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July 20, 2020

Submitted electronically via Regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS–2482–P
P.O. Box 8016
Baltimore, MD, 21244–8016

Re: 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

Dear Administrator Verma:

On behalf of TrialCard Incorporated (TrialCard), we appreciate the opportunity to submit these comments in response to the recent proposed rule titled, *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* (CMS–2482–P) (the Proposed Rule).[1]

TrialCard is a pharmaceutical services organization whose mission is to help make medications more accessible and affordable for patients. We are a technology-enabled pharmaceutical solutions company that delivers integrated solutions to increase patient and health care professional engagement in therapy.

We write, in particular, to express grave concerns regarding the proposed changes addressed in Section II.D of the Proposed Rule, which discusses the "Exclusion of Certain Manufacturer Sponsored Patient Assistance Programs ('PBM Accumulator Programs') from Determination of Best Price (§ 447.505) and Average Manufacturer Price (AMP) (§ 447.504)."[2] This proposal, if implemented, would impose a new standard that would be impossible to meet and, consequently, would have a severely detrimental impact on patients who are most in need of support services. Moreover, the proposed changes, if finalized, would be all the more detrimental to patients during the COVID–19 pandemic and public health emergency.

In these comments, we address the following concerns and important points regarding this proposal:

- **First, the proposal would impose a new standard that is impossible for manufacturers to meet and that, if finalized, could create a situation where assistance programs cannot feasibly be continued, resulting in patients being unable to afford and therefore losing access to important medications.** Specifically, the proposed requirement that manufacturers cannot exclude assistance provided to patients from Best Price determinations or AMP

[1] 85 Fed. Reg. 37286 (June 19, 2020).
[2] 85 Fed. Reg. at 37298–37299.

calculations unless the manufacturers "**ensure** that the benefits of their assistance programs . . . are provided entirely to the consumer"[3] is an untenable standard.

CMS states in the Proposed Rule that it "believe[s] manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure the benefit goes exclusively to the consumer or patient."[4] But that belief simply is not consistent with reality. The proposal is therefore based on a fundamentally flawed perception and a faulty premise that is inconsistent with how plan and PBM accumulator programs operate. Neither patients nor manufacturers have any control over whether or in what situations a plan or PBM may apply an accumulator program, or whether the payer chooses to be forthright about whether it has such a program in place or how it operates. Indeed, there is a disturbing and pervasive lack of transparency regarding plan and PBM accumulator programs. Accordingly, it is simply not possible for a manufacturer to "ensure" that the copay assistance provided is passed on entirely to the patient, even though that is what the manufacturer intends to occur.

In addition, CMS offers no support for its asserted "belie[f]" as stated in the Proposed Rule. Without appropriate factual support, this critical element of the proposal raises serious concerns that it is arbitrary and capricious under the Administrative Procedure Act (APA).[5] Further, if CMS contends that it *does* have support for this assertion, it has failed to disclose or provide notice of that information to the public, denying stakeholders of a meaningful opportunity to comment on the proposal. That likewise would appear to constitute violation of the APA.[6]

- **<u>Second</u>, the proposal is an inappropriate mechanism for addressing the issues raised by accumulator programs that CMS identifies in the Proposed Rule and, if finalized, would result in significant harm to patients and lead to negative health outcomes.** As CMS acknowledges in the Proposed Rule, accumulator programs "generate savings for the plan"[7] at the expense of—and often to the surprise of—the patient.[8] These accumulator programs divert

[3] 85 Fed. Reg. at 37299 (emphasis added).

[4] 85 Fed. Reg. at 37299.

[5] 5 U.S.C. § 706(2)(A); *see Motor Vehicle Manufacturers Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that agency "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made"); *see also South Carolina Pub. Serv. Comm'n v. FERC*, 762 F.3d 41, 54 (D.C. Cir. 2014) ("When applied to rulemaking proceedings, the substantial evidence test 'is identical to the familiar arbitrary and capricious standard,' which 'requires the Commission to specify the evidence on which it relied and to explain how that evidence supports the conclusion it reached'") (quoting *Wisconsin Gas Co. v. FERC*, 770 F.2d 1144, 1156 (D.C. Cir. 1985)); *Business Roundtable v. SEC*, 647 F.3d 1144, 1155 (D.C. Cir. 2011) (rejecting agency justification for rule as "*ipse dixit*, without any evidentiary support and unresponsive to the contrary claim" of regulated parties).

[6] 5 U.S.C. § 553(b)–(c); *see also American Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008) (explaining that APA's notice and comment requirements mandate disclosure of "'data' upon which the agency relies [in its rulemaking]'") (quoting *Chamber of Commerce v. SEC*, 443 F.3d 890, 899 (D.C. Cir. 2006)); *Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1, 7 (D.C. Cir. 1999) (ruling that "material that is used to support the agency's position on review must have been made public in the proceeding and exposed to refutation") (internal quotation marks omitted); *Connecticut Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530 (D.C. Cir. 1982) ("In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules.").

[7] 85 Fed. Reg. at 37298.

[8] 85 Fed. Reg. at 37298 ("As a result [of accumulator programs], the manufacturer assistance does not accrue towards a patient's deductible and the patient sometimes does not realize this until the manufacturer copayment assistance runs out and the patient receives a significantly larger bill for the drug. This results in the health plan delaying the application of its plan benefit to the patient to the detriment of the patient or consumer, thus generating savings for the plan.").

assistance that is provided to patients, exacerbating existing access, affordability, and adherence challenges for patients.

Yet, rather than seeking to reduce the harm inflicted by accumulator programs through transparency requirements imposed on plans and PBMs or through limits on the application of accumulator programs (as a number of states have enacted or are currently considering[9]), the Proposed Rule takes aim at the assistance programs that are designed and intended to facilitate access and affordability for patients. If finalized as proposed, this policy change would inflict further harm on patients by severely reducing or eliminating altogether the availability of established assistance programs on which many patients rely to afford important medicines. Manufacturers may conclude that they need to dramatically reduce—or completely cease—all assistance as they may not otherwise be able to "ensure" the specific result that the new standard would require.[10] That, in turn, would have negative consequences for health outcomes and lead to increased costs for the health care system, including government programs, and for society.

- **Third, these proposed changes—and their timing—are even more troubling in light of the ongoing COVID-19 pandemic and public health emergency.** In the current environment, COVID-19 continues to grip the nation and to exacerbate access barriers and financial hardships for individuals across the country, especially those with serious and chronic health conditions. As patients and consumers continue to face these unprecedented challenges and devastating circumstances, it is simply not an appropriate time to implement ill-considered and untested policies that cut off critical resources and restrict access avenues for patients. Instead, CMS should be looking for additional ways to support patients and to facilitate—rather than frustrate—patients' options for obtaining and maintaining access to appropriate care.

For all of these reasons, we strongly urge CMS to withdraw this proposal. We address these important points in further detail below, focusing on the untenable, unfair, and fundamentally flawed aspects of this proposal and its asserted premise, and the significant harm that would result for patients, if it is finalized.

I. Because of plan and PBM accumulator programs and related policies, there is not a feasible method for manufacturers to "ensure" that the benefit of assistance programs goes exclusively to consumers.

Under the standard articulated in the Proposed Rule, manufacturers would be required to "ensure that the benefits of their assistance programs . . . are provided entirely to the consumer" in order to apply the well-established exclusions to best price determinations and AMP calculations that are instrumental to the feasibility of providing important assistance to patients with health care needs. To apply this proposed new requirement would be to impose a standard that is inflexible, impractical, and impossible for manufacturers to meet in light of the way accumulator programs operate and the disturbing lack of transparency that both patients and manufacturers confront with respect to accumulator programs.

Both the patient and the manufacturer are often unaware of whether and under what circumstances the patient's health plan may apply an accumulator program. As CMS itself notes in the Proposed Rule, "[a]s a result [of accumulator programs], the manufacturer assistance does not accrue towards a patient's

[9] *See* H.B. 2166 (Arizona); H.B. 0465 (Illinois); S.B. 1596 (Virginia); H.B. 2770 (West Virginia); *see also, e.g.*, S.B. 313 (Georgia, sent to Governor for signature June 29, 2020); H.B. 469 (Ohio, introduced Jan. 14, 2020; referred to Health Committee Jan. 28, 2020).

[10] This is not an idle or speculative risk. For example, when the Medicaid Drug Rebate Program was first enacted, it failed to provide for a Best Price exclusion for discounts provided to safety-net providers; as a result, those providers faced significantly reduced levels of discounts—or, in many cases, discontinuation of such discounts entirely.

deductible *and the patient sometimes does not realize this* until the manufacturer copayment assistance runs out and the patient receives a significantly larger bill for the drug."[11] Indeed, many health plans do not (or refuse to) publish their policies on accounting for manufacturer support funds.[12] Further, even if a plan's accumulator program and related policies are discussed in plan policies, the language often is buried and obscured in lengthy or complex documents, which are available to patients and consumers (if at all) only *after* they have enrolled.[13] The descriptions of the accumulator programs, when provided, also are generally vague, ambiguous, and confusing.[14]

This lack of transparency regarding whether and when a plan or PBM might or might not apply an accumulator program is equally applicable to manufacturers. Manufacturers do not have control over and, typically, lack visibility as to whether and when an accumulator program may be applied to a particular prescription filled by a particular patient who happens to use a copay coupon. Simply put, the determination of how manufacturer support funds are accounted for is made solely and exclusively by the plans and PBMs—fully independent of the patient and the manufacturer.

CMS does not appear to appreciate this critically important reality in the Proposed Rule. For example, in the Preamble to the Proposed Rule, CMS states—quite incorrectly and without citing any support—as follows: "We believe manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure the benefit goes exclusively to the consumer or patient."[15] Unfortunately, that is a faulty premise underlying an alarming proposal. As a service provider that facilitates patient support services to a number of manufacturers, we are well versed in the variability and lack of transparency of copay accumulator programs. While manufacturers can (and do) establish program eligibility screening questions and practices that help prevent patients from participating if they do not meet appropriate criteria, there does not exist a method by which a manufacturer can **ensure** in all cases that an accumulator program will not be applied—for the very reason that manufacturers cannot control what plans and PBMs do or do not do, or whether the plans and PBMs choose to be forthright about their willingness to increase the sums that they decide not to cover for patients.

Manufacturers offering assistance ***to patients*** fully intend and desire that the benefits inure to those patients; but manufacturers cannot force plans to refrain from applying accumulator programs. As noted above, some states have acted to prohibit or limit plans' use of accumulator programs; unfortunately, however, CMS policies to date have allowed accumulator programs to continue and, indeed, proliferate—without any corresponding limits or transparency requirements.[16] This has occurred even though CMS

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[11] 85 Fed. Reg. at 37298 (emphasis added).

[12] *See, e.g.*, Carl Schmid, *Hidden Policies: The Search for Copay Accumulator Policies in Florida Qualified Health Plans*, Drug Channels (June 7, 2018) ("Patients are often unable to find out if their plan has a copay accumulator adjustment program."), *available at* https://www.drugchannels.net/2018/06/hidden-policies-search-for-copay.html.

[13] *See, e.g., id.* ("Through extensive research of plan documents and phone calls to plan customer service representatives, The AIDS Institute found that four out of six major insurers on the Florida marketplace had references to copay accumulator programs in their plan documents. . . . All plans buried the information, making it difficult to determine their policy.").

[14] *See, e.g., id.* ("Even when the information was somehow available, it was vague and ambiguous."). We are concerned that this failure may render plan evidence of coverage documents, marketing materials, and other statements to be either false or misleading.

[15] 85 Fed. Reg. at 37299.

[16] *See e.g.*, CMS, Final Rule, 2021 Notice of Benefit and Payment Parameters, 85 Fed. Reg. 29164, 29165–29166 (May 14, 2020) ("We are finalizing changes to the policy regarding whether drug manufacturer coupons must be applied towards the annual limitation on cost sharing. Specifically, we are revising § 156.130(h) to state that, to the extent consistent with applicable state law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing.").

has the authority to either prevent these accumulator programs or to require plans and PBMs to be transparent about their use of them.

In addition to this basic and fundamental accumulator program operation and corresponding transparency problem, there are a number of other practical issues and challenges that reinforce and exacerbate the inability of manufacturers to "ensure" that the full benefit of their assistance provided to a patient will, in fact, be realized by that patient and not diverted away from the patient by operation of an accumulator program or similar plan policy. For example, in the case of many self-funded plans, the plan sponsor has significant flexibility to change benefit design as it chooses. Moreover, many plans incorporate accumulator adjustments only for specific drugs as opposed to broadly for all drugs, thus further inhibiting the ability of manufacturers to establish coverage criteria around their programs to ensure the benefit of their assistance program goes solely to the consumer.

As CMS indicates in the Proposed Rule, the operation of an accumulator program involves a situation where "certain PBMs have instructed health plans to not allow the manufacturer copay assistance to be applied toward a patient's plan deductible," and where health plans "are being instructed or encouraged by their [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."[17] These "instructions" from PBMs to health plans are inconsistent with the intent of the manufacturers and completely outside of manufacturer control.

Fundamentally, it is unworkable and unfair to hold patients or manufacturers accountable for decisions and actions by plans and PBMs that neither patients nor manufacturers can control, and which plans and PBMs are not even required to (and typically do not) transparently disclose.[18] With implementation of accumulator programs on the rise,[19] if CMS wants to ensure that the benefits of patient assistance are fully realized by patients, then CMS should work to advance policies that require *insurers* to take steps necessary to do so. Manufacturers are unable to regulate the actions of insurers; the Agency, however, is empowered to do so, at least with respect to the vast majority of plans subject to CMS's authority.

II. The proposal is an inappropriate mechanism for addressing the issues raised by accumulator programs that CMS identifies in the Proposed Rule and, if finalized, would result in significant harm to patients and lead to negative health outcomes.

Because the proposed standard is unworkable for manufacturers and impossible to meet, the proposal, if implemented, likely would cause manufacturers to discontinue patient copay support programs. That, in turn, would result in significant negative health outcomes for patients and costly consequences for the health care system and society. As CMS acknowledges, accumulator programs "generate savings for the

[17] 85 Fed. Reg. at 37298.

[18] *See, e.g.*, The AIDS Institute, *Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients* (July 2020) ("Our research found that there is no consistency among health insurance companies regarding if and how they inform potential enrollees about any copay accumulator policies. And insurers are not required to include information on copay accumulator programs in the standardized Summary of Benefits template that is required by the Affordable Care Act (ACA)."), *available at* http://www.theaidsinstitute.org/sites/default/files/attachments/AI_CoPay_Accumulator_Adjustment_Brochure_w%20Appendix_FINAL.pdf.

[19] *See, e.g.*, Massachusetts Health Policy Commission, *Prescription Drug Coupon Study: Report to the Massachusetts Legislature* (July 2020), at 23–24 ("[T]he use of copay accumulator programs appears to be increasing nationwide. According to a survey of 49 plans and PBMs with 147 million covered lives, 34% of commercially-insured patients in 2018 were covered by payers that have implemented copay accumulators. Additionally, the survey found that another 28% of patients are enrolled in plans that plan to implement these programs in 2019 and beyond."); The AIDS Institute, *Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients* (July 2020), *supra* note 18.

plan" [20] at the expense of—and typically to the surprise of—the patient.[21] Rather than seeking to reduce the harm inflicted by accumulator programs, the Proposed Rule takes aim at the assistance designed to support access and affordability for patients. Moreover, the proposal, if finalized, would represent a fundamental change in CMS's long history of guidance and regulations that currently set forth a reasonable and workable pathway to provide assistance to patients in need. Patients have relied on the availability of this assistance to help access, afford, and adhere to the medicines their physicians prescribe. If finalized as proposed, the proposal would risk dismantling these programs to the detriment of patients across the country who have serious and chronic conditions and who—with a pandemic raging and causing related public health and economic crises—clearly need additional support.

1. Discontinuation of Manufacturer Copay Assistance Programs Would Hurt Patients Who Are Most in Need of Assistance; Would Lead to Increased Costs to the Health Care System and Society; and Would Fail to Achieve the Stated Goals of the Policy.

If the proposed changes were to be implemented, and manufacturer assistance to patients consequently threatened, limited, or discontinued, it would present an abrupt and serious impediment to patients' ability to afford and therefore continue therapy. For many patients who receive manufacturer copay assistance, it is a vital resource. The unworkable standard set forth in the Proposed Rule would jeopardize the availability of that assistance for vulnerable patients by creating a situation where it is either too risky or is financially unfeasible for manufacturers to offer such programs. The result would effectively penalize and significantly harm patients as a result of the accumulator policies that plans and PBMs have put in place. There is nothing in the Proposed Rule indicating that the Agency considered this issue, which raises additional and serious concerns under the APA.[22]

Many patients, particularly those who require specialty therapies for serious conditions that do not have generic alternatives or clinically appropriate substitutes, rely on copayment support to afford their medications.[23] Quite often, these medications are literally life-saving and necessary for the patient to survive.[24] In many cases, the medications are necessary to allow patients to work, to avoid

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[20] 85 Fed. Reg. at 37298.

[21] 85 Fed. Reg. at 37298 ("As a result [of accumulator programs], the manufacturer assistance does not accrue towards a patient's deductible and the patient sometimes does not realize this until the manufacturer copayment assistance runs out and the patient receives a significantly larger bill for the drug. This results in the health plan delaying the application of its plan benefit to the patient to the detriment of the patient or consumer, thus generating savings for the plan.").

[22] 5 U.S.C. § 706(2)(A); *see Motor Vehicle Manfacturers Ass'n*, 463 U.S. at 43 ("Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem"); *see also Owner-Operator Independent Drivers v. Federal Motor Carrier Safety Administration*, 494 F.3d 188, 205 (D.C. Cir. 2007) ("[W]e cannot uphold a rule based upon such a model when an important aspect of its methodology was wholly unexplained.").

[23] *See, e.g.*, IQVIA, Fact Sheet: An Evaluation of Co-Pay Card Utilization in Brands After Generic Competitor Launch (2018), *available at* https://www.iqvia.com/-/media/iqvia/pdfs/us-location-site/market-access/fact-sheet-evaluation-of-copay-card-utilization-post-loe.pdf?_=1594582678820; The AIDS Institute, *Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients* (July 2020), *supra* note 18, at 8.

[24] *See, e.g.*, Carl Schmid, *New Insurance Proposals Would Hurt Americans with HIV*, Washington Blade (Feb. 28, 2020), *available at* https://www.washingtonblade.com/2020/02/28/new-insurance-proposal-would-hurt-americans-with-hiv/ ("Americans living with HIV, hepatitis, and other illnesses such as cancer, multiple sclerosis, and hemophilia are used to fighting for their lives. A new proposal from the Trump administration could make that fight a whole lot harder and costlier."); *id.* ("Missing just a few doses can have disastrous consequences. One recent analysis found that interrupting HIV treatment for only two days was enough to increase an individual's viral load. And higher viral loads don't just impact the patient's life — they increase the chances of transmitting HIV to someone else. This will make it more difficult to achieve the goals of President Trump's historic Ending the HIV Epidemic initiative, which calls for increased access to antiretroviral medications for treatment and PrEP for prevention.").

hospitalizations or disability, and to care for children and others.[25] Multiple studies show that patients who are unable to meet their cost-sharing obligations for medicines abandon prescriptions, discontinue therapy, or are unable to adhere to the prescribed medication regimen.[26] Those harmful consequences for patients, in turn, drive up system costs through increased hospitalizations, deteriorating conditions, and other negative health outcomes, and also lead to additional societal costs through lost productivity and other issues.[27]

As a result, discontinuation of copay assistance support options would lead to significant additional costs for the health care system and for society, in addition to the profoundly negative impact for individual patients and their health outcomes.

Discontinuation of copay assistance programs also would produce a situation that harms patients without producing any meaningful effect on drug prices or Medicaid rebates. If CMS finalizes the unworkable standard set forth in the proposed rule, a highly likely result is that manufacturers will not be able to offer such programs. In turn, the absence of a manufacturer offer would mean that no resultant impact on best price would be realized. Thus, finalization of the proposal would leave patients with serious and chronic conditions without much-needed support, while making no positive progress toward achieving lower prices or other savings for Medicaid programs. We believe these are powerful additional reasons why the proposal should not be finalized. Indeed, the Proposed Rule reflects no consideration of these important issues or the impact that the proposal, if finalized, would have on patient stakeholders, contrary to the requirements of the APA.[28]

2. Copay Assistance Programs Do Not Drive Up Health System Costs.

CMS states in the Proposed Rule that "PBMs contend that [manufacturer copay assistance programs] steer consumers towards more expensive medications when there may be more cost saving options, such as generic substitution."[29] CMS cites no data or evidence for this statement; rather, it asserts only that this assertion is what "PBMs contend." CMS further states that this "contention" from PBMs forms the basis of why PBMs "offer" accumulator programs to health plans "and tout them as cost saving measures."[30]

We are deeply concerned that CMS appears to be advancing a fundamental shift in policy that will affect patient access to necessary medicines based solely on an unsupported assertion of what "PBMs contend." Implementation of such a dramatic change in the assistance available to patients across the country should not occur without additional explanation accompanied by concrete data and evidence to support it. A policy based on an unsupported assertion of what one group of stakeholders "contend" is arbitrary and capricious within the meaning of the APA.[31]

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[25] *See, e.g.,* Massachusetts Health Policy Commission, *Prescription Drug Coupon Study: Report to the Massachusetts Legislature* (July 2020), at 14 (Research indicates that increasing medication adherence has the potential to reduce emergency department visits, hospitalizations, and overall health care costs for patients managing chronic conditions.") (citing numerous studies).

[26] *See, e.g., id.*, and studies cited within.

[27] *See, e.g., id.*, and studies cited within.

[28] 5 U.S.C. § 706(2)(A); *see also Motor Vehicle Manfacturers Ass'n*, 463 U.S. at 43 (agency action is "arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem"); *Advocates for Highway and Auto Safety v. Federal Motor Carrier Safety Administration*, 429 F.3d 1136, 1147 (D.C. Cir. 2005) (holding that agency final rule was arbitrary and capricious because "the agency entirely failed to consider important aspects of the [training program] before it").

[29] 85 Fed. Reg. at 37298.

[30] *Id.*

[31] 5 U.S.C. § 706(2)(A); *see also Business Roundtable*, 647 F.3d at 1150 (vacating rule where agency "relied upon insufficient empirical data"); *Safe Extensions, Inc. v. FAA*, 509 F.3d 593, 605 (D.C. Cir. 2007) ("'An agency's

Moreover, contrary to what PBMs assert, real-world experience and data demonstrate that the types of medications involved in manufacturer copay assistance programs generally and in the vast majority of cases *do not* have generic equivalents or clinically appropriate substitutes available.[32] Indeed, "[r]esearch has shown that 87% of copay assistance programs are for brand-name drugs that do not have a generic equivalent,"[33] and that "co-pay card use on branded scripts post-[loss of exclusivity (LOE)] represents a sliver of the total commercial market, making up only 0.4% of volume across all products."[34]

Fundamentally, it simply is not the case that copay assistance is what "causes" a patient to take a particular drug—that assistance merely helps patients to better afford the medications they have already been prescribed and that have already been determined by the patient's health care provider to be medically necessary. Those prescribing decisions are made through physician-patient discussions and determinations.[35] Accordingly, the availability of copay assistance to help patients afford and adhere to their prescribed therapies does not drive up health care costs in the manner that "PBMs contend."[36]

In addition, data indicate that copay accumulator programs are ***not*** an effective mechanism for reducing costs. As stated by the Massachusetts Health Policy Commission (HPC), an independent state agency, in a recently published study regarding prescription drug coupons: "Due to the complexity of copay accumulator programs, they are unlikely to encourage patients to use lower cost alternatives."[37] Instead, HPC noted, "copay accumulators may preserve the affordability challenges that patients originally faced in their plan design, which could lead to lower access and adherence. In addition, these programs may increase administrative complexity for payers and PBMs and add confusion to patients navigating an

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unsupported assertion does not amount to substantial evidence'") (quoting *Algonquin Gas Transmission Co. v. FERC*, 948 F.2d 1305, 1313 (D.C. Cir. 1991)).

[32] *See, e.g.*, The AIDS Institute, *Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients* (July 2020), *supra* note 18, at 8 ("For many diseases, like HIV and hepatitis C, there are no generic alternatives to brand-name medications."); IQVIA, Fact Sheet: An Evaluation of Co-Pay Card Utilization in Brands After Generic Competitor Launch (2018), *supra* note 23, ("[C]o-pay card use on branded scripts post-[loss of exclusivity (LOE)] represents a sliver of the total commercial market, making up only 0.4% of volume across all products."); *id.* ("The total commercial volume for post-LOE products with a co-pay card program available (the brands and their generic counterparts) represent 11.1% of commercial volume. For prescriptions filled with a post-LOE brand that sponsors a patient support program, 14.5% of claims are associated with these programs."); *id.* ("When narrowing in on the total commercial volume for products where manufacturer co-pay assistance is available, only 3.4% of total volume is attributable to prescriptions using these programs.").

[33] The AIDS Institute, *Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients* (July 2020), *supra* note 18, at 4.

[34] IQVIA, Fact Sheet: An Evaluation of Co-Pay Card Utilization in Brands After Generic Competitor Launch (2018), *supra* note 23.

[35] *See, e.g.*, The AIDS Institute, *Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients* (July 2020), *supra* note 18, at 8 ("[R]esearch shows that copay cards do not influence overall drug pricing and do not steer patients toward more expensive drugs. Instead, these cards help patients afford the medications they've been prescribed."); *id.* at 4 ("Patients who rely on these medications rarely have a choice about whether to take the drug that was prescribed by their doctors or to take a different drug."); *id.* at 9 ("Patients with complex conditions work with their health care providers to find the right treatment, and they often have conversations about lower-cost options that are medically appropriate.").

[36] Indeed, a number of studies have shown that net drug prices, inclusive of manufacturer rebates to pharmacy benefit managers (PBMs) as a discount on the drug's list price, have remained relatively steady over recent years or, in some cases, decreased. *See, e.g.*, Adam J. Fein, *Surprise! Brand-Name Drug Prices Fell in 2019* (Jan. 9, 2020), *available at* https://www.drugchannels.net/2020/01/surprise-brand-name-drug-prices-fell-in.html. Moreover, research also shows that "copay assistance makes up a tiny sliver of overall pharmaceutical claims."). The AIDS Institute, *Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients* (July 2020), *supra* note 18, at 8.

[37] Massachusetts Health Policy Commission, *Prescription Drug Coupon Study: Report to the Massachusetts Legislature* (July 2020), at 24.

increasingly complicated health care system."[38] The Proposed Rule does not present any of these data or facts, reinforcing that CMS has not complied with its obligations under the APA.[39]

3. CMS Should Instead Protect Patient Access by Exercising the Agency's Authority to Regulate Plans' Use of and Transparency Regarding Accumulator Programs.

As noted above, if CMS wants to ensure that the benefits of patient assistance are fully realized by patients, then CMS should work to advance policies that require *insurers* to take steps necessary to do so. For example, CMS has authority to regulate—and has implemented regulations addressing—cost-sharing requirements, transparency requirements, standards for access to plan information, marketing and benefit design, and other certification standards for qualified health plans (QHPs).[40] Indeed, CMS has previously exercised the authority that the Agency has over plans to facilitate *increased* use of accumulator programs by plans and PBMs, rather than to protect patients from their negative clinical and financial consequences,[41] a step that is inconsistent with CMS's stated policy and objectives reflected in the Proposed Rule.

Moreover, CMS has not acted to establish basic and fundamental transparency requirements for the use of accumulator programs, notwithstanding its existing authority over plans permitting it to do so. Such transparency requirements are essential to ensure that patients are aware and provided with meaningful notice of when and how accumulator programs may apply. In addition, it is important that this information be provided and available to consumers *before* they commit to enrollment in a plan. Accordingly, CMS should withdraw the proposal at this time and reconsider it—if ever—only after appropriate standards and transparency requirements for accumulator programs are in place.

In addition, we strongly urge CMS to reconsider accumulator program limits beyond transparency requirements. For example, CMS has previously considered policy options that would place limitations on accumulator programs, particularly when a medically appropriate generic equivalent is available.[42]

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[38] *Id.* (citing additional sources); *see also* The AIDS Institute, *Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients* (July 2020), *supra* note 18, at 5 & 13.

[39] *See* 5 U.S.C. § 706(2)(A); *see also Motor Vehicle Manfacturers Ass'n*, 463 U.S. at 43 ("[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made'") (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U. S. 156, 168 (1962)); *id.* ("Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem.").

[40] *See, e.g.*, 45 C.F.R. §§ 156.130 (Cost-sharing requirements), 156.220 (Transparency in coverage), 156.221 (Access to and exchange of health data and plan information), 156.225 (Marketing and benefit design of QHPs), 156.250 (Meaningful access to qualified health plan information).

[41] *See* CMS, Final Rule, 2021 Notice of Benefit and Payment Parameters, 85 Fed. Reg. 29164, 29165–29166 (May 14, 2020) (revising regulations regarding cost-sharing requirements at § 156.130(h) "to state that, to the extent consistent with applicable state law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing."); *see also* Massachusetts Health Policy Commission Health Policy Commission, *Prescription Drug Coupon Study: Report to the Massachusetts Legislature* (July 2020), at 23–24 (stating that "the use of copay accumulator programs appears to be increasing nationwide" and discussing "a survey of 49 plans and PBMs with 147 million covered lives" which found that "34% of commercially-insured patients in 2018 were covered by payers that have implemented copay accumulators" and that "another 28% of patients are enrolled in plans that plan to implement these programs in 2019 and beyond"); The AIDS Institute, *Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients*, *supra* note 18.

[42] *See* CMS, Final Rule, 2020 Notice of Benefit and Payment Parameters, 84 Fed. Reg. 17454 (April 25, 2019) (finalizing, under 45 C.F.R. § 156.130(h)(1), that notwithstanding any other provision of § 156.130, and to the extent consistent with applicable state law, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to

CMS subsequently, unfortunately, retreated from that policy—much to the disappointment of patient advocates and other stakeholders, and we are concerned that current CMS policies are facilitating and causing a significant proliferation of accumulator programs, despite the fact that CMS has noted that, as a result of accumulator programs, "the health plan is benefiting from the manufacturer sponsored copay assistance program instead of the patient (consumer)" in a manner that is "to the detriment of the patient or consumer."[43] The Proposed Rule reflects that CMS's policy objective is to ensure that patients are the beneficiaries of assistance programs, but it acts in a manner inconsistent with that objective by allowing accumulator programs to be applied. CMS should honor its commitment to patients and withdraw this proposal that is contrary to that commitment.

III. The Proposal Is Inconsistent with the President's Pandemic-Related Executive Orders.

Importantly, a recent Executive Order regarding ways to "address th[e] economic emergency" resulting from the COVID-19 pandemic urges federal agencies to "rescind[], modify[], waiv[e], or provid[e] exemptions from regulations and other requirements that may inhibit economic recovery, consistent with applicable law and with protection of the public health and safety, . . . and with budgetary priorities and operational feasibility."[44] Consistent with that Executive Order, we strongly encourage CMS to reconsider and modify its current policies with respect to accumulator programs and to withdraw the current proposal that would impose a new and unworkable standard for exclusions of manufacturer assistance amounts to patients in connection with Best Price and AMP determinations. The proposal cannot be squared with the clear, direct mandate of the Executive Order.

In the current environment, COVID-19 continues to grip the nation and to exacerbate access barriers and financial hardships for individuals across the country, especially those with serious and chronic health conditions. As patients and consumers continue to face these unprecedented challenges and devastating circumstances, it is simply not an appropriate time to implement policies that cut off critical resources and restrict access avenues for patients. Instead, and as reflected in the recent Executive Order addressing "Regulatory Relief To Support Economic Recovery,"[45] CMS should actively consider and seek to advance *additional* ways to support patients and to facilitate—rather than frustrate—patients' options for obtaining and maintaining access to appropriate care.

We emphasize that, as a consequence of the current pandemic and the need to ensure public health and respond to the economic crisis, we and other stakeholders have seen an increased need for programs focused on patient access and affordability. As patient needs continue to persist and escalate, both clinically and economically, the disruption and harm that would result from the proposal, if finalized, would be enormous and devastating. Indeed, this proposal, if finalized, will exacerbate the overwhelming challenges that patients and health care providers face. The need for assistance to patients, as substantial as it was before, is heightened and is all the more clear now given the deteriorating employment and economic conditions that individuals across the country are confronting. Patients and their families are struggling to navigate unprecedented challenges. Unfortunately, however, the current proposal would only accelerate and increase off of these debilitating harms.

As a result, we reiterate our strong opposition to the proposal, and we urge CMS not to finalize it—certainly not in the current environment and without any safeguards for transparency regarding the operation of accumulator programs. The proposed standard is unworkable, unreasonable, and unfair.

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enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing).

[43] 85 Fed. Reg. at 37298 & 37299.

[44] Executive Order 13924, Regulatory Relief To Support Economic Recovery, 85 Fed. Reg. 31,353 (May 22, 2020).

[45] *Id*.

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We believe at the core of every health policy decision should be a desire to improve the ability of the health care system to deliver services to patients who need them. This proposal, however, runs counter to that goal. For the reasons outlined in this letter, we strongly urge CMS to withdraw the proposed revisions to the regulations regarding the exclusion of certain manufacturer sponsored patient assistance programs from Determination of Best Price and AMP under 42 C.F.R. §§ 447.505 and 447.504.

Sincerely,

Mark Bouck
President & CEO
TrialCard

CC: Michele Atchison, Chief Compliance Officer, TrialCard
Frederick Fry, Senior Vice President, Commercial Solutions, TrialCard
Jason Zemcik, Senior Director, Product Management, TrialCard