



July 20, 2020

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Docket No. CMS-2482-P, “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”

Introduction

On behalf of National Taxpayers Union (NTU), I write in response to the Center for Medicare and Medicaid Services’ (CMS) Proposed Rule, “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.” Although NTU shares CMS’ goal of reducing out of pocket drug costs for American patients, we urge CMS to withdraw the portions of the Proposed Rule that would expand the definition of “line extension” and change how accumulator adjustment programs impact manufacturers’ best price obligations in Medicaid.

NTU’s Stake in Prescription Drug Policy

NTU is the nation’s oldest taxpayer advocacy organization, and our advocates and experts have been stakeholders in prescription drug policy for decades. Policymakers in Washington, D.C. and in the states exercise significant leverage over whether a drug is approved or not, how it may be marketed, and (in the case of Medicare and Medicaid) how that approved and marketed drug is priced. While we seek limited government interference in the development, approval, marketing, and pricing of prescription drugs, NTU also acknowledges that the generic drug competition ushered in by the Hatch-Waxman law has made the United States the only country in the world that:

“...can boast of such a successful policy environment that both encourages discoveries to reach patients (nearly 90 percent of newly launched drugs worldwide are available here) and controls costs (over 90 percent of prescriptions written in the U.S. are for generics).”¹

¹ Sepp, Pete. “Hatch-Waxman Drug Patent Law Meets Middle Age – and Taxpayers Can Celebrate.” National Taxpayers Union, April 1, 2019. Retrieved from:

<https://www.ntu.org/publications/detail/hatch-waxman-drug-patent-law-meets-middle-age-and-taxpayers-can-celebrate>

To that end, we work actively with Congress, federal agencies, and state capitals to craft pro-taxpayer, pro-consumer, and market-oriented prescription drug policy.² We have generally supported value-based approaches to providing care - including drug therapies - both in concept and often in practice. Taxpayers can benefit if value-based care is properly implemented. As we noted in 2018:

“Value-based health care has more potential than any other model for delivering what free-market public policy advocates have long sought: stronger patient-provider relationships, consumers empowered with decision-making over how to deploy resources, limited government interference in the evolution of services, and nimble programs capable of embracing evidence-based results. Ultimately, this approach boils down to paying for individualized drug therapies whose effectiveness is based on measurable outcomes -- prevention of costlier problems and treatments down the line. This will foster an organic fiscal responsibility that is far more durable than complex rules, price controls, or rationing.”³

Unfortunately, at least two major portions of the Agency’s Proposed Rule are significantly flawed, and would distort the market dynamics that bring patients new treatments while also providing cost assistance for the most economically vulnerable Americans.

New Definitions for “Line Extension” and “New Formulation”

The Agency’s Proposed Expansion of the “Line Extension” Definition Goes Well Beyond the Statutory Language

The statutory definition of a “line extension” in the Affordable Care Act (ACA) is quite limited. It reads:

“In this subparagraph, the term ‘line extension’ means, with respect to a drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.”⁴

The Agency proposes effectively expanding this definition, by adding at least eight different types of drug improvements, changes, or developments to the Agency’s interpretation of what constitutes a “new formulation.” In addition to extended release formulations, the *only* specific change the statute mentions, the Agency proposes adding to the definition of “new formulation”:

- Changes in dosage form;
- Changes in strength;
- Changes in route of administration;

² See: Sepp, Pete, “Prescription Drug Costs: Better Ways to Help Patients and Taxpayers.” National Taxpayers Union, December 6, 2018. Retrieved from: <https://www.ntu.org/publications/detail/prescription-drug-costs-better-ways-to-help-patients-and-taxpayers>; and Lautz, Andrew, “Pro-Taxpayer Ways to Increase the Availability and Use of Biosimilars.” National Taxpayers Union, September 16, 2019. Retrieved from: <https://www.ntu.org/publications/detail/pro-taxpayer-ways-to-increase-the-availability-and-use-of-biosimilars>

³ Sepp, Pete. "Prescription Drug Costs: Better Ways to Help Patients and Taxpayers." National Taxpayers Union, December 6, 2018. Retrieved from: <https://www.ntu.org/publications/detail/prescription-drug-costs-better-ways-to-help-patients-and-taxpayers>

⁴ 42 U.S.C. 1396r-8(c)(2)(C)

- Changes in ingredients;
- Changes in pharmacodynamics;
- Changes in pharmacokinetics;
- Changes in indication (i.e., particular conditions, symptoms, or diseases a drug treats) “accompanied by marketing as a separately identifiable drug”; and
- Combination drugs, “such as a drug that is a combination of two or more drugs or a drug that is a combination of a drug and a device.”

This is a significant expansion of the definition beyond what lawmakers wrote in the statute. The Agency offers as a defense for this expansion:

“Based on the definition of line extension that was included in the Affordable Care Act, we believe that the statute gives us discretion and authority to interpret the term ‘line extension’ broadly.”

Nowhere in the statute, which both the Secretary of Health and Human Services⁵ and the Administrator of the Centers for Medicare and Medicaid Services⁶ have deemed a “failure,” did lawmakers give CMS the authority or the encouragement to define “line extension” broadly. The same argument applies to the definition of “new formulation.”

The Agency’s extraordinary expansion of a fairly limited definition in law runs counter to this Administration’s deregulatory agenda. NTU recently wrote of the Administration’s Executive Order 13924, “Regulatory Relief To Support Economic Recovery”:

“Reining in unnecessary impositions upon the private market is the appropriate approach to ensuring greater prosperity for all, but the principles of deregulation can also be used to promote public health access and reduce healthcare costs.”⁷

The Agency’s proposed changes to the definitions of “line extension” and “new formulations” run counter to the approach NTU described above - they place *new* and unnecessary impositions on the private market, rather than reining them in.

Most importantly, many of the above additions to the definition of “new formulation” represent improvements to a drug, for both the patients taking them and the providers administering them. For example, a change in the route of administration could involve an injectable drug becoming a tablet instead. A change in strength could mean a patient has to take a particular drug less often. The Agency’s Proposed Rule would punish these

⁵ Secretary Alex Azar. “The failure of Obamacare and the success of our efforts to stabilize the health insurance market should be a lesson for all future efforts. Empowering decision-makers closest to patients is both the way of the future and a return to what we love about American healthcare.” Twitter, October 3, 2018. Retrieved from: <https://twitter.com/SecAzar/status/1047599965651030016> (Accessed July 8, 2020.)

⁶ Verma, Seema. “Thank Obamacare for the Rise of the Uninsured.” CMS.gov, September 13, 2019. Retrieved from: <https://www.cms.gov/blog/thank-obamacare-rise-uninsured> (Accessed July 8, 2020.)

⁷ Aiello, Thomas. “President Trump Prioritizes Deregulation to Advance the Economic Recovery.” National Taxpayers Union, May 20, 2020. Retrieved from: <https://www.ntu.org/publications/detail/president-trump-prioritizes-deregulation-to-advance-the-economic-recovery> (Accessed July 8, 2020.)

innovations by making manufacturers pay higher rebates for these drugs. While NTU believes many aspects of the Medicaid Drug Rebate Program (MDRP) are flawed, at the very minimum the Agency should avoid regulatory expansions that increase the rebates manufacturers pay in the MDRP. These rebate costs are ultimately paid by patients, who are harmed by either less innovation in the prescription drug space or higher health care costs. Over the longer term, as the development of innovative care slows, taxpayers providing support to government health care programs bear heavier burdens than they otherwise would due to more expensive care such as surgeries and longer hospital stays.

The Agency's Inclusion of New Indications as a Line Extension Could Adversely Impact the Fight for COVID-19 Treatments

One of the eight expansions the Agency proposes for the definition of “new formulation” is a change in indication. This proposed expansion could not come at a worse time for patients, providers, or manufacturers, given hundreds of clinical trials are testing the safety and effectiveness of using existing drugs to treat COVID-19.⁸ A recent news report cited over 30 specific, existing drugs that are currently in clinical trials as potential COVID-19 treatments or cures.⁹

To its credit, the Agency noted in its current Proposed Rule that commenters critiqued a similar provision in a previous proposed rule, from 2012:

“We received several comments stating that the proposal was not feasible because the approval of a new indication for an already approved drug may not result in a different drug product and it would not be logical that a drug is a line extension of itself.”

The Agency's concession to these critics in 2020, though, falls well short. The Agency suggests only applying the additional rebate if “the manufacturer markets the drug in such a way that it is a separately identifiable drug product.” This is, at face value, an absurd limitation. The Agency essentially says here that if a manufacturer finds that an existing drug can apply to a new condition or disease, it can only avoid the additional rebate if it *doesn't market* this drug's new indication to patients and providers. This amounts to a gag rule on manufacturers who make the effort to discover new uses for existing drugs.

The Medicaid Drug Rebate Program Is Flawed, and Additional Rebates Will Lead To Either Less Innovation or Higher Costs for Patients

NTU must note that the entire structure of the Medicaid Drug Rebate Program (MDRP) is flawed, and that at a minimum the Agency should remove the provisions of this Proposed Rule that expand rebates under the MDRP.

⁸ National Institutes of Health (NIH) U.S. National Library of Medicine. (July 8, 2020). ClinicalTrials.gov Search for “COVID-19.” Retrieved from: <https://clinicaltrials.gov/ct2/results?cond=COVID-19> (Accessed July 8, 2020.)

⁹ Blankenship, Kyle; Kansteiner, Frasier. “UPDATED: Which old drugs are in trials for new COVID-19 use? Here's a rundown.” *Fierce Pharma*, May 4, 2020. Retrieved from: <https://www.fiercepharma.com/pharma/drugmakers-look-to-repurposed-meds-as-possible-therapies-for-covid-19-list> (Accessed July 8, 2020.)

The value of additional rebates are not realized by Medicaid patients at the point of sale. Medicaid cost-sharing requirements are already quite low, including for generic, preferred brand name, and non-preferred brand name drugs.¹⁰ This is consistent with the goals of the Medicaid program to provide low-cost health coverage to low-income Americans and vulnerable populations. However, these low cost-sharing requirements mean that every additional dollar of Medicaid rebates benefit state Medicaid agencies and the federal government, not patients or providers.

The value of Medicaid rebates is already extraordinary relative to gross drug spending in the program. According to the Medicaid and CHIP Payment and Access Commission (MACPAC):

“In fiscal year (FY) 2017, Medicaid spent approximately \$64.0 billion on outpatient prescription drugs and collected \$34.9 billion in rebates, bringing net drug spending to \$29.1 billion (Table 1). Net spending for outpatient drugs accounted for about 5.1 percent of total Medicaid benefit spending.”¹¹

While these rebates may, at face value, be paid by manufacturers, this distortion of market dynamics pushes the costs of providing health goods and services onto nearly every other payer, including patients, providers, insurers, and manufacturers. Among the impacts of MDRP rebates are:

- Less capital and lower incentives for manufacturers to pursue the risky and expensive process of researching, developing, seeking approval for, and marketing new drugs;
- The potential for higher launch prices for new drugs that *do* make it to market, as manufacturers seek to counteract the effect of discounts that reduce the value of their drugs by 50 percent or more; and
- Less private sector negotiation over drug prices between plans and manufacturers.¹²

This all translates to less innovation for patients and providers, and higher health care costs for patients and for the taxpayers who support federal health programs. Given all of the above reasons, NTU recommends the Agency withdraw its proposed expansion of the definitions for “line extension” and “new formulation.”

¹⁰ Kaiser Family Foundation. (January 1, 2020). “Premium and Cost-Sharing Requirements for Selected Services for Medicaid Adults.” Retrieved from: <https://www.kff.org/health-reform/state-indicator/premium-and-cost-sharing-requirements-for-selected-services-for-medicaid-expansion-adults/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (Accessed July 8, 2020.)

¹¹ Medicaid and CHIP Payment and Access Commission. (February 2019). “Medicaid Drug Spending Trends.” Retrieved from: <https://www.macpac.gov/wp-content/uploads/2019/02/Medicaid-Drug-Spending-Trends.pdf> (Accessed July 8, 2020.)

¹² For more on these effects, see: Hayes, Tara O’Neill. “Primer: The Medicaid Drug Rebate Program.” American Action Forum, February 7, 2019. Retrieved from: <https://www.americanactionforum.org/research/primer-the-medicaid-drug-rebate-program/> (Accessed July 7, 2020.)

Exclusion of Manufacturer-Sponsored Patient Assistance From Best Price Determinations

The Agency's Proposed Exclusion Would Interfere With an Important Market Mechanism for Reducing Out-of-Pocket Drug Costs

The Agency has proposed excluding manufacturer-sponsored patient assistance programs from best price determinations in Medicaid, so long as the manufacturer cannot ensure “that the benefits of their assistance programs ... are provided entirely to the consumer.” This is a flawed proposal that will adversely impact a key, market-based mechanism for manufacturers to assist some of America’s most vulnerable patients.

A 2014 analysis from the IMS Institute for Healthcare Informatics found that manufacturer-sponsored patient assistance programs helped millions of patients save an average of \$40 per prescription.¹³ The Agency notes that some stakeholders claim these programs “steer consumers towards more expensive medications when there may be more cost saving options, such as generic substitution,” but the same 2014 analysis found that 459 of 526 patient savings programs (87 percent) were for brand name drugs with no bioequivalent generic products. Whether the Agency intends to or not, their proposed changes would interfere with a key private sector effort to reduce drug costs for patients. This is not just NTU’s opinion; see here from *Politico*’s Prescription Pulse newsletter:

“CMS’ solution is to turn copay coupons into discounts unless the manufacturer ensures the patients is [sic] in a plan that does not use accumulator programs. The problem is that manufacturers rarely if ever know when that is the case — and with the new definition of best price included in the rule, a discount of that size (hundreds if not thousands of dollars) could translate to virtually pennies for a best price payment.”¹⁴

This will have many of the same impacts described above for the proposed additional MDRP rebates -- less innovation and higher health care costs for patients, and for higher costs for the taxpayers that support federal health programs.

Patients Should Not Be Punished for Using Patient Assistance Programs

Broadly speaking, the Agency errs in putting the onus on manufacturers to ensure that plans are passing along the full savings of manufacturer-sponsored assistance programs to patients. The Agency admits that the problem here, so-called accumulator programs, is driven by plans, not manufacturers:

“We have learned that some health plans (which meet the definition of provider when determining best price) are being instructed or encouraged by their pharmacy benefit managers (PBMs) to apply manufacturer sponsored patient assistance programs, such as patient copay assistance programs, to the benefit of the plan, instead of entirely to the patient.”

¹³ IMS Institute for Healthcare Informatics. (February 2014). “Patient Savings Program Use Analysis.” Retrieved from: <https://docplayer.net/23226848-February-2014-patient-savings-program-use-analysis.html> (Accessed July 8, 2020.)

¹⁴ Owerhohle, Sarah. “Business as usual on drug prices.” *Politico*, July 8, 2020. Retrieved from: <https://www.politico.com/newsletters/prescription-pulse/2020/07/08/business-as-usual-on-drug-prices-489733> (Accessed July 8, 2020.)

The Agency also admits that plans realize the benefits of these accumulator programs, not patients:

“As demonstrated by the example above, the health plan is benefiting from the manufacturer sponsored copay assistance program instead of the patient (consumer). However, manufacturers, in these instances, claim they are not aware of when these practices by the health plans take place, and therefore, make reasonable assumptions that their discount programs meet the criteria at § 447.505(c) that exclude such programs from best price.”

Given the Agency understands the nature of this interaction between manufacturer-sponsored patient assistance programs and plan-sponsored accumulator programs, it makes little sense the Agency would put the burden on manufacturers to guarantee assistance program savings are fully realized by patients. Manufacturers are literally incapable of doing so, since they have no control over plan-sponsored accumulator programs.

The Agency has not given adequate consideration to the flaws with this proposal, and NTU recommends the Agency withdraw its proposed changes to how patient assistance programs impact best price.

Conclusion

NTU will continue to engage with the Agency on pro-taxpayer, pro-consumer, and market-oriented prescription drug policy. NTU has praised CMS for its commitment to market-based health reform on numerous occasions,¹⁵¹⁶¹⁷ and we look forward to opportunities to work with the Agency in the near future. However, we request that you withdraw two key provisions of your Proposed Rule: 1) the proposed expansion of the definitions for “line extension” and “new formulation,” and 2) the changes in how manufacturer-sponsored assistance programs impact Medicaid best price. Thank you for your consideration, and should you have any questions I am at your service.

Sincerely,

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¹⁵ Lautz, Andrew. “How a Drugmaker Voluntarily Lowered Their Prices for Medicare Patients.” National Taxpayers Union, September 9, 2019. Retrieved from:

<https://www.ntu.org/publications/detail/how-a-drugmaker-voluntarily-lowered-their-prices-for-medicare-patients>

¹⁶ Lautz, Andrew. “The Case Against Medicare for All? Look No Further Than Medicare Advantage.” National Taxpayers Union, September 26, 2019. Retrieved from:

<https://www.ntu.org/publications/detail/the-case-against-medicare-for-all-look-no-further-than-medicare-advantage>

¹⁷ Lautz, Andrew. “CMS Insulin Model Uses Public-Private Partnerships to Save Seniors Money.” National Taxpayers Union, May 28, 2020. Retrieved from:

<https://www.ntu.org/publications/detail/cms-insulin-model-uses-public-private-partnerships-to-save-seniors-money>