

## CMS Proposed Rule Supports Value-Based Purchasing for Drugs

On June 19, 2020 the *Centers for Medicare & Medicaid Services* (CMS) issued a proposed rule regarding *Medicaid Drug Rebate Program* (MDRP) regulations, with the aim of lowering drug prices, increasing patient access, and encouraging innovation in the insurance and pharmaceutical industries.<sup>1</sup> This proposal is consistent with the Trump Administration's *Blueprint to Lower Drug Prices* (Blueprint) released in May 2018, in which the administration highlighted its goal to "avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid" and to "speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers."<sup>2</sup> The proposed rule seeks to accomplish the Blueprint's goals by reducing regulatory barriers that have previously prevented commercial plans and states from entering into *value-based purchasing* (VBP) arrangements with drug manufacturers.<sup>3</sup>

Over the past decade, there have been significant strides in the development of curative therapies.<sup>4</sup> In 2017, the *U.S. Food & Drug Administration* (FDA) approved its first gene therapy<sup>5</sup> – since then, three additional gene therapies have been approved.<sup>6</sup> This exponential growth in the approval of curative therapies has highlighted the need for innovation in drug payment models, putting increasing pressure on CMS to remove the regulatory barriers that allow for such innovation.<sup>7</sup> The Administrator of CMS, Seema Verma, cited this urgency for new drug payment models to keep pace with the pharmaceutical industry's innovation in curative therapies in announcing the proposed rule.<sup>8</sup> With its publication of the proposed rule, CMS highlighted the potential of the adoption of VBP arrangements by state Medicaid programs and commercial payors in increasing patient access to innovative treatments, lowering healthcare spending, and encouraging innovation in the pharmaceutical industry.<sup>9</sup>

The proposed rule seeks to increase patient access to innovative drugs by allowing for payors to facilitate VBP arrangements.<sup>10</sup> Despite the rapid emergence of curative therapies, patient accessibility to these treatments remains largely restricted.<sup>11</sup> Due to the high price tag and the novelty of curative therapies, many patients are finding it difficult to obtain coverage from their insurance provider for curative therapies.<sup>12</sup> Under traditional payment models, there is significant financial risk for insurers to provide coverage for curative treatments such as gene therapy.<sup>13</sup> For example, Luxturna, a one-time gene therapy treatment, approved by the FDA in 2017 to treat a rare form of inherited vision loss,

has a list price of \$850,000.<sup>14</sup> Given the high cost of treatment, under traditional payment models, many insurance companies would wait to cover the treatment until the drug had demonstrated efficacy.<sup>15</sup> However, for a drug designed to treat rare diseases, treating enough patients to reach the insurance provider's threshold of demonstrated efficacy could take several years, preventing patients from receiving that treatment in the interim.<sup>16</sup> However, under a VBP arrangement, payors and drug manufacturers could agree to drug rebates based on patient outcomes.<sup>17</sup> The Luxturna manufacturer has pursued a VBP arrangement with select payors to offer a rebate based on the efficacy of the drug at 30 days, 90 days, and 30 months.<sup>18</sup> Outcome-based VBP arrangements such as this can mitigate some of the risk that is preventing payors from covering these curative treatments. Subsequently, with the risk of coverage minimized under a VBP arrangement, payors could expand coverage for curative treatments, increasing patient access to the novel therapies.<sup>19</sup>

Moreover, the expansion of patient access to curative treatments has the potential to decrease healthcare spending as a whole.<sup>20</sup> Treating the symptoms and complications of the conditions most frequently addressed with curative therapies over the course of a patient's lifetime is costly.<sup>21</sup> However, if treated by emerging curative therapies, lifetime costs for these conditions may be significantly reduced.<sup>22</sup> For example, the lifetime costs of hemophilia A, a condition with a curative treatment that is currently under FDA priority review, can exceed \$25 million per person.<sup>23</sup> However, a new, one-time gene therapy designed to treat hemophilia A is projected to cost \$2 to \$3 million for a single treatment.<sup>24</sup> If approved, this treatment could reduce lifetime healthcare expenditures by more than \$20 million per patient.<sup>25</sup> However, the reduction in healthcare expenditures can only be realized if there is substantial improvement in patient access to these curative treatments, highlighting the need for flexibility to implement VBP arrangements for such drugs.<sup>26</sup>

Finally, the proposed rule aims to encourage further innovation in the pharmaceutical industry. Drug manufacturers invest significant resources in the development of new drugs with the intention that they will receive a profit generated from drug reimbursement. Under a VBP arrangement, drug manufacturers must be confident in the efficacy of their drug to ensure that they will not lose money in rebates to payors for ineffective drugs.<sup>27</sup> This demand for quality may serve to encourage increased

competition and further innovation in the pharmaceutical industry.<sup>28</sup>

Despite the promising implications of VBP arrangements, regulatory roadblocks have prevented these benefits from being realized.<sup>29</sup> For the past 30 years, MDRP regulations have largely impeded the implementation of VBP arrangements.<sup>30</sup> Under the MDRP, to be covered under Medicaid, drug manufacturers must enter into a rebate agreement with CMS, affirming that they will rebate a portion of what state Medicaid programs pay for the drug back to the states.<sup>31</sup> The size of the rebate is determined by what is commonly known as the “best price” rule.<sup>32</sup> Under this requirement, the rebate required to be paid to the states is either: (1) a certain percentage (23.1%, 17.1%, or 13%, depending on the type of drug) of the drug’s *average manufacturer price* (AMP); or, (2) the manufacturer’s “best price,”<sup>33</sup> i.e., the lowest price after rebates and discounts that a drug manufacturer offers to any other party (e.g., retailer, provider, wholesaler) in the U.S.<sup>34</sup> The “best price” rule is largely attributed to the lack of VBP arrangements currently in effect.<sup>35</sup>

Under the current MDRP requirements, manufacturers are required to rebate states so that the net price of the drug paid by state Medicaid programs is no greater than that manufacturer’s “best price.”<sup>36</sup> For example, a drug manufacturer could enter into a VBP arrangement with a commercial payor wherein the manufacturer receives reimbursement only if the drug is effective in treating a patient.<sup>37</sup> If, in a single beneficiary of the commercial payor, the drug is not effective, the lowest net price for a single unit of that drug paid by the commercial payor would be \$0.<sup>38</sup> Subsequently, under the MDRP’s current definition of “best price,” the best price of that drug is \$0.<sup>39</sup> This means that the manufacturer would be required to rebate the entire price of the drug to states regardless of overall patient outcomes.<sup>40</sup> This possibility has prevented manufacturers from entering into VBP arrangements.<sup>41</sup> Additionally, many payors are interested in entering into VBP arrangements with manufacturers that consist of rebates contingent on patient outcomes over an extended period to evaluate the performance of a drug over a patient’s lifetime.<sup>42</sup> This is to mitigate the financial burden taken on by the payor if, for example, after 10 years, disabling side effects present or the effectiveness of the drug diminishes over time.<sup>43</sup> However, because of the “best price” rule, manufacturers cannot offer rebates contingent on a drug’s performance more than 3 years after the drug is administered to a patient since that would reduce the price of the drug beyond the 12-quarter MDRP reporting period.<sup>44</sup> The lack of flexibility to evaluate patient outcomes from a drug over a longer period of time has diminished the appeal of VBP arrangements.<sup>45</sup>

To address the limitations of current MDRP requirements, the proposed rule redefines the “best price” reporting requirements for manufacturers.<sup>46</sup> Instead of reporting using the current method of reporting the lowest price of a single unit offered in the U.S., manufacturers can report the best

price of “*bundled sales*.”<sup>47</sup> This would allow manufacturers to report the lowest average net price of a drug.<sup>48</sup> For each VBP arrangement entered into by the manufacturer, the manufacturer would calculate the average net price of all the units sold under that arrangement and report the lowest average net price as the “*best price*.”<sup>49</sup> For example, a manufacturer could enter into an agreement requiring the sale of 500 units at \$1,000 per unit, with a rebate of 75% if the patient has a negative outcome.<sup>50</sup> Since all of the units sold in the agreement were subject to the same performance terms, a manufacturer could treat this agreement as a bundled sale.<sup>51</sup> If 10 patients have a negative outcome, the manufacturer would then calculate the average net price as follows:

$$\begin{aligned} 500 \text{ units} \times \$1,000 &= \$500,000 - [10 \text{ patients with a} \\ &\text{negative outcome} \times \\ &(\$1,000 \times 75\%)] = \$492,500 \div 500 = \$985^{52} \end{aligned}$$

If \$985 was the lowest average net price of all of the agreements entered into by the manufacturer for that drug, then the manufacturer would report \$985 as the best price.<sup>53</sup> Alternatively, the proposed rule allows for manufacturers to report “*best price points*” to enable VBP arrangements that have multiple price points for a drug depending on the patient outcome realized.<sup>54</sup> Under this structure, manufacturers would report a set of best prices based on the various outcome- or evidence-based measures offered by the manufacturer through its various VBP arrangements.<sup>55</sup> The manufacturer would supplement these “*best price points*” with a single “*best price*.”<sup>56</sup> This would allow for state Medicaid programs to participate in VBP arrangements with drug manufacturers while still ensuring the best price is being awarded to Medicaid and keeping the integrity of the MDRP intact.<sup>57</sup> Additionally, to address the restriction of the three-year evaluation period caused by the MDRP 12-quarter reporting period, the proposed rule allows for manufacturers to make changes to the reported AMP or best price outside of the 12-quarter reporting period, to allow for VBP arrangements that consider outcomes beyond a three-year period.<sup>58</sup>

Thus far, there has been support for VBP arrangements from industry stakeholders.<sup>59</sup> Over the past few years, commercial payors and drug manufacturers alike have been calling for changes in regulation that would allow for the facilitation of VBP arrangements.<sup>60</sup> Some stakeholders, such as Harvard Pilgrim Health Plan and pharmaceutical companies Spark Therapeutics and Repatha, have already begun small-scale VBP arrangements.<sup>61</sup> However, many industry players remain skeptical over the value of VBP arrangements.<sup>62</sup> Critics emphasize the complexity of developing VBP arrangements and cite concerns that VBPs may encourage pharmaceutical companies to set higher drug prices.<sup>63</sup> In announcing the proposed rule, Verma stated that the proposed rule “*doesn’t necessarily guarantee low prices, but what it does do is it provides a tool in the toolbox for plans to negotiate with manufacturers.*”<sup>64</sup> The proposed rule is open for public comment until July 20, 2020.<sup>65</sup>

1 “CMS Issues Proposed Rule to Empower Commercial Plans and States to Negotiate Payment for Innovative New Therapies Based on Patient Outcomes” Centers for Medicare and Medicaid, June 19, 2020, <https://www.cms.gov/newsroom/press-releases/cms-issues-proposed-rule-empower-commercial-plans-and-states-negotiate-payment-innovative-new> (Accessed 6/19/20); “Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements” Federal Register, Vol. 85, No. 119 37286 (June 19, 2020), p.

2 “President Donald J. Trump’s Blueprint To Lower Drug Prices” The White House, May 11, 2018, <https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/> (Accessed 6/19/20).

3 Centers for Medicare and Medicaid, June 19, 2020.

4 “Precision Financing Solutions for Durable/ Potentially Curative Therapies” MIT Center for Biomedical Innovation FoCUS, January 24, 2019, accessed via <https://newdigs.mit.edu/sites/default/files/MIT%20FoCUS%20recision%20Financing%202019F201v023.pdf> (Accessed 6/19/20).

5 “FDA approval brings first gene therapy to the United States,” U.S. Food & Drug Administration, August 30, 2017, <https://www.fda.gov/news-events/press-announcements/fda-approval-brings-first-gene-therapy-united-states> (Accessed 6/19/20).

6 Centers for Medicare and Medicaid, June 19, 2020.

7 “CMS’s Proposed Rule On Value-Based Purchasing For Prescription Drugs: New Tools For Negotiating Prices For The Next Generation of Therapies” By Seema Verma, Health Affairs, June 17, 2020, <https://www.HealthAffairs.org/doi/10.1377/hblog20200617.728496/full/> (Accessed 6/19/20).

8 *Ibid.*

9 Centers for Medicare and Medicaid, June 19, 2020.

10 Verma, June 17, 2020).

11 “Are Payers Ready To Address The Financial Challenges Associated With Gene Therapy?” By Michael Ciarametaro, et al., Health Affairs, June 28, 2018, <https://www.HealthAffairs.org/doi/10.1377/hblog20180626.330036/full/> (Accessed 6/18/20).

12 *Ibid.*

13 *Ibid.*

14 “Juno And Other Gene Therapy Players Are Hot Despite Ongoing Pricing Debates” By Arlene Weintraub, Forbes, <https://www.forbes.com/sites/arnelneweintraub/2018/01/18/juno-and-other-gene-therapy-players-are-hot-despite-ongoing-pricing-debates/#22f1fc585fd9> (Accessed 6/19/20); U.S. Food and Drug Administration, December 18, 2017.

15 “Ciarametaro, et al., June 28, 2018.

16 *Ibid.*

17 Centers for Medicare and Medicaid, June 19, 2020.

18 Weintraub, (Accessed 6/19/20)

19 *Ibid.*

20 Verma, June 17, 2020.

21 “Putting The Costs And Benefits Of New Gene Therapies Into Perspective” By Joshua T. Cohen James D. Chambers Madison C. Silver Pei-Jung Lin Peter J. Neumann, Health Affairs, September 4, 2019, <https://www.HealthAffairs.org/doi/10.1377/hblog20190827.553404/full/> (Accessed 6/19/20).

22 *Ibid.*

23 “FDA Accepts BioMarin’s Submission for Valrox, a Gene Therapy for Hemophilia A” By Mark Terry, BioSpace, February 21, 2020, <https://www.biospace.com/article/fda-agrees-to-review-biomarin-s-hemophilia-a-gene-therapy-application/#:~:text=FDA%20Accepts%20BioMarin's%20Submission%20for%20Valrox%2C%20a%20Gene%20Therapy%20fo>

r%20Hemophilia%20A,-  
Published%3A%20Feb%202021&text=The%20U.S.%20Food%20and%20Drug,was%20accepted%20for%20Priority%20Review.  
(Accessed 6/19/20).

24 *Ibid.*

25 *Ibid.*

26 Verma, June 17, 2020.

27 *Ibid.*

28 *Ibid.*

29 “Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements” Federal Register, Vol. 85, No. 119 (June 19, 2020), p. 37288.

30 Verma, June 17, 2020.

31 “Understanding the Medicaid Prescription Drug Rebate Program” By Rachel Dolan, Kaiser Family Foundation, November 12, 2019, <https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/> (Accessed 6/19/20); “Payment for Covered Outpatient Drugs” 42 U.S. Code § 1396r–8 (c)(1)(C) (2019).

32 Verma, June 17, 2020.

33 Dolan, November 12, 2019.

34 *Ibid.*; “Payment for Covered Outpatient Drugs” 42 U.S. Code § 1396r–8 (c) (1) (C) (2019); Verma, June 17, 2020.

35 Federal Register, Vol. 85, No. 119.

36 *Ibid.*, p. 37288.

37 *Ibid.*, p. 37291.

38 *Ibid.*

39 *Ibid.*

40 *Ibid.*

41 *Ibid.*, p. 37288.

42 *Ibid.*, p. 37288.

43 *Ibid.*, p. 37288.

44 *Ibid.*, p. 37288.

45 Verma, June 17, 2020.

46 Federal Register, Vol. 85, No. 119, p. 37292.

47 *Ibid.*

48 *Ibid.*

49 *Ibid.*

50 *Ibid.*

51 *Ibid.*

52 *Ibid.*

53 *Ibid.*

54 *Ibid.*, p. 37293.

55 *Ibid.*

56 *Ibid.*

57 *Ibid.*

58 *Ibid.*, p. 37301.

59 “Outcomes-based Pricing Not A Panacea For High Priced Drugs” By John LaMattina, Forbes, March 27, 2019, <https://www.forbes.com/sites/johnlamattina/2019/03/27/outcome-s-based-pricing-not-a-panacea-for-high-priced-drugs/#10f173e15c23> (Accessed 6/19/20).

60 *Ibid.*

61 *Ibid.*

62 “As a cure for high drug prices, outcomes-based deals aren’t delivering yet” By Harris Meyer, Modern Healthcare, March 23, 2019, <https://www.modernhealthcare.com/insurance/cure-high-drug-prices-outcomes-based-deals-arent-delivering-yet> (Accessed 6/19/20).

63 *Ibid.*

64 “CMS aims to spur value-based payment arrangements between drugmakers and insurers, including Medicaid” By Rich Daly, Healthcare Financial Management Association, June 19, 2020, <https://www.hfma.org/topics/news/2020/06/cms-aims-to-spur-value-based-payment-arrangements-between-drugma.html> (Accessed 6/19/20)

65 Federal Register, Vol. 85, No. 119, p. 37286.





**(800)FYI - VALU**

*Providing Solutions  
in the Era of  
Healthcare Reform*

Founded in 1993, HCC is a  
nationally recognized healthcare  
economic financial consulting firm

- [HCC Home](#)
- [Firm Profile](#)
- [HCC Services](#)
- [HCC Experts](#)
- [Clients & Projects](#)
- [HCC News](#)
- [Upcoming Events](#)
- [Contact Us](#)
- [Email Us](#)

## HCC Services

- [Valuation Consulting](#)
- [Commercial Reasonableness Opinions](#)
- [Commercial Payor Reimbursement Benchmarking](#)
- [Litigation Support & Expert Witness](#)
- [Financial Feasibility Analysis & Modeling](#)
- [Intermediary Services](#)
- [Certificate of Need](#)
- [ACO Value Metrics & Capital Formation](#)
- [Strategic Consulting](#)
- [Industry Research Services](#)



**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 25 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 2,000 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).



**Jessica L. Bailey-Wheaton**, Esq., is Senior Vice President and General Counsel of 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.

She serves on the editorial boards of NACVA's *The Value Examiner* and of the American Health Lawyers Association's (AHLA's) *Journal of Health & Life Sciences Law*. Additionally, she is the current Chair of the American Bar Association's (ABA) Young Lawyers Division (YLD) Health Law Committee and the YLD Liaison for the ABA Health Law Section's Membership Committee. She has previously presented before the ABA, NACVA, and the National Society of Certified Healthcare Business Consultants (NSCHBC).

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, focuses on developing Fair Market Value and Commercial Reasonableness opinions related to healthcare enterprises, assets, and services. In addition he 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 and ancillary services and technical component (ASTC) revenue streams. Mr. Chen holds the Certified Valuation Analyst (CVA) designation from NACVA.