to deliver care.[39]

Overall, the Trump Administration's Medicare Part B proposal seeks to address concerns with the inflated drug expenditures relative to other countries. With the incorporation of the IPI model, the CAP, and the ASP add-on modifications, this proposal aims to decrease the costs of drugs while putting financial risk on private vendors rather than on physicians and HOPDs. Compared to past programs that incorporated similar measures, the success of this proposal remains uncertain. However, the ability of this program to succeed may largely rely on the input of stakeholders to identify concerns and unintended consequences of the model during the comment period, which ends on Monday, December 31, 2018.[40]

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**Todd A. Zigrang**, MBA, MHA, ASA, FACHE, is the President of **HEALTH CAPITAL CONSULTANTS** (HCC), where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 20 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 1,000 transactions and joint ventures. Mr. Zigrang is also considered an expert in the field of healthcare compensation for physicians, executives and other professionals.

Mr. Zigrang is the co-author of "*The Adviser's Guide to Healthcare – 2nd Edition*" [2015 – AICPA], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies; Business Appraisal Practice*; and, *NACVA QuickRead*. In addition to his contributions as an author, Mr. Zigrang has served as faculty before professional and trade associations such as the American Society of Appraisers (ASA); American Health Lawyers Associate (AHLA); the American Bar Association (ABA); the National Association of Certified Valuators and Analysts (NACVA); Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute.

Mr. Zigrang holds a Master of Science in Health Administration (MHA) and a Master of Business Administration (MBA) from the University of Missouri at Columbia. He is a Fellow of the American College of Healthcare Executives (FACHE) and holds the Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers, where he has served as President of the St. Louis Chapter, and is current Chair of the ASA Healthcare Special Interest Group (HSIG).

**John R. Chwarzinski**, MSF, MAE, is Senior Vice President of **HEALTH CAPITAL CONSULTANTS** (HCC). Mr. Chwarzinski's areas of expertise include advanced statistical analysis, econometric modeling, as well as, economic and financial analysis. Mr. Chwarzinski is the co-author of peer-reviewed and industry articles published in *Business Valuation Review* and *NACVA QuickRead*, and he has spoken before the Virginia Medical Group Management Association (VMGMA) and the Midwest Accountable Care Organization Expo. Mr. Chwarzinski holds a Master's Degree in Economics from the University of Missouri – St. Louis, as well as, a Master's Degree in Finance from the John M. Olin School of Business at Washington University in St. Louis. He is a member of the St. Louis Chapter of the American Society of Appraisers, as well as a candidate for the Accredited Senior Appraiser designation from the American Society of Appraisers.

**Jessica L. Bailey-Wheaton**, Esq., is Vice President and General Counsel of **HEALTH CAPITAL CONSULTANTS** (HCC), where she conducts project management and consulting services related to the impact of both federal and state regulations on healthcare exempt organization transactions and provides research services necessary to support certified opinions of value related to the Fair Market Value and Commercial Reasonableness of transactions related to healthcare enterprises, assets, and services. Ms. Bailey-Wheaton is a member of the Missouri and Illinois Bars and holds a J.D., with a concentration in Health Law, from Saint Louis University School of Law, where she served as Fall Managing Editor for the *Journal of Health Law & Policy*.

**Daniel J. Chen**, MSF, CVA, is a Senior Financial Analyst at **HEALTH CAPITAL CONSULTANTS** (HCC), where he develops fair market value and commercial reasonableness opinions related to healthcare enterprises, assets, and services. In addition, Mr. Chen prepares, reviews and analyzes forecasted and pro forma financial statements to determine the most probable future net economic benefit related to healthcare enterprises, assets, and services, and applies utilization demand and reimbursement trends to project professional medical revenue streams, as well as ancillary services and technical component (ASTC) revenue streams. Mr. Chen has a Master of Science in Finance from Washington University St. Louis.