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

Medicare Part D Proposed Rule Seeks to Lower Drug Spending

On November 26, 2018, the *Centers for Medicare & Medicaid Services* (CMS) issued a proposed rule regarding *Medicare Part D* and *Medicare Advantage* (MA) drug pricing with the intention of lowering high drug costs and reducing out-of-pocket spending for patients.[1] This proposal is consistent with the Trump Administration's *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (Blueprint) released earlier this year,[2] spurring the release of this proposal as well as other drug pricing proposals, such as the Medicare Part B international pricing index model[3] and the 340B prescription discount program (the final rule which will take effect January 1, 2019).[4] The utilization of the proposed reform strategies set forth by the Blueprint, along with this proposed Part D and MA drug pricing rule, seeks to: *improve competition*; *increase negotiation*; *incentivize lower list prices*; and, *lower out-of-pocket costs.*[5]

This proposed rule is principally focused granting greater flexibility for plans as regards "*protected class*" drugs, i.e., classes of drugs that Part D plans are required to cover with limited exceptions.[6] This proposal was prompted in part by the challenges related to the rapidly increasing price of drugs in protected drug classes (antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics).[7] For example, Latuda®, a drug that more than 100,000 Medicare beneficiaries utilize, has increased in price by approximately 19% every year between 2013 and 2017, subsequently increasing costs for beneficiaries.[8] In addition, because Part D plans must cover all available products with very few exceptions, the nature of these protected classes results in Part D plans having limited ability to negotiate their pricing, allowing the pharmaceutical industry to raise their prices with minimal plan pushback.[9] For example, drugs in Part D protected classes have discounts of approximately 6%, while discounts for the same drugs in a typical private market are 20 to 30%.[10] These limited discounts result in increased costs for beneficiaries, and the new proposal attempts to mitigate these challenges for both the consumers and the plans. While the proposed rule keeps all six protected drug classes, it aims to increase flexibility for plans to negotiate discounts so that Part D consumers receive lower costs.[11]

In addition, the rule proposes three new exceptions for Part D plans to better manage the protected drug classes to lower drug costs for beneficiaries and payors.[12] The first exception would allow plan sponsors to "*implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indication*."[13] Under this exception, prior authorization would be necessary to determine whether a drug that has more than one intended use is being used for the protected class indication, regardless of its status as a new start or existing therapy.[14] Additionally, the exception utilizes a step therapy requirement (i.e., utilizing less expensive drug therapies before transitioning into higher cost options), which applies only to new starts of medication, and must receive the approval of the plan's pharmacy and therapeutics committee, which CMS believes is a cost-effective utilization management tool.[15] For example, instead of starting a Medicare beneficiary on an expensive biologic, the beneficiary would start on a lower-cost biosimilar that could potentially be just as effective.[16]

The second exception would "*exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market*."[17] For example, a manufacturer might introduce a more expensive, enhanced version of a drug while withdrawing the older, less expensive version from the market.[18] Under the current regulations, this leaves Part D plans with no option to add the new (more expensive) drug to their formularies, consequently raising costs for enrollees and Part D plans.[19] However, the exception would allow Part D insurers to remove coverage from new formulation drugs, regardless if the older version is still on the market.[20]

The third exception allows plans to "*exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period*."[21] This exclusion would allow Part D sponsors to exclude a protected class drug whose price increases (relative to the price in a baseline month and year) beyond the rate of inflation, utilizing calculations from the *Consumer Price Index for all Urban Consumers* (CPI-U).[22]

Partnership for Part D Access, which is comprised of patient advocacy groups, has expressed concern about the potential implications of these proposed changes, e.g., it may force beneficiaries to switch to less-costly, but

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potentially less-effective, drugs.[23] Other advocacy groups believe that utilization management practices already in place limit patient access and employing additional tools such as prior authorization and step therapy could further delay access to care.[24] The *Community Oncology Alliance* (COA) has also commented on the access issue, claiming that navigation through drug hurdles would be an unnecessary burden for beneficiaries and would delay cancer treatment, leading to potentially fatal consequences.[25]

In addition to the above provisions, the proposed rule contains less controversial measures. For example, Part D e-prescribing standards would be updated to increase the utilization of *Real Time Benefit Tools* (RTBT), requiring each Part D plan to implement one RTBT starting before or on January 1, 2020.[26] This tool would help inform prescribers whether there are less expensive therapy alternatives under a beneficiary's prescription drug benefit, potentially resulting in improved medication adherence and lower drug, as well as out-of-pocket, costs.[27] Part D explanations of benefits (EOB) sent to plan members would also be revised to include drug pricing information and lower cost therapeutic alternatives.[28] In addition, Part D sponsors would be restricted from prohibiting or penalizing pharmacies from disclosing a lower cash price to an enrollee to help lower out-of-pocket costs for beneficiaries (i.e., gag clauses).[29]

As currently defined, negotiated drug prices "*must include all pharmacy payment adjustments except those contingent amounts that cannot be 'reasonably be determined' at the point-of-sale*."[30] Due to this definition, negotiated prices often lack performance adjustments, as they typically occur after the point-of-sale.[31] As a result, CMS will potentially implement a policy that would consider the negotiated price "*as the baseline, or lowest possible payment to a pharmacy*."[32] Redefining this term would mean that the price would need to include all price concessions that could possibly flow from network pharmacies, as well as any dispensing fees, but exclude any additional contingent amounts.[33] CMS estimates that beneficiaries would save $7.1 to $9.2 billion over 10 years; however, the cost to the government over this time period would be approximately $13.6 to $16.6 billion due to the expected growth in Medicare's direct subsidies of plan premiums and low income premium subsidies.[34]

Under the proposed rule, MA plans would also implement prior authorization and step therapy for Part B (i.e., physician administered) drugs as a utilization management tool to better ensure low overall, or per unit, payments for Medicare beneficiaries.[35] The intended outcome for the utilization of step therapy would be increased savings, resulting in a decrease in MA premiums. However, similar to Part D step therapy, one concern is that this requirement would restrict access to medications.[36] However, CMS assures that there would be patient protections to guard against discriminatory practices, such as denying approval based on disease, with an expedited appeals process in place for when a physician recommends a medication exception.[37]

This proposed rule, which seeks to lower drug costs and reduce out-of-pocket spending for patients, is consistent with the aims articulated by the Trump Administration in the Blueprint and other drug pricing proposals released this year. This newest effort seeks to allow increased negotiation, mainly in Part D plans, for lower costs and inclusion of alternative therapies to beneficiaries. Although the intent is to lower drug costs, patient advocacy groups have expressed concern that some of the proposed changes could potentially limit patient access to more effective and beneficial drugs. The proposed rule is open for public comment until January 25, 2019.[38]

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Todd A. Zigrang, MBA, MHA, CVA, 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.