March 2, 2020

The Honorable Alex M. Azar II
Secretary of the U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: **Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans (CMS-9916-P)**

Dear Secretary Azar:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the U.S. Department of Health & Human Services' (HHS's) proposed rule, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans[1] (the proposed rule).

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone.

Comprehensive, affordable, and accessible prescription drug coverage is important to preventing, treating, and curing acute and chronic medical conditions, as well as improving quality of life and reducing spending on other health care services.[2] PhRMA is deeply concerned about HHS's proposal to permit group health plans and health insurance issuers to use accumulator adjustment programs without limitation, which will result in higher prescription drug costs for millions of patients across the Nation. Specifically, this proposed rule would allow plans and issuers to exclude the value of manufacturer cost-sharing assistance from accruing towards the statutorily required annual limitation on cost sharing regardless of whether a medically appropriate generic equivalent is available. As discussed in detail below, this proposed change in policy would have sweeping effects. It would compromise patients' ability to adhere to prescribed medicines at a moment when insurance coverage for medicines continues to erode; it would put patient health and financial security in danger; it would run directly counter to the Administration's stated policy of lowering patient out-of-pocket costs for prescription drugs; and it could undermine the appeal and availability of high-deductible health plans (HDHPs) by potentially requiring plan

[1] 84 Fed. Reg. 7088 (Feb. 6, 2020).
[2] Congressional Budget Office. Offsetting effects of prescription drug use on Medicare's spending for medical services. 2012. https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/MedicalOffsets_One-col.pdf.

sponsors to choose between allowing cost-sharing assistance to count as patient spending and offering a health savings account (HSA) in combination with the plan.

Equally concerning, this proposed rule is a complete reversal of final regulatory action taken by HHS less than a year ago. It is contrary to statute and existing regulations, and it is arbitrary and capricious. An incorrect HHS interpretation and application of 16-year-old Internal Revenue Service (IRS) guidance is the sole justification offered for this policy shift – a shift that could dramatically erode both access to and enrollment in HSA-eligible HDHPs, contrary to this Administration's stated health policy objectives. For these reasons, we urge HHS to withdraw this proposal and to enforce the policy finalized in the 2020 Notice of Benefit and Payment Parameters (NBPP) final rule.[3]

In addition to the concerns regarding HHS's proposal on manufacturer cost-sharing assistance, we have the following comments:

- *Medical loss ratio (MLR).* PhRMA supports the proposal to require health insurance issuers to reduce incurred claims on their MLR reports to reflect the value of price concessions retained by pharmacy benefit managers (PBMs). Current MLR reporting rules do not ensure that the substantial discounts and rebates paid by biopharmaceutical companies to PBMs are reflected in reported claims in the MLR calculation. In the absence of comprehensive reform that would require issuers to pass rebates through to patients at the point of sale, enrollees should, at a minimum, share in the full amount of any rebates or discounts negotiated on prescription drugs by ensuring they are reflected in reduced premiums or higher MLR rebates.
- *Value-based insurance design (VBID)*. We are concerned that the VBID model qualified health plan (QHP) that HHS is promoting inappropriately marks certain classes of drugs for cost-sharing increases. This approach does not satisfy generally accepted standards for VBID.
- *Risk adjustment*. We welcome the proposed HHS approach to risk adjustment, including its continued use and calibration of prescription drug categories in the risk adjustment model.
- *Premium adjustment percentage*. PhRMA remains concerned by the decision last year, proposed to be continued this year, to base key parameters on a measure of premium increases that includes individual market premiums, which will increase costs for patients in both exchanges and employer-sponsored plans.
- *Excepted benefit Health Reimbursement Arrangements (HRAs)*. While we remain concerned that permitting employer-funded HRAs to pay for individual market health insurance coverage could substantially undermine employer-sponsored health coverage, we agree with HHS's proposal to impose notice requirements on non-federal governmental plan excepted benefit HRAs.

[3] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 17454, 17544-46 (Apr. 25, 2019); 45 C.F.R. § 156.130(h).

Cost Sharing Requirements (§ 156.130)

Under a health plan accumulator adjustment program, plans refuse to accrue the value of manufacturer assistance that helps patients finance their cost sharing toward the plan's deductible or annual limitation on cost sharing (i.e., their out-of-pocket spending limit). When such programs are implemented by health plans, they can substantially increase patients' out-of-pocket costs, increasing financial burden and health risk, especially for those with serious illnesses. Given the sustained trend toward less generous coverage for prescription drugs in commercial health insurance, accumulator adjustment programs undermine medication adherence, which can increase overall health care costs.

Last year, HHS provided important, and we believe appropriate, guidance on the use of such programs, stating unequivocally that, except in limited circumstances where a medically appropriate generic equivalent is available, "amounts paid toward cost sharing using any form of direct support offered by drug manufacturers must be counted toward the annual limitation on cost sharing."[4] In this year's proposed rule, HHS proposes to permit health plans to exclude manufacturer cost-sharing assistance from the accumulator toward a plan's annual limitation on cost sharing in all cases – a complete, 180-degree reversal unsupported by any rational justification and without adequate consideration of the harmful impact to patients. PhRMA urges HHS to abandon this arbitrary and abrupt rule change, affirm last year's regulation, and withdraw its nonenforcement policy with respect to the prohibition on certain accumulator adjustment programs.[5]

In the following comments on the proposed rule, we restate the policy concerns that we identified in our comments last year with respect to accumulator adjustment programs, which would proliferate should HHS follow through on this proposal. In addition to these policy concerns, *HHS's proposed action is contrary to law and arbitrary and capricious, and therefore cannot be finalized*. The statutory[6] and HHS regulatory[7] definitions of cost sharing do not support the HHS proposal, and the proposed rule fails to explain why or how HHS can now simply "interpret" cost sharing not to include manufacturer assistance, in light of the existing statute and regulation, as well as the fact that the interpretation would not apply to many other types of patient assistance or financing mechanisms that similarly eliminate, reduce, or delay patient out-of-pocket spending for covered services.

Further, HHS's only stated rationale for this proposal is that the current prohibition on accumulator adjustment programs *could potentially* conflict with 16-year-old IRS guidance—on the requirements for a participant in an HDHP to be eligible to contribute to an HSA. HHS and IRS do not definitively state whether this conflict exists. In reality, as detailed below, no such conflict exists; therefore, HHS has provided no rational basis for this policy change. Should HHS

[4] *Id.* at 17545.
[5] FAQs About Affordable Care Act Implementation Part 40, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf (Aug. 26, 2019).
[6] Patient Protection and Affordable Care Act § 1302(c)(3), 42 U.S.C. § 18022(c)(3).
[7] 45 C.F.R. §§ 155.20, 156.20.

have some alternative basis for this change, it must provide it for public comment, so stakeholders have an opportunity to respond.

Finally, this proposed change is arbitrary because it is based on incorrect factual premises, misstating the commercial realities of manufacturer cost-sharing assistance, and failing to articulate any rational basis to distinguish manufacturer cost-sharing assistance from other third-party assistance (which would still be required to apply to the annual limitation on cost sharing).

PhRMA also notes that this proposal, if finalized, would undermine two important Administration priorities: (1) it would cause patient out-of-pocket cost exposure to spike at the pharmacy counter; and (2) it would make it more difficult for individuals and employers to contribute to HSAs. In sum, this proposal undermines the Administration's priorities and does not further the public interest.

Accumulator Adjustment Programs Put Patients at Risk, and HHS Wisely Prohibited Their Use Except in Limited Circumstances

HHS's current policy to prohibit accumulator adjustment programs, except when a medically appropriate generic equivalent is available, correctly shields patients with significant medical needs from high cost sharing on necessary medications when no alternative options are available.[8] The same concerns that led HHS to clarify – less than a year ago – that the statute and regulation require this outcome, and HHS's failure to identify any changed circumstances that necessitate this complete reversal, should result in HHS abandoning this proposal.

When cost sharing rises, patients are more likely to abandon their medicines. In 2017, 69 percent of commercially insured patients did not fill their new prescriptions when they had to pay more than $250 out of pocket, while only about 11 percent of patients with out-of-pocket costs of less than $30 abandoned their prescriptions at the pharmacy.[9] Thus, higher patient out-of-pocket costs frequently lead to medicines that have been prescribed by a health care provider – and that a health plan has agreed to cover – never reaching the patient because a financial barrier was erected around appropriate treatment. It is the health insurer that dictates what insured patients will be required to pay for covered items and services, including prescription drugs.

Troublingly, the out-of-pocket burden for patients is growing because of rapidly increasing patient cost sharing for brand medicines, a result of the increased use of deductibles and coinsurance in the commercial market.[10] From 2007 to 2017, commercial market enrollee spending on deductibles increased 205 percent, exposing patients to higher out-of-pocket costs,

[8] In fact, in the 2020 NBPP final rule, HHS reasoned "where there is no generic equivalent available or medically appropriate alternative, it is less likely that the manufacturer's coupon would disincentivize a lower cost alternative and thereby distort the market." 84 Fed. Reg. at 17545.

[9] IQVIA. Patient affordability part two. May 2018. https://www.iqvia.com/locations/united-states/patient-affordability-part-two.

[10] IQVIA. Patient affordability part one. May 2018. https://www.iqvia.com/locations/united-states/patient-affordability-part-one.

which vastly outpaced wage growth.[11] In addition to increasing deductibles, plans increasingly rely more heavily on coinsurance than copays, which impairs out-of-pocket spending predictability for patients. Since 2016, commercial health plans have been more likely to require coinsurance instead of copays for specialty drugs.[12] The proliferation of HDHPs also contributes to rising patient cost exposure due to the large deductibles that characterize this type of plan. In 2019, the average annual deductible for enrollees in employer-sponsored HDHPs was $2,486.[13] From 2007 to 2017, the percentage of adults enrolled in employer-sponsored HDHPs increased from 14.8 percent to 43.4 percent.[14]

Even employers who offer HDHPs understand that these plans may present affordability challenges to their enrollees. One survey found that 29 percent of employers said their number one challenge with HDHPs was that medications are unaffordable for enrollees before the deductible is met.[15] For these reasons, cost-sharing assistance is an important protection for patients to access prescribed medications that both prescribers and plans agree is appropriate. Multiple studies report that manufacturer cost-sharing assistance is associated with higher adherence and lower rates of therapy discontinuation.[16] For patients at risk of prescription drug abandonment due to high cost sharing, another study found that cost-sharing assistance programs typically reduced patients' monthly out-of-pocket costs to a level where they were much less likely to abandon therapy.[17]

Nonadherence leads to serious negative health consequences for patients and results in significant additional costs to the U.S. health care system. Nonadherence is estimated to cause approximately 125,000 deaths and at least 10 percent of hospitalizations, and to cost the U.S. health care system between $100 billion and $289 billion a year.[18]

Ignoring the harms to patient adherence and well-being, health plans and PBMs have begun instituting accumulator adjustment programs, under which patients are penalized for using cost-sharing assistance by means of the plans not counting such assistance toward the patient's

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[11] Peterson-Kaiser Family Foundation. Tracking the rise in premium contributions and cost-sharing for families with large employer coverage. August 2019. https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/.

[12] Pharmacy Benefit Management Institute, 2019 trends in specialty drug benefits report. 2019. https://www.pbmi.com/ItemDetail?iProductCode=SPECIALTY_2019&Category=SPECIALTY.

[13] Kaiser Family Foundation. 2019 employer health benefits survey - section 7: employee cost sharing. September 2019. https://www.kff.org/report-section/ehbs-2019-section-7-employee-cost-sharing/.

[14] Centers for Disease Control. High-deductible health plan enrollment among adults aged 18-64 with employment-based insurance coverage. August 2018. https://www.cdc.gov/nchs/data/databriefs/db317.pdf.

[15] Pharmacy Benefit Management Institute. 2018 trends in drug benefit design. 2018. https://www.pbmi.com/PBMI/Research_Reports/Drug_Benefit_Report/PBMI/Research%20Reports/Store/BDR.aspx?hkey=bfcca9f8-610e-4eca-a908-8ff451bb2f87.

[16] See, e.g., Daugherty JB Maciejewski, ML, & Farley JF. The impact of manufacturer coupon use in the statin market. J. Managed Care Pharmacy; 2013;19:765-772; Daubresse M et al. Effect of prescription drug coupons on statin itilization and expenditures: a retrospective cohort study, Pharmacotherapy; 2017;37:12-24.

[17] Starner, CI, et al., Specialty drug coupons lower out-of-pocket costs and may improve adherence at the risk of increasing premiums, 33 Health Affairs. 2014;33(10):1761-1769.

[18] Viswanathan M, Golin CE, Jones CD, et al. Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review. Ann Intern Med; 2012;157:785-795.

deductible or annual limitation on cost sharing. As a result, patients end up facing higher required cost sharing than is specified under their plans. These programs can leave patients with thousands of dollars in unexpected costs at the pharmacy, when a patients' cost-sharing assistance for the year is exhausted, for example, resulting in exactly the problems that cost-sharing assistance is designed to solve: prescription abandonment, poor health outcomes, and unnecessary medical spending. If patients cannot pay their full cost sharing at the pharmacy, they are typically turned away and leave the pharmacy without the medicine their doctor prescribed. For example, researchers have found that – after the implementation of an accumulator adjustment program – HDHP enrollees taking autoimmune specialty drugs had a 20 percent higher level of treatment discontinuation.[19]

Health plans and PBMs claim that accumulator adjustment programs are necessary in order to control drug costs. They claim that these programs help prevent cost-sharing assistance from driving patients towards a more expensive branded drug when a generic equivalent is available. However, the influence of manufacturer assistance in allegedly subverting formularies and other utilization management methods that promote use of low-cost therapies is overstated. In fact, cost-sharing assistance is most commonly used for medicines *without* a generic equivalent. In 2017, less than one percent of all commercial market medicine claims were filled with cost-sharing assistance for a branded medicine where a generic equivalent was available.[20] Another study found that, among the most utilized drugs by spending, a majority of branded drugs with manufacturer assistance had no generic substitute.[21]

Employers and insurers frequently cite studies that estimate the cost impacts of manufacturer assistance, but these studies often focus on the uncommon instances in which a generic alternative is available,[22] the exact situation where an accumulator adjustment program would have been permitted under the 2020 NBPP final rule's policy. When plans and PBMs impose accumulator adjustment programs for drugs with no generic equivalents, plan costs may decrease in part because patients may be forced to abandon their prescribed medicines.[23]

Further, plans and PBMs have a wide array of tools available to manage the pharmacy benefit in order to control costs, including utilization management techniques such as drug exclusion lists, prior authorization, and step therapy. Data show that these tools are well utilized, with 94 percent of employers using prior authorization and 86 percent using step therapy.[24] These techniques

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[19] Sherman, BW, et al., Impact of a co-pay accumulator adjustment program on specialty drug adherence, Am J Manag Care. 2019 Jul;25(7):335-340.
[20] IQVIA. An evaluation of co-pay card utilization in brands after generic launch. February 2018. https://www.iqvia.com/locations/united-states/library/fact-sheets/evaluation-of-co-pay-card-utilization.
[21] Van Nuys, K, et al. USC Schaeffer. A perspective on prescription drug copayment coupons. 2018. https://healthpolicy.usc.edu/wp-content/uploads/2018/02/2018.02_Prescription20Copay20Coupons20White20Paper_Final-2.pdf.
[22] Dafny, L, et al., National Bureau of Economic Research. When discounts raise costs: the effect of copay coupons on generic utilization. 2016. https://www.nber.org/papers/w22745.
[23] Sherman, BW, et al., Impact of a co-pay accumulator adjustment program on specialty drug adherence, Am J Manag Care. 2019 Jul;25(7):335-340.
[24] Pharmacy Benefit Management Institute. Trends in specialty drug benefits report. 2019. https://www.pbmi.com/ItemDetail?iProductCode=SPECIALTY_2019&Category=SPECIALTY.

steer patients toward lower-cost therapies, and, unlike for accumulator adjustment programs, patients can use appeals processes to access medically appropriate medicines. Patients have no such remedy for accumulator adjustment programs. Further, cost-sharing assistance does not circumvent the utilization management techniques of plans and PBMs: if patients are prescribed a medication that has cost-sharing assistance, and they are eligible for benefits under their plan, they would only be able to access it at the pharmacy after meeting all requisite utilization management requirements the plan may have put on that medicine.

Additionally, plans and PBMs can control access to brand medicines by excluding them from their formularies. Regulations promulgated by HHS require that plans subject to the essential health benefits (EHB) requirements cover at least the greater of one drug in each United States Pharmacopeia category and class or the same number of prescription drugs in each category and class as the EHB-benchmark plan.[25] Under the current safe harbor, large group and self-insured plans have a great deal of flexibility to develop formularies with limited access to branded products.

For these reasons, we believe the policy reversal in this proposed rule – in addition to being unlawful – is completely inappropriate and punitive towards patients who rely on prescription drugs to manage their health. The Administration has prioritized reducing what patients pay for prescription drugs,[26] and PhRMA agrees that the status quo is not working in the best interest of patients and that our health care system needs to change. However, this policy would dramatically increase patient costs at the pharmacy by undermining a critical option to help make drugs more affordable and accessible for *patients* (despite payers' best efforts to do otherwise). HHS correctly clarified in last year's rulemaking that accumulator adjustment programs are prohibited, except in the narrow case when cost-sharing assistance is offered for a brand drug for which a medically appropriate generic equivalent is available, which PhRMA acknowledges is a scenario that presents different considerations.

HHS's Proposed Rule Is Contrary to the Statutory Definition of "Cost-Sharing"

In addition to the policy considerations noted, HHS's proposed rule is not consistent with the statutory or regulatory definition of cost sharing because federal law requires that amounts charged as deductibles, coinsurance, or copayments under a health plan count toward the plan's annual limitation on cost sharing, without limiting the sources of funds that maybe be used to pay those amounts. The statutory annual limitation on cost sharing provision provides that "[t]he cost-sharing incurred under a health plan with respect to self-only coverage or coverage other than self-only coverage for a plan year. . . shall not exceed [specified amounts].[27] The statute then expressly defines "cost-sharing" for this purpose:

(A) In general.

[25] 45 CFR § 156.122(a)(1)

[26] U.S. Department of Health and Human Services. American patients first: The Trump Administration blueprint to lower drug prices and reduce out-of-pocket costs. May 2018. https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

[27] Patient Protection and Affordable Care Act § 1302(c)(1), 42 U.S.C. § 18022(c)(1).

> The term "cost-sharing" includes—
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> > (i) *deductibles, coinsurance, copayments, or similar charges*; *and*
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> > (ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of title 26) [i.e., amounts paid by a beneficiary for medical care for the beneficiary and his or her spouse and dependents, "*but only to the extent such amounts are not compensated for by insurance or otherwise*"] with respect to essential health benefits covered under the plan.
>
> (B) Exceptions.
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> Such term does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.[28]

The statutory definition does not qualify "deductibles," "coinsurance," or "copayments" based on whether a patient receives compensation for them. The "cost-sharing" definition that applies for annual limitation on cost sharing purposes clearly includes two distinct categories: (1) deductibles, coinsurance, copayments, and similar charges (with no qualification regarding how or by whom they are paid); and (2) other expenditures for medical expenses (provided that those particular expenses are not compensated by "insurance or otherwise"). Because all provisions of a statute must be considered together, the presence in clause (ii) of the limitation on expenses that are compensated by "insurance or otherwise," and its absence from clause (i), should be given its obvious meaning: that clause (i) expenses *should be included* in cost sharing even if the insured individual is compensated for them.[29] Accordingly, the statute does not permit HHS to exclude, from the annual limitation on cost sharing, deductibles, coinsurance, copayments, or similar charges for any essential health benefits – whether paid using manufacturer cost-sharing assistance or not. HHS makes no real attempt to reconcile its novel interpretation with the statutory text. It instead says, without citation to any authority, that it is proposing to "interpret the definition of cost sharing to exclude expenditures covered by drug manufacturer coupons."[30]

HHS goes on to say that "coupon amounts reduce the costs incurred by an enrollee under the health plan because they reduce the amount that the enrollee is required to pay at the point-of-sale in order to obtain coverage for the drug. The value of the coupon is not a cost incurred by or charged to the enrollee."[31] This reflects a fundamental misunderstanding of how manufacturer cost-sharing assistance works and calls into question the logical underpinnings of the proposed rule. Based on how the National Council for Prescription Drug Programs (NCPDP)—the HHS-designated standard-setting organization of electronic pharmacy transactions—has explained how cost-sharing assistance is operationalized (*See* Attachment A - NCPDP, Upstream Reporting

[28] *Id*. § 1302(c)(3), 42 U.S.C. § 18022(c)(3) (emphases added).
[29] *Cf.* Motion Picture Ass'n of Am., Inc. v. FCC, 309 F.3d 796, 802 (D.C. Cir. 2002) (discerning the meaning of a statute by relying on differences between neighboring provisions of a statute).
[30] 85 Fed. Reg. at 7136.
[31] *Id*.

of Copay Assistance Issues Brief),[32] these are factually incorrect statements. Cost-sharing assistance amounts do not affect the amount *incurred* by an enrollee under the health plan. No matter how the cost-sharing assistance is processed, it does not change the cost charged to the enrollee, which is established by the health plan and remains fixed under the health plan. The cost-sharing assistance is simply a separate source of funds some enrollees may rely upon to help pay the amount due (or incurred) under the plan benefit design at that point in time, much as secondary insurance, help from a family member, or other forms of patient assistance (discussed in further detail below) might, and is therefore equally required to count under the statute as "cost-sharing."

HHS Fails to Explain or Even Acknowledge its Reversal of its Interpretation of "Cost Sharing"

In addition, the proposed rule is arbitrary and capricious because it is based on an interpretation of the statutory definition of "cost-sharing" that is diametrically opposed to HHS's prior regulatory interpretation of this term, and HHS has failed to acknowledge, much less explain the basis for this shift, as principles of administrative law require HHS to do.[33]

The existing HHS regulation defines "cost-sharing" as "any expenditure required by *or on behalf of* an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services."[34] This definition makes explicit the meaning of the statute, as explained above. A third-party payment of amounts incurred by or charged to the enrollee do not cause those amounts to no longer be "cost-sharing." While our prior discussion indicates why this is the only reasonable interpretation of the statute, we emphasize here that whatever basis HHS may have for shifting its interpretation, it has an obligation both to acknowledge that this is a different interpretation than what exists in the current regulation and to provide a rational explanation for why it is changing this interpretation, which it failed to do in the proposed rule.

HHS Lacks Any Reasonable Justification for its Proposed Rule

Even if HHS had correctly interpreted the statutory definition of cost-sharing, the only rationale HHS provides for this proposal is its belated discovery that the rule it finalized last year "could create a conflict" with 2004 guidance from the IRS regarding the conditions under which a participant in an HDHP would be permitted to contribute to an HSA, and that health insurance issuers and sponsors of group health plans "potentially" might not be able to comply with both last year's final rule and the 2004 IRS guidance.[35] We disagree.

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[32] *See generally* NCPDP, *Upstream Reporting of Copay Assistance Issues Brief* (ver. 1.0, 2018).

[33] *See*, *e.g.*, *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) ("agency must at least 'display awareness that it is changing position' and 'show that there are good reasons for the new policy.' . . . '. . . a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy.' It follows that an '[u]nexplained inconsistency' in agency policy is 'a reason for holding an interpretation to be an arbitrary and capricious change from agency practice.' . . . An arbitrary and capricious regulation of this sort is itself unlawful") (internal citations omitted).

[34] 45 C.F.R. §§ 155.20, 156.20 (emphasis added).

[35] 85 Fed. Reg. at 7135, 7136.

HHS and IRS cannot reasonably argue that anything in the Internal Revenue Code (Code) or IRS regulations and guidance would prohibit an individual enrolled in an HDHP from contributing to an HSA solely because the plan counts manufacturer cost-sharing assistance toward the plan's deductible. Any final rule based on that premise would be contrary to law and arbitrary and capricious.

Under the HSA provisions in the Code (HSA statute), an individual must be enrolled in a "high deductible health plan," among other statutory requirements, in order to be eligible to contribute to an HSA.[36] A "high deductible health plan" is defined as a "health plan" that has "an annual deductible" of an amount at least equal to a level set annually by a statutory formula, and has a maximum annual limitation on cost sharing not greater than an amount set annually by a statutory formula.[37] Reading the HSA statute as a whole, it is clear that Congress anticipated that individuals other than the patient could pay cost-sharing amounts that could appropriately be accumulated to the deductible in an HDHP. This is because, in defining the expenses that may be reimbursed by the *HSA itself*, Congress required that the expenses be for medical care "but only to the extent such amounts are not compensated for by insurance or otherwise."[38] This is the same section of the Code in which HDHP is defined, and the definition of HDHP includes no similar requirement that expenses attributed to the deductible cannot be "compensated for by insurance or otherwise" – this, despite having imposed the same limitation on HSAs and clearly recognizing the possibility that amounts treated as cost sharing under the HDHP could nonetheless be reimbursed by another source.[39] The Code therefore supports the conclusion that having manufacturer cost-sharing assistance accumulate toward the HDHP's deductible does not disqualify the participant – or an employer on the participant's behalf – from contributing to an HSA.

Further, dictionary definitions contemporaneous with enactment of the HSA statute, in the Medicare Prescription Drug, Improvement and Modernization Act of 2003, confirm that a "deductible" was then, as now, understood to define a portion of an insured's losses that would be "deducted" from the benefit paid by the insurer, but it was not understood as a restriction on *who* paid that portion of the losses, as long as it was not the insurer.[40] Indeed, IRS has always interpreted the high-deductible requirement to be a limitation on whether the plan pays benefits, not who pays amounts incurred by the patients before the plan starts paying: "a plan is an HDHP

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[36] 26 U.S.C. § 223(c)(1)(A).
[37] *Id*. § 223(c)(2).
[38] *Id*. § 223(d)(1), (2).
[39] A participant in a HDHP is also prohibited from being covered by certain other health plans in order to contribute to an HSA. *Id*. § 223(c)(1)(A)(ii). There is no plausible argument that manufacturer assistance is such a "health plan," and that is not IRS's position. If manufacturer assistance were a "health plan," participants in a HDHP could not make HSA contributions if they receive manufacturer assistance, regardless of how the assistance is accumulated to the deductible.
[40] *Merriam-Webster's Collegiate Dictionary* 324 (11th ed., 2004) ("a clause in an insurance policy that relieves the insurer of responsibility for a specified loss of the kind insured against; *also*: the amount of the loss specified in such a clause"); *American Heritage College Dictionary* 369 (4th ed., 2004) ("A clause in an insurance policy that exempts the insurer from paying a specified amount in the event of a claim"); *see also* Bryan A. Garner, *A Dictionary of Modern American Usage* 191 (1998) ("capable of being (i.e. usu. lawfully) subtracted").

only if, under the terms of the plan and without regard to which family member or members incur expenses, *no amounts are payable from the HDHP* until the family has incurred annual covered medical expenses in excess of the minimum annual deductible . . . except for preventive care, *a plan may not provide benefits for any year until the deductible for that year is met*."[41]

The only support HHS points to for this potential conflict is an IRS notice that does not address manufacturer cost-sharing assistance and thus has no relevance to manufacturer (or other third-party) assistance.

Because there has been considerable confusion about what the IRS notice says, we believe the relevant provision, Q&A-9, should be reviewed in its entirety:

> Q–9. May an individual who is covered by an HDHP and also has a discount card that enables the user to obtain discounts for health care services or products, contribute to an HSA?
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> A–9. Yes. Discount cards that entitle holders to obtain discounts for health care services or products at managed care market rates will not disqualify an individual from being an eligible individual for HSA purposes if the individual is required to pay the costs of the health care (taking into account the discount) until the deductible of the HDHP is satisfied.
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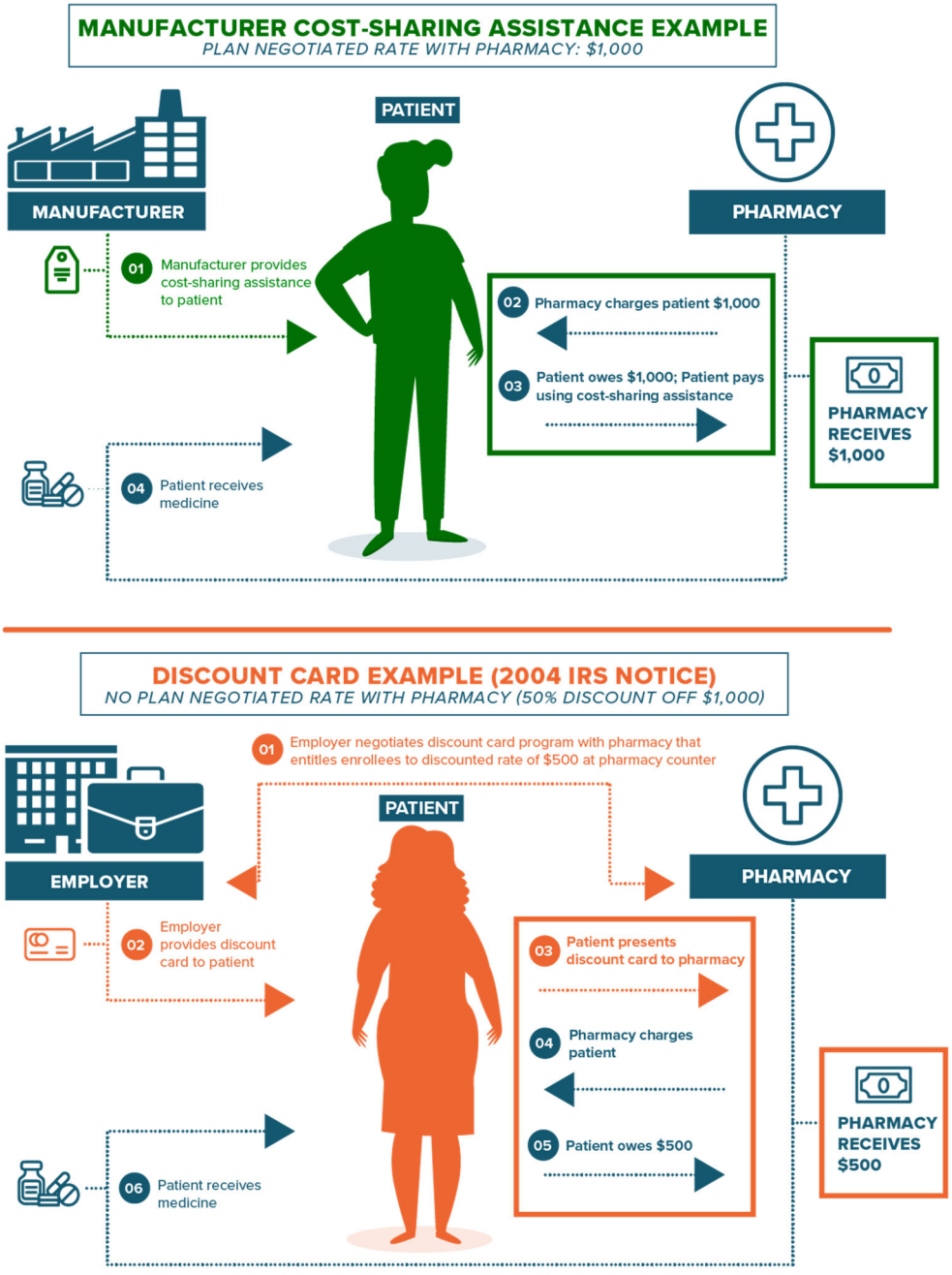
> *Example*. An employer provides its employees with a pharmacy discount card. For a fixed annual fee (paid by the employer), each employee receives a card that entitles the holder to choose any participating pharmacy. During the one-year life of the card, the card holder receives discounts of 15 percent to 50 percent off the usual and customary fees charged by the providers, with no dollar cap on the amount of discounts received during the year. The cardholder is responsible for paying the costs of any drugs (taking into account the discount) until the deductible of any other health plan covering the individual is satisfied. An employee who is otherwise eligible for an HSA will not become ineligible solely as a result of having this benefit.[42]

The facts described in this Q&A, both in the initial answer and in the example, bear no similarity to what occurs when a patient uses manufacturer assistance to help pay cost sharing under a health plan at the pharmacy. In the case of cost-sharing assistance, the pharmacist first determines, through an electronic transaction, the patient's cost sharing incurred under the health plan, and the health plan attributes that amount to the deductible and the annual limitation on cost sharing. As accurately explained by NCPDP,[43] the pharmacist then checks what value remains on the patient's cost-sharing assistance and applies this as a credit to the balance due from the patient, much like a gift card or a credit card payment would be applied. The amount available from the manufacturer cost-sharing assistance is often capped. The pharmacy receives

[41] Notice 2004-2, 2004-2 I.R.B. 269, 269 (emphases added).
[42] Notice 2004-50, Q&A-9, 2004-33 I.R.B. 196, 198.
[43] NCPDP, *supra* note 32.

the same payment it would for each drug dispensed, regardless of whether cost-sharing assistance is applied.

Q&A-9 describes an entirely different scenario in which a "discount card" is *bought* for otherwise HSA-eligible individuals in order *to access "managed care market rates"* at pharmacies, and only the amount actually paid to the pharmacy for each drug is counted toward the patient's deductible and annual limitation on cost sharing. An individual who has such a discount card has *unlimited access* to those discounts, and there is *no indication that anyone is paying the pharmacy anything for each dispensed drug other than the amount received from the patient*.



By contrast, manufacturer cost-sharing assistance is not offered by the plan sponsor but rather by a third party, and it merely helps pay cost sharing incurred, which the enrollee is still responsible for under the plan. Thus, far from presenting a conflict with last year's HHS rule, this Q&A supports the notion that an HDHP should credit to the deductible the full amount that the plan permits the pharmacy to collect for a drug, *including* manufacturer cost-sharing assistance. Manufacturer assistance does not change the rate the pharmacy charges, nor the amount the pharmacy is able to collect for each prescription, and, as such, the full amount should count toward the deductible (and the annual limitation on cost sharing). The IRS Q&A, like the HSA statutory text, reinforces that an individual can be eligible to contribute to an HSA as long as the *health plan* does not pay a benefit below the deductible.

Apart from the text of the Q&A, the Q&A's context reinforces that HHS is mistaken in viewing this Q&A as relevant to manufacturer cost-sharing assistance. An article in a leading medical journal, published in 2004 contemporaneously with the IRS guidance, noted that the country's health plan benefit designs were at a moment of transition with the advent of some benefits for which patients did not have insurance benefits but were able to access "insurer-negotiated discounted prices," which the author noted was the model "currently . . . found primarily for prescription drugs (discount cards)."[44] This discussion in this article further clarifies that IRS's reference to a prescription drug "discount card" describes a situation in which the amount the patient is charged for the drug by the pharmacy is reduced (and that there is no payment to the pharmacy for the drug other than what the patient pays directly).

In addition, the NCPDP has explained that, as late as 2018, the pharmacy industry, and the HHS-designated pharmacy electronic transaction standards, had no reliable method for health plans to track whether particular third parties are providing cost-sharing assistance for patients covered in commercial health plans.[45] If Q&A-9 actually described a situation in which a third party pays a portion of the pharmacy charge, and that amount cannot be credited to the plan's deductible, the industry and the HHS-recognized transaction standards would have developed a way to implement that process in the intervening 16 years. They have not.

There simply is no conflict between this Q&A and the well-established practice of manufacturer cost-sharing assistance applying to a health plan's deductible and the annual limitation on cost sharing. Instead, it seems as though HHS has found a 16-year-old IRS Notice, rarely cited and never applied in the manner proposed here, relating to an entirely different factual scenario, drafted at a time when these federal cost-sharing protections did not exist – and now seeks to rely on it as the *sole* justification to institute a significant policy reversal that would have a harmful impact on patients. An IRS notice that was issued prior to the statute establishing the annual limitation on cost sharing, and that has never been interpreted to relate to cost-sharing assistance, should not be used to reverse a finalized HHS regulation promulgated under this statute. HHS's analysis that there *may* be a conflict is particularly flawed because the IRS notice is not legally

[44] Robinson, JC. Reinvention of health insurance in the consumer era. JAMA. 2004 Apr 21;291(15):1880-6.
[45] NCPDP, *supra* note 43, at 17.

binding and instead is merely a guidance document.[46] It is particularly arbitrary for HHS to change course based on a potential conflict purportedly created by a non-binding guidance document issued by another agency.

Since Q&A-9 provides no rational basis for this dramatic policy change, HHS must abandon the change. In addition, even if HHS's interpretation of Q&A-9 were correct, this would still not be a justification for permitting manufacturer assistance to be excluded from the annual limitation on cost sharing when Q&A-9 relates only to deductibles set by HDHPs; health plans could choose to exclude cost-sharing assistance from the deductible while still applying them to the annual limitation on cost sharing, as they are required to do under the statute and regulation. HHS has provided no rational explanation to regulate the annual limitation on cost sharing in this way, given that Q&A-9 relates only to deductibles. Should HHS persist, it should provide a new opportunity for public comment prior to finalizing so that stakeholders may address any new rationale HHS may provide.[47]

The Proposed Rule Would Capriciously Permit Manufacturer Assistance to be Excluded from the Annual Limitation on Cost Sharing While Continuing to Require Other Forms of Assistance to be Included

The proposed rule is also arbitrary and capricious because it fails to acknowledge that many other forms of patient assistance exist, beyond manufacturer support, and therefore fails to explain either why it is reasonable to single out manufacturer assistance, or how its policy, more broadly applied, would impact these other types of assistance.

Beyond manufacturer assistance, patients may also receive assistance from other third parties, such as employers (who commonly make contributions to employee HSAs) or family members to support pharmacy or other cost sharing. For example:

- In a recent survey, 50 million – or 20 percent – of American adults reported donating to a crowdfunding campaign to help raise money for a medical bill or treatment through sites like GoFundMe.[48] Online donations made through GoFundMe can be withdrawn directly to a patient's bank account,[49] so a provider or insurer is unable to track when this type of assistance is used towards incurred cost-sharing obligations.

[46] *See generally Reed v. Commissioner*, T.C. Memo 2014-41, at *3 (2014) ("informal guidance, such as the FAQs posted to the IRS' Web site, is not an authoritative source of Federal tax law").

[47] That neither HHS nor IRS has apparently definitively explained whether an actual conflict exists between the IRS guidance and last year's HHS rule, when it is fully within their authority to definitively decide this question, demonstrates that there is no actual conflict and HHS's reliance on the *potential* of an *alleged* conflict, without saying whether an actual conflict exists, is itself an arbitrary and capricious basis upon which to change its entirely correct interpretation under last year's rule. *See Motor Veh. Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also PBG Corp. v. LTV. Corp.*, 496 U.S. 633, 645 (1990) (where a conflict may exist, the inquiry should focus on whether the agency rules "*actually conflicted* with any provision" of statutory schemes implemented by other agencies, not whether there is merely a potential conflict).

[48] NORC. Millions of Americans donate through crowdfunding sites to help others pay for medical bills. February 2020. https://www.norc.org/NewsEventsPublications/PressReleases/Pages/millions-of-americans-donate-through-crowdfunding-sites-to-help-others-pay-for-medical-bills.aspx.

[49] GoFundMe. Answers to common fundraising questions. https://www.gofundme.com/c/questions.

- Manufacturer assistance for durable medical equipment is not uncommon. For example, Insulet operates a patient assistance program for its insulin management system for patients (including insured patients) unable to afford out-of-pocket obligations.[50] Medtronic[51] and ConvaTec[52] operate similar programs to address patient affordability challenges with their insulin and ostomy supply products, respectively.
- When an individual incurs cost sharing liability for medical services, such as an emergency room visit, it is not uncommon for the enrollee to pay the required deductible or coinsurance over time, despite the entire cost accumulating to the deductible and out-of-pocket maximum at once. In a survey of patients who had a hospital or emergency room visit in the past year, 44 percent used a payment plan to address out-of-pocket expenses for services received.[53] CarePayment is one company that partners with health care providers to offer their patients payment options for their cost sharing obligations with zero percent interest, made possible by fees paid by health care providers to CarePayment.[54] In situations where a facilitator like CarePayment is not in place, the hospital may administer a payment plan directly and may even incur bad debt at some point in time should the patient be unable to pay back the full amount incurred.

The proposed rule creates a contradiction with respect to these other types of assistance, and perhaps places them in legal limbo. On one hand, there is no indication from the proposed rule that other types of patient assistance, like those listed above, would not be required to count toward the annual limitation on cost sharing. This has always been the policy in the past, and health plans do not generally know whether a hospital or other health care provider has forgiven cost sharing or been unable to collect cost sharing and has written those amounts off as bad debt. Plans are still required to count such amounts toward out-of-pocket limits. This is not an insignificant sum, as uncompensated care (defined as bad debt and charity care, at cost) made up 4.2 percent or $34.8 billion, of hospital expenses in 2017.[55] HHS has provided no explanation, let alone a rational one, as to why manufacturer cost-sharing assistance need not be counted when all these other forms of assistance must be.

On the other hand, HHS's mistaken interpretation of the IRS HDHP guidance seems to suggest that counting *any form of patient assistance* toward the deductible or annual limitation on cost sharing could disqualify a participant from contributing to an HSA. This interpretation could throw these other forms of assistance (such as funds raised through GoFundMe or amounts financed through a payment plan or a third party) into legal limbo, creating massive uncertainty

[50] Omnipod. The Omnipod insulin management system financial assistance program. https://www.myomnipod.com/become-a-podder/insurance-coverage/financial-assistance-program.
[51] Medtronic. Ordering and billing: Financial assistance. http://www.medtronicdiabetes.com/customer-support/ordering-and-billing/billing.
[52] ConvaTec. Patient assistance program. https://meplus.convatec.com/articles/patient-assistance-program/.
[53] PYMNTS. The challenging landscape of healthcare payment plans. 2019. https://www.pymnts.com/wp-content/uploads/2019/02/Healthcare-Payment-Plans-January-2019.pdf.
[54] *See, e.g.*, CarePayment. About us. https://www.carepayment.com/about-us/; Parasail. ProPatient by Parasail: simple medical payment plans—zero interest added. https://www.parasail.com/propatient/.
[55] American Hospital Association. TrendWatch Chartbook 2018: trends affecting hospitals and health systems. 2018. https://www.aha.org/system/files/2018-07/2018-aha-chartbook.pdf.

and severe patient access problems. Either way, the standard for manufacturer cost-sharing assistance proposed by HHS is contradictory, and the lack of explanation makes it capricious.

The Proposed Rule Is Inconsistent with the Administration's Health Policy Objectives

In addition to the legal and public policy infirmities identified above, the proposed rule is inconsistent with President Trump's own stated objectives—and Executive Orders—for his Administration's health care policy. In its "American Patients First" drug pricing policy blueprint, the Trump Administration expressed the goal of improving patient drug adherence by lowering out-of-pocket spending.[56] The 2020 NBPP final rule's statement that plans are required to count towards the annual limitation on cost sharing amounts paid using manufacturer assistance for drugs that lack medically appropriate generic equivalents aligned with this objective. It did so by protecting patients from facing massive, unexpected bills for drugs without alternatives as a result of plans implementing accumulator adjustment programs, while also ensuring that assistance is not abused to support the purchase of higher-priced branded drugs over appropriate generic equivalents. The proposed rule, by contrast, would use an IRS notice, promulgated by a prior administration, and never before used to address cost sharing, to reverse these important patient protections.

But the proposed rule does worse than merely roll back the protections established last year. Although the proposed rule claims that it would permit issuers and plans to have "flexibility" and determine whether to include or exclude manufacturer cost-sharing assistance from the annual limitation on cost sharing and to "continue longstanding practices" in this regard, it could actually coerce HDHPs to apply accumulator adjustment programs. Taken as a whole, the proposed rule gives plan sponsors and health insurance issuers a choice between either including manufacturer assistance in the accumulator or offering an HSA-eligible HDHP, but not both, as many HDHPs do today. Additionally, while the proposed regulations purport to leave room for state policy and states' rights to regulate insurance, the agency's implied position that HDHPs might be compelled to use accumulator adjustment programs could undercut recent state legislation to govern the market conduct of insurers within their state (including limitations on accumulator adjustment programs).[57] A footnote to the rule makes explicit that including cost-

[56] U.S. Department of Health and Human Services. American patients first: The Trump Administration blueprint to lower drug prices and reduce out-of-pocket costs. May 2018. https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

[57] To date, the following states have banned accumulator adjustment programs: VA, WV, IL, and AZ. Additionally, HHS notes that states may limit the flexibility that health insurance issuers have to include or exclude drug manufacturer cost-sharing assistance from the annual limitation on cost sharing (84 Fed. Reg. at 7136). States would only be able to address the possible harms caused by accumulator adjustment programs for enrollees in the individual market and in fully insured group health plans, which comprise only 39 percent of the employer-sponsored market (KFF. 2018 employer health benefits survey). Nearly 96 million enrollees are covered by self-insured group health plans regulated under the Employee Retirement Income Security Act of 1974 (ERISA); therefore, these enrollees would not be offered protection from state accumulator adjustment program bans. It is crucial that HHS continues to prohibit accumulator adjustment programs, per the 2020 NBPP final rule (KFF. Health insurance coverage of the total population. 2018; KFF. 2018 employer health benefits survey).

sharing assistance in the deductible accumulator "could disqualify an individual from making HSA contributions," under HHS's apparent misunderstanding of IRS Notice 2004-50, Q&A-9.[58]

Placing plans and issuers in such a lose-lose situation is even more directly inconsistent with Administration priorities than rolling back the 2020 NBPP final rule's policy. President Trump has made promotion of HSAs a centerpiece of his health policy, including in his Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First, issued June 24, 2019.[59] That Executive Order requires the Secretary to "issue guidance to expand the ability of patients to select high-deductible health plans that can be used alongside a health savings account." The proposed rule either would require that plans and issuers force participants to abandon HSAs, just as the Trump Administration's efforts to promote HSAs are beginning to achieve success,[60] or, alternatively, it would drive up patient costs at the pharmacy counter, potentially undermining treatment that may have been well established for years with the help of manufacturer assistance. The Trump Administration would be giving plans and issuers no real choice and would put patients' interests second to those of the health plans that apply accumulator adjustment programs.

Disclosures Should Be Designed So That Patients Are Not Surprised by This Change

If HHS were to finalize this misguided policy reversal, it should impose robust disclosure and transparency requirements on plan sponsors, health insurance issuers, and their PBMs. Plan disclosures of existing accumulator adjustment programs are woefully inadequate in both their content and the method by which they are provided. PBMs and their plan sponsor and issuer clients have often deceptively described accumulator adjustment programs as a *benefit* to plan participants, when they do nothing but undermine the purpose of manufacturer assistance and increase costs to patients. For example, UnitedHealthcare has described its accumulator adjustment program as "benefit plan protection" and says that program would still permit patients to use manufacturer assistance to "help reduce your out-of-pocket costs,"[61] even though the impact of this accumulator adjustment program is precisely to eliminate the benefit of manufacturer assistance in helping patients pay out-of-pocket costs.

The first time many beneficiaries learn of these accumulator adjustment programs is when they go to a pharmacy counter or doctor's office and face substantially higher cost sharing than they have in the past, often for drugs that have maintained their health for years and for which patients

[58] 85 Fed. Reg. at 7136 n.115.
[59] U.S. Department of Health and Human Services. American patients first: The Trump Administration blueprint to lower drug prices and reduce out-of-pocket costs. May 2018. https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.
[60] The percentage of covered workers enrolled in an HSA-eligible HDHP increased for the first time under the Trump Administration in 2019, to 23 percent from 19 percent in 2018. Among employers the offer health coverage, the percentage that offer an HSA-eligible HDHP increased from 17 percent in 2017 to 26 percent in 2019 (KFF. 2019 employer health benefits survey).
[61] UnitedHealthcare. Coupon adjustment: benefit plan protection. 2018. https://www.myuhc.com/content/myuhc/Member/Assets/Pdfs/UHC75611-062018_B2C-CMP-Sellsheet_CCAA-Coupon_FINAL.pdf.

may now need to forego other essential needs in order to afford.[62] If HHS were to proceed to essentially require these accumulator adjustment programs (or risk participants losing HSA eligibility), it should require plans and issuers to proactively provide written notice to each enrollee in the plan that manufacturer assistance will no longer count toward deductibles and the annual limitation on cost sharing due to new federal regulatory action.[63] Such notice should use a form prescribed by HHS, subject to public notice and comment. These notices would need to explain the impact of these programs in plain English (and other languages), including examples of the adverse impact on cost sharing for typical patients. Plans and issuers cannot be allowed to use misleading notices to make patients believe these programs benefit them.

Medical Loss Ratio: Reimbursement for Clinical Services Provided to Enrollees (§ 158.140)

PhRMA supports the proposal to require health insurance issuers to reduce their reported incurred claims to reflect the value of all price concessions, including manufacturer rebates retained by the issuer's PBM and not passed through to the enrollee or issuer. PhRMA is concerned, in general, with the practice of issuers or PBMs receiving price concessions on prescription drugs and not sharing the benefit of those concessions with enrollees. Current MLR reporting rules do not ensure that the substantial discounts and rebates paid by biopharmaceutical companies to PBMs are reflected in reported claims in the MLR calculation. In fact, in some cases they may be getting applied to plan administrative costs, artificially depressing them.[64] Enrollees should be able to share in the benefit by having price concessions for prescription drugs reflected in reduced premiums or higher MLR rebates (just as is done with negotiated rates for medical benefits). Therefore, as HHS has proposed, all price concessions, including those retained by PBMs, should be taken into account in determining MLR rebate obligations.[65] As HHS noted, this change appropriately aligns commercial MLR reporting with the existing reporting rules for Medicare and Medicaid managed care.

Biopharmaceutical companies negotiate substantial rebates and discounts with PBMs and health plans. Rebates, discounts, and other price concessions to health insurers, PBMs, the government, and others have more than doubled since 2012, totaling $166 billion in 2018.[66] In the commercial market, an increasing share of these discounts and rebates are retained by intermediaries

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[62] Sherman, BW, et al., Impact of a co-pay accumulator adjustment program on specialty drug adherence, Am J Manag Care. 2019 Jul;25(7):335-340.

[63] In our comment letter responding to the Transparency in Coverage proposed rule (CMS-9915-P, 84 Fed. Reg. 65464 (Nov. 27, 2019)), we also note that such information on accumulator adjustment programs should be made available in machine-readable files. This information would give more insight into health plans' cost sharing design.

[64] 85 Fed.Reg. at 7140.

[65] We also support HHS's proposal to define PBM in a functional sense, as an "entity providing pharmacy benefit management services to the issuer and are associated with administering the issuer's prescription drug benefits." Proposed 45 C.F.R. § 158.160(b)(2)(vii). We agree that it is important for HHS include a functional definition that reflects the range of services PBMs offer and accounts for the complex corporate structures and vertically integrated arrangements between PBMs and other entities (e.g., health plans). We believe a functional definition will also help capture other entities that essentially provide PBM services. *See* Fein, AJ. Drug Channels. Drug channels news roundup, May 2019: Express Scripts' new GPO…." May 2019.

[66] Fein, AJ. Drug Channels. The gross-to-net bubble reached a record $166 billion in 2018. April 2019. https://www.drugchannels.net/2019/04/the-gross-to-net-bubble-reached-record.html.

involved in distributing or paying for medicines, rather than directly passed on to patients. Compared to list price growth, rebates and other discounts reduced average net price growth for brand medicines by nearly three-quarters in 2018. In that year, net price growth was just 0.3 percent, less than the rate of inflation.[67] Companies that research, develop, and manufacture medicines received and retained just 54 percent of total point-of-sale spending on brand drugs in 2018, due to increasing rebates, fees, and other price concessions. Meanwhile, the share of spending received by other stakeholders increased from 33 percent in 2013 to 46 percent in 2018.[68]

As the HHS Office of Inspector General has noted, the current rebate framework may incentivize both PBMs and health plans to favor medicines that carry higher rebates.[69] These misaligned incentives may also be the result of the types of arrangements PBMs commonly negotiate with their health plan clients, which allow PBMs to retain a portion of negotiated rebates and/or other price concessions as compensation for their services pursuant to their arrangements with those plans, or which may guarantee a minimum level of rebates to the plan sponsor.[70] Lack of transparency in contracts between employers and PBMs has led many plan sponsors to question the share of rebate savings being passed through, how much the PBM is retaining for administrative fees, and whether the PBM is disclosing and passing on other price concessions, such as savings from price protection rebates.[71] Manufacturers are not party to these arrangements.

PhRMA supports HHS's efforts to address misaligned incentives in the supply chain with this proposal. HHS estimates its proposal could increase MLR rebates by more than $18 million a year,[72] reflecting millions of dollars in price concessions that might not otherwise be made available to patients. We also support HHS's proposal to make a conforming change to require plans to report prescription drug rebates and price concessions as non-claims costs, and to make these amendments effective for the 2021 MLR reporting year. Medicare and Medicaid managed care plans already reduce incurred claims for direct and indirect remuneration, so there should be little effort needed to apply the same rules to commercial health insurance. This change will extend to policyholders the same relief HHS has already provided for itself in Medicare and Medicaid.

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[67] IQVIA. The global use of medicine in 2019 and outlook to 2023. January 2019. https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.

[68] Berkeley Research Group. Revising the pharmaceutical supply chain: 2013-2018: figure 1. January 2020. https://www.thinkbrg.com/newsroom-publications-revisit-pharma-supply-chain.html.

[69] Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2340, 2341 (Feb. 6, 2019).

[70] Altarum. The impact of prescription drug rebates on health plans and consumers. April 2018. https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf.

[71] Midwestern Business Group on Health. Drawing a line in the sand: employers must rethink pharmacy benefit strategies. September 2017. https://higherlogicdownload.s3.amazonaws.com/MBGH/4f7f512a-e946-4060-9575-b27c65545cb8/UploadedImages/Specialty%20Pharmacy/DMJ_MBGH_Line_in_the_Sand_RV12_9617.pdf.

[72] 85 Fed. Reg. at 7152.

However, the HHS proposal does not address health plans' common practice of using negotiated rebates to reduce premiums for all enrollees, rather than to directly lower costs for patients taking the rebated medication. PhRMA supports moving toward commercial supply chain and pricing arrangements that would allow the full discounted price of a drug to be reflected at the point of sale, allowing patients to benefit directly from these substantial price concessions. When patients face deductibles or coinsurance, health plans typically base patients' cost sharing at the pharmacy counter on a medicine's list price, rather than the discounted price paid by the plan. Notably, more than half of commercially insured patients' out-of-pocket spending for brand medicines is based on list price.[73] We welcome the fact that some health insurers and their PBMs have begun developing plan designs in which at least some price concessions are passed through and reflected in reduced patient cost sharing, and we hope this trend continues moving forward.[74]

Promoting Value-Based Insurance Design

VBID has been explored by commercial and Medicare health plans as a way to incentivize patient choices about their care that better align with the value of the full range of prevention, diagnosis, and treatment options and health care management strategies available to them. As such, VBID represents a potential opportunity to overcome barriers in existing benefit designs that impede patients' ability to gain access to the items and services that are most valuable to them, such as very high cost sharing for clinically appropriate medicines. That said, achieving the goals of VBID, while also advancing the related goal of delivering patient-centered, high-quality care, requires VBID to be carefully constructed in ways that recognize the value of medical advances, the value of items and services based on individual patient circumstances, needs, and preferences, and differing perspectives on value and variability among patients.

VBID should be accompanied by meaningful, relevant measures of clinical quality and patient satisfaction to ensure VBID achieves the goals of incentivizing patient choice and improving health outcomes. In considering VBID as a solution, CMS should consider the following recommendations and patient protections:

- VBID should achieve the goal of reducing beneficiary cost sharing for items and services that help achieve desired clinical and related health outcomes (e.g., quality of life and productivity) and are valued by the individual patient.
- Plans should rely on the full body of relevant, valid evidence in creating benefits that adjust cost sharing for items and services under VBID.
- VBID should be accompanied by meaningful, relevant measures of clinical quality and patient satisfaction to ensure the goals of incentivizing patient choice and improving health outcomes are met.

[73] IQVIA. Patient affordability part one. May 2018. https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-one.
[74] Fein, AJ. Drug Channels. Employers slowly warm to point-of-sale rebates—but must move faster for insulin. September 2019. https://www.drugchannels.net/2019/09/employers-slowly-warm-to-point-of-sale.html.

- Benefits should assure patients and providers have access to a broad choice of health care services and treatment options and allow for tailoring of care to meeting patients' specific needs based on varying clinical circumstances, comorbidities, genetic variations, and patient preference.
- VBID should be transparent in design and implementation, with opportunity for input on benefit design from a range of stakeholders, particularly patients and clinicians.

HHS cites work from the Center for Value-based Insurance Design at the University of Michigan (the VBID-X project) in identifying high-value services and drugs for which an issuer may want to consider offering with low or zero consumer cost sharing, and low-value services for which an issuer should consider setting at higher consumer cost sharing. PhRMA appreciates that several classes of drugs are listed in the high-value category and encourages plans and issuers to lower cost sharing for these and other medicines that improve the quality of life and health of patients. Better use of medicines, such as improved adherence to needed treatments, offers the opportunity for better results for patients and an estimated $213 billion per year in health care savings.[75] Researchers have also found that every additional dollar spent on medicines for adherent patients with chronic diseases like congestive heart failure, high blood pressure, diabetes, and high cholesterol generates $3 to $10 dollars in savings on emergency room visits and inpatient hospitalizations.[76]

However, we are concerned that some aspects of the "value based" model QHP proposed by HHS, specifically its reference to "non-preferred branded drugs" as a category for which cost sharing should increase, does not meet the above criteria for VBID. As HHS encourages plans to develop VBID benefit packages, it should not be encouraging plans to increase cost sharing in entire service categories without the appropriate clinical consideration. Plans already have incentives and broad flexibility to adjust cost sharing for non-preferred drugs and make their cost sharing and formulary decisions recognizing that access to these drugs is important for certain patients based on their clinical profile and personal preferences.

The VBID-X model's authors apparently made their recommendation without any explicit consideration of the relative clinical value of a non-preferred drug versus a preferred one, and instead recommend increasing non-preferred drug copays "to finance the increased coverage of the selected high-value services," on the assumption that non-preferred drugs "are likely to be overused."[77] This approach to non-preferred drugs specifically contradicts our recommended principles for VBID, in that it would limit patients' and providers' choice of therapies without consideration for their varying clinical circumstances or patient preference.

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[75] IMS Institute for Healthcare Informatics. Avoidable costs in U.S. healthcare: the $200 billion opportunity from using medicines more responsibly. June 2013.

[76] Roebuck MC, Lieberman JN, Gemmill-Toyama M, et al. Medical adherence leads to lower health care use and costs despite increased drug spending. Health Affairs; 2011;30(1):91-99.

[77] Richardson, H., et al. Health Affairs Blog. V-BID X: creating a value-based insurance design plan for the exchange Market. July 2019. https://www.healthaffairs.org/do/10.1377/hblog20190714.437267/full/.

Moreover, it contradicts the values set forth by the progenitors of VBID itself. Dr. Mark Fendrick, a leading proponent of VBID, often says that the clinical benefit derived from an item or service depends on who is using it, who is delivering the service, and where it is being delivered.[78] Furthering these principles, the Research Consortium for Health Care Value Assessment, a partnership between Altarum and VBID Health (in which PhRMA participates) have produced a framework for defining low value care. This framework argues that low value care should be: 1) strongly backed by clinical evidence, 2) low in heterogeneity of value across patients and settings, 3) easy to measure using claims data, and 4) non-controversial.[79] Classifying an entire category of medicines as "low value" does not meet these principles or criteria at all.

As previously mentioned, PhRMA strongly believes that VBID should be transparent in design and implementation. Only a small group of participants had any input at all in the VBID-X model: HHS, two insurance industry association representatives, two state regulators, and three academic professors, all convened by a private foundation.[80] No representatives of patients or their advocacy organizations, no providers, and no manufacturers were asked to participate in the model's development. HHS should not develop, and certainly should not publicly promote, dramatic changes to benefit packages without a full and fair opportunity to receive and consider the views of all parties. We suggest that HHS conduct its future development of VBID strategies in public view, in compliance with Federal Advisory Committee Act, and after soliciting stakeholder input prior to implementation.

HHS Risk Adjustment (§ 153.320)

PhRMA supports HHS's decision to continue including prescription drug categories (RXCs) as an element in calculating adult risk scores. RXCs are an appropriate and important element in the model since they improve the model's predictive accuracy, especially for certain condition categories in which the predicted medical expense for a patient varies dramatically depending on whether or not a patient is receiving active treatment. We recognize that as drug prices change—and in some cases, decline—it may be appropriate to recalibrate or constrain the coefficients for particular RXCs to reflect the current market environment.

While these recalibrations are appropriate if they are necessary to improve the model's predictive accuracy, we continue to believe that it is unlikely that insurers game the model by encouraging providers to prescribe particular treatments when they are unnecessary. The professional independence and ethical standards of health care providers would prevent them from prescribing drugs that they did not believe were medically necessary and appropriate. In

[78] University of Michigan Center for Value-Based Insurance Design. Understanding clinical nuance. https://vbidcenter.org/initiatives/v-bid-clinical-nuance/.
[79] Research Consortium for Health Care Value Assessment. A framework for addressing low-value care. June 2019. https://www.hcvalueassessment.org/application/files/3015/6139/5177/Concept_Paper_No._2_-_Addressing_Low-Value_Care.pdf.
[80] Chernew, ME., et al. Health Care Markets & Regulations Lab. V-BID X: creating a value-based insurance design plan for the exchange market. June 2019. http://vbidcenter.org/wp-content/uploads/2019/09/VBID-X-White-Paper-92019.pdf.

addition, enrollee cost sharing would likely prevent patients from filling prescriptions of dubious clinical benefit. We think the much greater concern is that the risk adjustment model could fail to adequately compensate issuers for enrollees with serious chronic conditions, and this could cause issuers to discourage enrollment by these patients, or design formularies or utilization management practices to make it difficult for patients to access innovative medicines. Thus, we encourage HHS to evaluate the model continually to ensure it fully captures the cost of the current standard of care for conditions in the model.

Premium Adjustment Percentage (§ 156.130)

PhRMA continues to oppose HHS's decision to incorporate individual market premium rates into the calculation of the annual premium adjustment percentage. Doing so automatically increases costs for enrollees by lowering the value of premium tax credits and establishes higher annual limitations on cost sharing. It is inappropriate to for HHS to do this, especially when health insurance premiums and out-of-pocket medical costs remain unaffordable for many. The decision to adopt this methodology for the premium adjustment percentage's calculation is an entirely discretionary one, which has, by HHS's own analysis, resulted in 100,000 people losing coverage in the exchange.[81] Further, this impacts millions more people who obtain coverage through their employers and will face higher out-of-pocket spending. HHS should revert to its prior premium adjustment percentage methodology.

Excepted Benefit HRAs Offered by Non-Federal Government Plan Sponsors (§ 146.145)

We remain concerned that permitting employer-funded HRAs to pay for individual market health insurance coverage could substantially undermine employer-sponsored health coverage, to the detriment of healthy and sick employees alike who rely on robust employer-sponsored benefits. PhRMA supports HHS's proposal to require non-federal governmental sponsors of excepted benefit HRAs to provide similar notices to plan participants as those that are required under the Employee Retirement Income Security Act of 1974 (ERISA) for private employers' excepted benefit HRAs. The permissible uses of excepted benefit HRAs are intentionally limited, so it is important that participants, including those covered by non-federal governmental plans, understand the limits of this form of plan.

[81] 85 Fed. Reg. at 7151.

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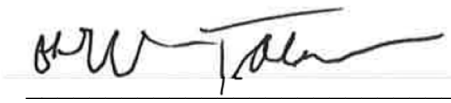
PhRMA appreciates the opportunity to provide comments regarding this proposed rule. Please feel free to contact Lisa Joldersma (202-835-3400) if we can provide any further information or if you have any questions about the topics discussed in our comments. We look forward to continuing to engage with HHS on these important issues.

Sincerely,



Lisa Joldersma
Senior Vice President
Policy and Research

Lisa Lowenstein
Assistant General Counsel

Attachment A - NCPDP, Upstream Reporting of Copay Assistance Issues Brief

Upstream Reporting of Copay Assistance Issues Brief

Version 1.0

June 2018

National Council for Prescription Drug Programs
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Upstream Reporting of Copay Assistance Issues Brief

Version 1.0

Published by:
National Council for Prescription Drug Programs

Publication History:
Version 1.0 June 2018

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Disclaimer

While all information in this document is believed to be correct at the time of writing, this document is for educational purposes only and does not purport to provide legal advice. If you require legal advice, you should consult with an attorney. The information provided here is for reference use only and does not constitute the rendering of legal, financial, or other professional advice or recommendations by NCPDP.

The existence of a link or organizational reference in any of the following materials should not be assumed as an endorsement by NCPDP.

The writers of this issues brief will review and possibly update their recommendations should any significant changes occur.

This document is for Education and Awareness Use Only.

1. Background

Commercial health insurance plans typically include a deductible and/or coinsurance provision as part of their benefit. Plans can be structured where the member pays an up-front and/or ongoing out-of-pocket (OOP) amount to share the costs of their coverage. For instance, a health plan may require a member first pay $500 in deductible before program benefits begin, and then a 15% coinsurance until some maximum OOP amount has been reached.

With increasingly expensive medications and the increase in commercial plans that include higher deductibles, ensuring patients can afford their prescribed treatment is a growing challenge for the industry. Programs, which may or may not be needs-based, have been developed to assist patients with their out-of-pocket costs. These supplemental programs are commonly referred to as "copay assist", "voucher", "manufacturer coupons" and "patient assistance", among other names. Examples include, but are not limited to, brand drug programs funded by pharmaceutical manufacturers/suppliers and not-for-profit organizations who offer assistance for specific disease states or medications.

NCPDP formed the WG1 Upstream Reporting of Copay Assistance Task Group to explore options for reporting these supplemental programs' contributions toward a patient's liability to a prior payer, such as a commercial health plan. This might enable the prior payer to calculate a patient's actual OOP expenses after all programs have been billed and apply those expenses to commercial plan accumulators.

Based on the task group's research, the complexities related to the stated issue became more apparent. As a result, the scope of the task group was limited to examining scenarios that involve a commercial payer, a supplemental prescription assistance program and the potential for reporting the information utilizing an NCPDP transaction.

The task group is aware of proprietary methods for reporting or collecting copay assistance information; these were not reviewed as part of the research. Only existing NCPDP standard transactions were reviewed as potential solutions.

2. Purpose

The purpose of this issues brief is to document the results of the task group research and not to provide recommendations or solutions. The research includes:

- Program types
- Possible use cases
- Viability of using the NCPDP Telecommunication Standard Information Reporting (Nx) Transaction
- Other Obstacles to solutions

For questions related to this issues brief contact info@ncpdp.org.

3. Types of Prescription Assistance

There are many different types of programs available to patients to reduce their out-of-pocket pharmacy costs. The two main classes of programs include but are not limited to:

- Copay Assistance or Manufacturer Coupon Programs:
  These programs are generally funded by the drug manufacturer for the specific product being dispensed and are considered non-needs-based, where there are usually no income requirements for the patient to qualify for the program. These programs may or may not require the patient have a specific diagnosis to be eligible. These programs may have per use, monthly or annual limits on the amount they will contribute and are offered at the sole discretion of the manufacturer.

- Patient Assistance Programs:
  These programs are generally funded by foundations, charitable organizations, or drug manufacturers. If these programs are administered by a non-profit entity, they will have filed the appropriate tax documents. These programs have qualification requirements (such as financial need, clinical, geographic or socio-economic status) patients must meet to be eligible for assistance.

For the purposes of this document, the terms “copay assistance” or “manufacturer coupon” shall refer to all non-needs-based programs, while the term “patient assistance” will refer to needs-based types of programs. The general term “prescription assistance” will be used broadly to refer to both types of programs.

4. Use Case

Commercial plans track member qualified spending in order to determine when deductibles and other financial accumulators are met. Prescription assistance programs are not linked with commercial health insurance plans, therefore the monetary assistance provided by the former are not considered when the commercial plan is tracking the member's financial accumulators.

There is currently no standard mechanism to share transaction data between prescription assistance programs and commercial health insurance programs. There are two separate transactions processed by the same processor or different processors – the primary (commercial) claim and the claim for the prescription assistance program. The commercial plan may not have knowledge of the prescription assistance program. Ultimately, the primary payer wants to differentiate the amount the patient paid versus any amounts paid on their behalf by specific payer types.

Example Scenario 1:
Jane Doe has a prescription for Drug A. Drug A is estimated to cost $24,000 per year. Jane's health plan has a $5,000 deductible and once that is met she pays 20%. Drug A's manufacturer offers a coupon program that Jane can use, limiting her out of pocket cost to $250/month. At year end, although Jane's plan has recorded that she met her $5,000 deductible, the manufacturer coupon actually reduced her out-of- pocket to $3,000.

Example Scenario 2:
There is a charitable foundation where Jane can apply for financial assistance. Jane meets the income requirements for the disease state grant fund and is awarded $5,000 over the next 12 months. She uses these funds for doctors' visits, home therapy and prescriptions. Her medical insurance does not count these funds towards those expenses and her prescription coverage would likely follow suit.

5. Research

5.1 Prescription Assistance Billing Methods

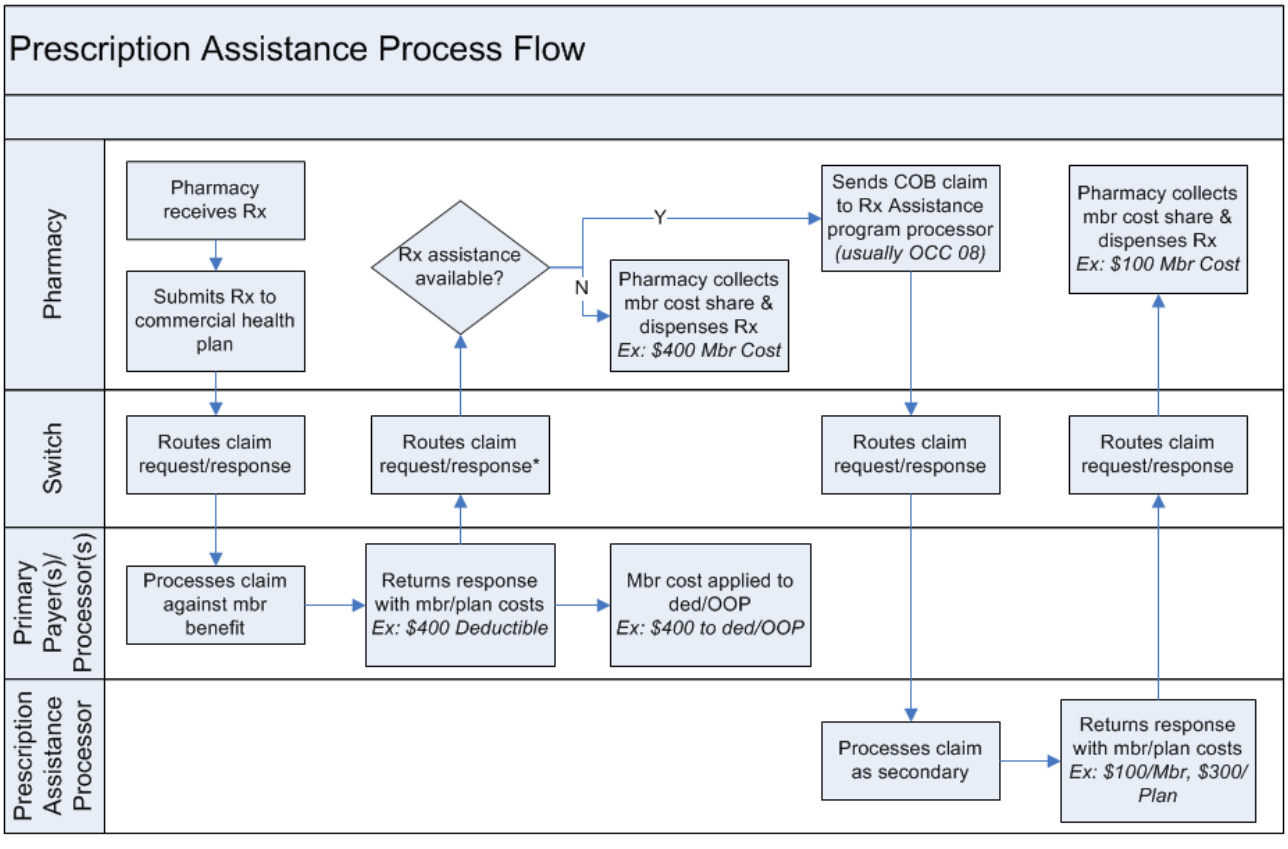
Prescription assistance programs are typically billed as coordination of benefit (COB) claim transactions. The primary payer is billed and provides a response with the patient's cost share information and then the prescription assistance program is billed. These COB claims are normally billed via NCPDP Telecommunication Standard version D.0 with the following Other Coverage Codes (308-C8):

- 03: Other Coverage Billed – claim rejected - Code used in coordination of benefits transactions to convey that all payers billed have returned rejected responses indicating the claim is not covered. This is typically used when the patient has valid insurance coverage, but the plan does not cover the submitted transaction.

- 08: Claim is billing for patient financial responsibility only - Code used in coordination of benefits transactions to convey that at least one payer has been billed and returned an approved response; and the current claim is a billing for other payer patient financial responsibility amounts only.

In the case of Other Coverage Code 08, it allows the prescription assistance program to pay for some portion of the cost that would normally be part of the patient's cost share.

See diagram below:



**where eCoupon may be applied (described below)*

Since the prescription assistance is processed after all commercial claim billing and is typically submitted to a different payer/processor, the commercial plan is not aware of the prescription assistance program or the

amount it may have covered. In the process flow above, the commercial plan has assessed a patient cost share of $400, which could have applied to the patient's deductible and/or maximum out-of-pocket. However, a prescription assistance program has covered $300 of that cost, reducing the patient's total cost share to $100, which is not reflected in the patient's commercial accumulators.

Copay assistance and other prescription assistance programs may have other billing mechanisms in place, including but not limited to:

- Universal Claim Form (UCF): Pharmacy submits a paper claim or other request to the prescription assistance program for reimbursement.
- "eCoupons": These types of programs can be applied at the switch, where the prescription assistance is applied and the member's cost share is reduced in the claim response to the pharmacy.
- Direct Member Reimbursement: Patients may submit a request for reimbursement of some portion of their cost share directly to the prescription assistance program outside of the pharmacy workflow.

5.2 Reporting of Final Patient Costs

Since the application of the prescription assistance happens after the original claim transaction, a reporting mechanism would be required for the commercial plan to account for the prescription assistance and be able to calculate the patient's final out-of-pocket expenses as they apply to commercial plan accumulators. Any reporting developed will also need to consider the ramifications of multiple downstream payers in determining which amounts to report and how they will be reported.

The following NCPDP Telecommunication Standard transaction and Batch Standard file format were researched to determine whether they would be viable methods for communicating this information:

- **Information Reporting (Nx) Transaction**
- **Batch Standard File**

5.3 The Nx Transaction as a Reporting Option

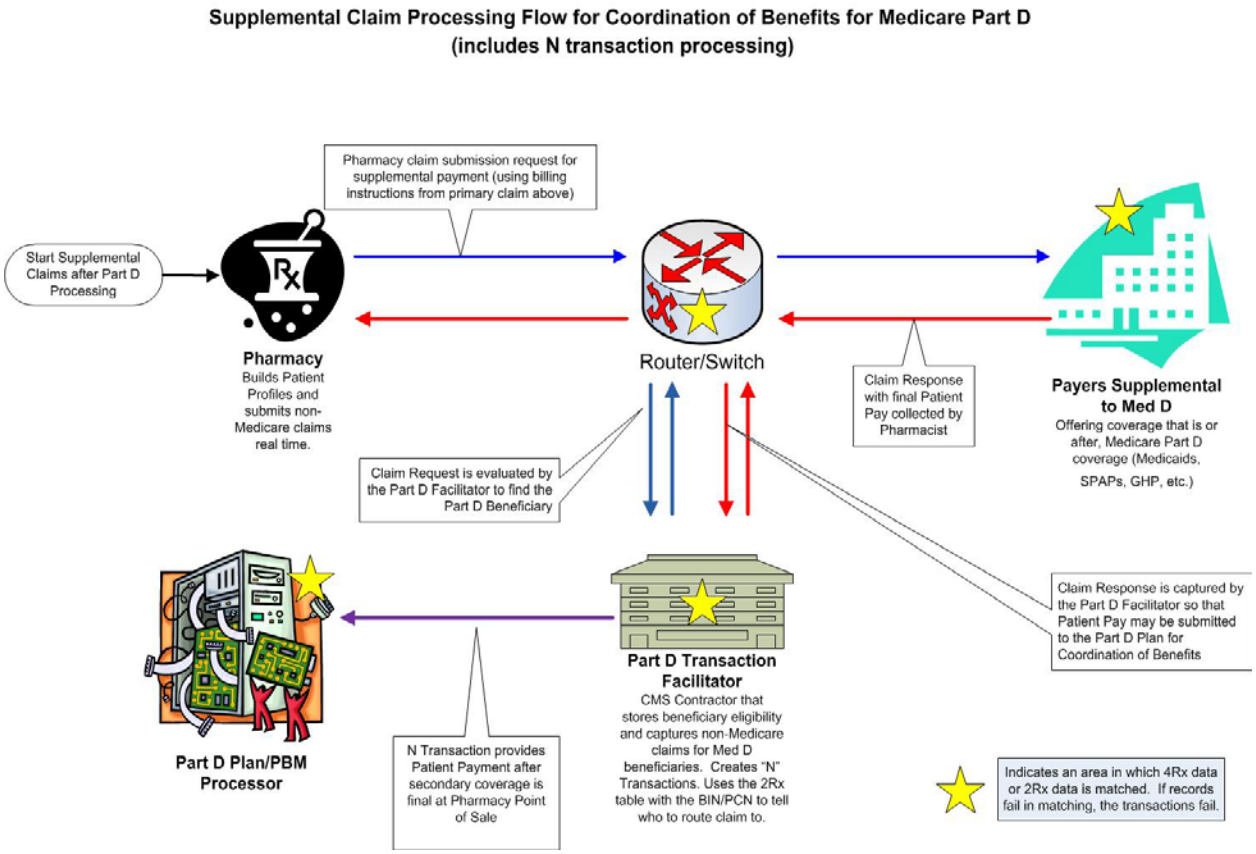
Today, the Information Reporting Transaction (Nx) is used to report financial transactions for the purpose of tracking Medicare Part D payments. This transaction can be submitted in real time or via a batch file. At a high level, the Centers for Medicare & Medicaid Services' (CMS) Benefits Coordination & Recovery Center (BCRC) compiles data on a Medicare Part D beneficiary's other coverage, which is provided to CMS. In turn, CMS provides that data to the Part D Sponsor and the Part D Transaction Facilitator.

As shown in the diagram[1] below, the Part D Transaction Facilitator process is triggered by the submission of a pharmacy transaction to a payer supplemental to Part D. If the supplemental payer returns a paid response, the Part D Transaction Facilitator captures pertinent claim information to create and transmit the Nx to the Part D Plan Sponsor/Processor. The Part D Plan Sponsor/Processor matches the Nx received to their claim by cross-referencing the submitted member information on the Nx to the known Other Health Information (OHI) on file for the member.

For more information on the process by which Nx transactions are sent for Medicare Part D, see the NCPDP white paper, *Overview of the Medicare Part D Prescription Drug Coordination of Benefits (COB) Process* on

[1] Source: July 2013 NCPDP *Overview of the Medicare Part D Prescription Drug Coordination of Benefits (COB) Process* document.

the NCPDP website.



The N transaction contains the following field for supplemental payment information, which could be sent to the primary payer/processor to reconcile the patient's commercial accumulators, if they are able to accept and match an N transaction to a commercial claim:

- **433-DX: PATIENT PAID AMOUNT SUBMITTED**: This data is copied from field 505-F5, PATIENT PAY AMOUNT in the response transaction from the Supplemental Payer to the pharmacy.

  In the earlier example for the prescription assistance process flow, the primary payer assessed a patient pay amount of $400. A COB claim billed to the prescription assistance payer was assessed a patient pay amount of $100. In this case, field 433-DX in the Nx would be populated with a value of $100.

With this information, the primary commercial processor would have access to the patient's final out-of-pocket expense and could calculate the copay assistance received.

6. Obstacles to use of the N Transaction

While the Nx, either real-time or batch, could technically be used for the purpose of reporting supplemental payments from prescription assistance programs back to commercial plans, there are several obstacles to its use described below.

6.1 Creation of the Nx

Under Medicare Part D, the Part D Transaction Facilitator creates and sends the N transaction when a COB claim is processed for a Medicare Part D beneficiary, as identified in the CMS Eligibility File. In the absence of a transaction facilitator or a centralized membership database, the process to use the N transaction outside of Part D would require some entity to appropriately create and send the Nx (in real time or batch) to the commercial plan.

Under a commercial model, the only two entities that are known to be aware of both the primary and secondary or supplemental payer(s) of a claim are the pharmacy and the switch. Since the coupon processor does not receive the BIN, PCN, Cardholder ID, and Group ID (4Rx) in the COB segment of the claim transaction, they would be unable to generate an Nx or know where to send it.

6.2 Applying the Nx

Upon receipt of the N transaction, the payer/processor would need to be able to complete three key functions: accepting, matching and applying the N transaction.

1. Accept the N transaction
   A payer/processor would need the ability to accept an N transaction from a source reporting data for a copay assistance program.

2. Match the N transaction
   A payer/processor would need to match the Nx to the original claim billing.

The payer/processor would need to be able to match the Nx to the original claim billing. This would be challenging without a member's other health information (OHI). Under Part D, plan sponsors are provided the OHI for their beneficiaries, including the 4Rx data. The N transaction is populated with the 4Rx data used to process the supplemental payment, not the primary or prior payer's 4Rx data. The commercial plan must then crosswalk the Nx against the OHI for their membership to identify a claim to match to the Nx. Prescription Assistance programs often employ "on the fly" eligibility, which complicates the matching process. Typical "on the fly" programs create a member ID by combing unique patient data elements, such as name, date of birth, ZIP code, etc.

In the absence of a centralized member database and eligibility sharing process, a commercial plan and prescription assistance programs may need to agree to, and create a process to share, eligibility information to match the Nx to a claim. If the commercial plan does not have this crosswalk from their membership data to the other health information of prescription assistance programs, they may be unable to match the Nx.

For example, the original claim could have been submitted and processed with the 4Rx data shown on the left in the grid (below), while the supplemental prescription assistance COB claim could have been processed with the 4Rx data on the right. The N transaction would be populated with the values from the prescription assistance claim, so the commercial plan would need to be able to crosswalk those values to their member and the specific claim.

Txn Field	Field Name	Commercial Plan Submitted Value	Rx Assistance Program Submitted Value
101-A1	BIN NUMBER	123456	789456
104-A4	PROCESSOR CONTROL NUMBER	RXPLAN	VALUE
302-C2	CARDHOLDER ID	867530900	123456789
301-C1	GROUP ID	PLAN2	COUPON2

3. Apply the N transaction
   A commercial plan would apply the information in a manner they deem appropriate. One possible application of this data is to adjust patient accumulators.

7. Other Considerations

7.1 Distinguishing Copay Assistance vs. Patient Assistance Programs

Commercial plans may want or need to distinguish between patient assistance programs and copay assistance programs when updating their patients' accumulators.

Although not available in NCPDP's Telecommunication Standard version D.0, version F2 does support the Adjudicated Program Type field that can be used in the claim response to the pharmacy to communicate the type of program that adjudicated the claim. As of the publication of this document, the Telecommunication Standard version F2 has not been implemented by the industry.

- **ADJUDICATED PROGRAM TYPE (A28-ZR)**: The type of prescription benefit plan/program under which the claim was adjudicated. One of the following values in this field in the claim response from the subsequent processor may help to identify claims where the member cost was reduced and the type of prescription assistance program.

  6 = *Manufacturer Sponsored Patient Pay Reduction Program – pharmaceutical manufacturer sponsored program used to reduce patient pay amount (such as copayment/coinsurance or self-pay/cash payment).*
  24 = *Independent Charity Patient Assistance Program - Patient assistance program funded by a 501(c) charitable organization in which assistance is awarded in an independent manner based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.*
  25 = *Manufacturer Patient Assistance Program - Pharmaceutical manufacturer sponsored program that provides product to low income patients for free or nominal cost. Income qualifications are typically at or below 200 percent of the federal poverty level (FPL) and patients have insufficient or no prescription drug coverage. Funding for this program cannot be paid from a 501(c).*

7.2 Patient Consent

Federal and state privacy laws and regulations must be considered when sharing patient information. Nothing in this document should be construed as legal advice; entities are encouraged to seek the input of legal counsel.

Right to the Information

In the absence of guidance governing the sharing of prescription assistance payment information to commercial plans for the specific purposes of managing member accumulators, it is unknown whether a commercial plan has a right to this information. Payers, pharmacies, and switches may wish to conduct their own legal review as to the appropriateness of sharing the prescription assistance payment information and whether patient consent is necessary to send or receive it.

It is possible that every entity may need to obtain and store its own patient consent in order to adhere to state or federal privacy requirements or contractual obligations (e.g. audits).

Patient Education

It is entirely possible that patients do not understand the scope and implications of data sharing that occurs in pharmacy-related transactions. Each participant in the process of upstream reporting of prescription assistance (commercial plan/prescription assistance program/pharmacy) should provide information to the patient regarding how their information may be used to avoid confusion or dissatisfaction. The language

included in a Notice of Privacy Practices, a certificate of coverage or as part of a program enrollment most likely does not address the details of data sharing specific to the use case addressed in this issues brief. In addition, those documents may not address the nuances of agreements signed by pharmacies with payers (reporting requirements, etc.). A patient should be aware that information related to prescription assistance programs could be reported to their commercial plan and that it may impact how their accumulators (deductible, out-of-pocket) are calculated.

As an example, if a patient has a $5,000 deductible and the initial claim processed by the commercial plan reflects a $2,500 OOP (the patient's responsibility for the current fill) which is also applied to the patient's deductible accumulator. Yet if copay assistance is applied, in the amount of $1,000, then the patient's actual OOP expense is $1,500. If the $1,000 is reported to the commercial plan, the deductible may be adjusted to reflect $1,500, not $2,500. It will take the patient longer to meet their deductible obligation if the prescription assistance information is reported, and they may not realize they have consented to the data being shared for that purpose.

Scope of Patient Consent

Currently, there is no industry standard to capture patient consent for this purpose. Some considerations related to the scope of consent include the following:

- What constitutes proof of patient consent?
- What information is covered?
- Does proof of patient consent vary according to the entity collecting it?
- For prescription assistance programs, patient consent must be at the program or offer level.
- With whom may the information be shared?
- For what purposes may the information be used?
- Effective period of the patient consent.
- Patient acknowledgement/authorization.

Obtaining and Storing Patient Consent

The following entities may need to obtain and store patient consent as well as verify if they have the right to delegate the consent to another entity.

Commercial Plan / Primary Payer

- Existing plan documentation may have language about privacy, data sharing and member rights; modifications may be needed to support data sharing related to copay assistance.
- The commercial plan may want to validate their authority to use data received from a supplemental plan.

Prescription Assistance Program

Prescription assistance programs will need to determine if they will accept the patient consent obtained by the commercial plan before sharing information, or if they will obtain their own patient consent directly from the patient. If the prescription assistance program is sharing the data and has determined patient consent is required, obtaining patient consent could be accomplished during the enrollment/activation process or via verbiage on the program collateral (card, brochure or website) if allowed under applicable law or regulation. (If it is deemed a signed consent form is the necessary vehicle, the latter would not apply.)

Challenges to obtaining patient consent include but are not limited to:

- Some programs may not have patient initiated activation or enrollment prior to the claim submission therefore there may be no opportunity to obtain patient consent. (Program collateral may have verbiage which implies consent).
- Electronic coupons (eCoupons) offer no mechanism for obtaining patient consent as they are applied automatically at the switch without prior patient knowledge.

Pharmacy

- Pharmacy is the only business entity (aside from the switch) that sees both transactions.
- The process involved with storage and access of patient consent would be burdensome to existing workflow at pharmacies.
- Pharmacies will need to review and consider all contractual terms that may apply to patient consent for data sharing.

Communicating Patient Consent

Mechanism

The mechanism used for communicating patient consent will depend on the entity that collects it and the entity to which it is being transmitted.

Based on a review of the Telecommunication Standard, no existing data elements were identified as viable solutions for communicating patient consent. The following data elements were considered for communication of patient consent and deemed unacceptable:

- **SUBMISSION CLARIFICATION CODE(420-DK)**: This field is available in the B1/B3 claim billing transactions today; most commonly used in situations where the claim would otherwise reject without the submission of the code. The code transmitted is indicating the pharmacist is clarifying the submission. *Currently there are no values associated for patient consent for information sharing. In addition, the business case of communicating consent doesn't conform to the defined use of this data element.*
- **MESSAGE (504-F4)**: This field is used to return free-text messaging from the payer to the pharmacy. Pharmacy systems would need to search for key words related to patient consent. *This field is not available in pharmacy-to-payer or payer-to-payer transactions.*
- **ADDITIONAL MESSAGE INFORMATION (526-FQ)**: Similar to the Message field, this field transmits free text messaging to the pharmacy and *is not available in pharmacy-to-payer or payer-to-payer transactions.*
- **APPROVED MESSAGE CODE (548-6F)**: There are many different approved message codes available, although none refer to patient consent for releasing supplemental payment information back to a primary payer. *In addition, the business case of communicating consent doesn't conform to the defined use of this data element.*

Additional Consideration: Use of Flags

Another consideration for communication of patient consent to the pharmacy is the concept of a consent flag on the billing response transaction. Currently such a flag or indicator does not exist in the applicable NCPDP transactions and a new data element would have to be requested for a future version. Agreement would be needed that the indicator represents the existence of documented patient consent and is deemed acceptable as proof of patient consent. Multiple indicators may be needed to support situations such as a prescription assistance program may want its consent flag to indicate the patient has agreed to the sharing of their data, whereas a commercial health plan's flag may indicate consent to receive data

from prescription assistance programs.

7.3 Pharmacy Participation

It may be difficult to engage pharmacies for the purpose of providing downstream claim detail information to an upstream payer. Pharmacies may not be contractually obligated to provide this data and there is no reimbursement for this activity. Additionally, there may be concerns about violating patient confidentiality.

Because of the current lack of distinct identifiers for program type, pharmacies could have trouble distinguishing patient assistance programs from other supplemental programs that are not needs-based. This could be problematic for accurate reporting in the event that the reporting is required, for instance, only for programs that are not needs-based. The Adjudicated Program Type, as described in Section 4.3, should partially or fully remedy the program type identification problem.

7.4 Patient Resistance

Patients may be unwilling to provide their consent for data sharing if prescription assistance payments no longer apply towards their out-of-pocket expenses. From the patient's perspective, it will appear they have to wait longer and incur additional expenses to meet deductibles and other out-of-pocket limits.

7.5 Manufacturer Resistance

Since the goal of the manufacturer is increased uptake and adherence to their drug, any negative impact to the patient is likely to also have a negative effect on their program. As a result, manufacturers may opt to discontinue point-of-sale patient assistance programs and look for alternative methods to assist patients.

7.6 Reversal Process/Correction of a Claim

Additional research would be needed to identify and develop the processes needed to ensure proper accounting of claim reversals and corrections.

7.7 Cost of Reporting Mechanism

There will be costs to develop and implement new processes to support the reporting of the data which will impact commercial plans, pharmacies, and prescription assistance programs. Stakeholders are encouraged to consider the financial impact to their workflows and data storage requirements.

8. Summary

The purpose of this issues brief was to review and analyze the issue of reporting prescription assistance to upstream payer(s). This document provides the results of research into potential solutions using NCPDP standards/transactions, many of which are only partial solutions, and identifies known obstacles to these solutions. Due to the complexities and challenges associated with this issue, recommendations and solutions are not included.

Commercial plans track member qualified spending in order to determine when deductibles and other financial accumulators are met. Prescription assistance programs are not linked with commercial health insurance plans, therefore the monetary assistance provided by the former are not considered when the commercial plan is tracking the member's financial accumulators.

Given the lack of a standard mechanism to share transaction data between prescription assistance programs and commercial health insurance plans, the WG1 Upstream Reporting of Copay Assistance Task Group researched potential solutions leveraging NCPDP standards. Areas reviewed included the types of prescription assistance programs (copay vs. patient assistance), billing methods and reporting of final costs.

Reporting options that can be systematically implemented are limited, including those using existing standard transactions, due to the complexity of the information involved. Among the key challenges is the ability to "match" the patient between programs. The prescription assistance program may or may not have sufficient patient identifying information for the commercial plan to match and apply the supplemental amounts accurately. Without a systematic, automated mechanism to support patient matching, any solutions would pose a significant burden on stakeholders to accurately link a patient among programs.

Another key challenge is the issue of patient consent. Given the myriad laws and regulations that apply, determining the validity of patient consent to obtain, share, and store information related to supplemental claims is viewed as a significant burden to the implementation of a systematic solution.

If this is a problem the industry wants to solve holistically, all impacted stakeholders will need to come together to address the issues identified within this document, as well as the other issues that are likely to arise when more discussion occurs.

9. Appendix A. Stakeholders

Commercial Health Insurance

Any healthcare policy that is not administered or provided by a government program.

Commercial Plan Sponsor

An employer or similar group benefit health plan, an insurer, or other financially responsible entity.

Coupon Vendor (non-claim activity)

Marketing services companies that manage prescription medicine coupon programs on behalf of pharmaceutical manufacturers.

Intermediary

An entity performing services on behalf of the pharmaceutical manufacturer, such as patient enrollment verification, data aggregation, etc.

Patient

An individual who has received, is receiving, or intends to receive health care services. (Health care services as defined by federal and state regulations.) Can be a cardholder, subscriber, member, beneficiary, or dependent.

Pharmacy

An entity responsible for dispensing and distributing medicine under applicable legal and ethical guidelines to ensure the correct and safe supply of medical products to the general public.

Pharmaceutical Manufacturer

A company that makes and sells pharmaceuticals. Some manufacturers fund prescription assistance programs for one or more of their drugs.

Prescriber

A licensed entity that prescribes prescription drugs and provides professional medical services, such as clinical services respective to the prescribing function. The entity may be a clinic or independent prescriber, hospital, or care facility.

Prescription Assistance Program Processor

An entity or third party administrator (TPA) responsible for processing claims and administering prescription drug programs on behalf of a pharmaceutical manufacturer or other sponsor.

Processor/Pharmacy Benefit Manager (PBM)/Adjudicator

Administers prescription drug programs, as well as manages costs for a plan sponsor to achieve the most effective utilization of prescription drug expenditures, such as benefit design, formulary management, rebate contracting, retrospective Drug Use Review (DUR), prospective DUR, network administration, disease state management, and so forth.

Supplemental Program

Offers benefits or coverage after primary coverage has been applied. These benefits may reduce the patient's financial responsibility determined by prior payers.

Switch

An entity that accepts an electronic transaction from another organization and electronically routes the transaction to a receiving entity. A switch/intermediary may perform value added services including detailed editing/messaging of input/output data for validity and accuracy and translating data from one format to another.

10. Appendix B. Glossary

Accumulators

A running total of qualified expenses that apply to a member's deductible and Out of Pocket (OOP) maximum for a specific time period.

Benefits Coordination & Recovery Center (BCRC)

A federal contractor which consolidates the activities that support the collection, management, and reporting of other insurance coverage for Medicare beneficiaries. The purposes of the COB program are to identify the health benefits available to a Medicare beneficiary and to coordinate the payment process to prevent mistaken payment of Medicare benefits. The BCRC does not process claims, nor does it handle any mistaken payment recoveries or claims specific inquiries. The Medicare intermediaries and carriers are responsible for processing claims submitted for primary or secondary payment.

BIN/PCN/Group Number

The BIN (Bank Identification Number), PCN (Processor Control Number), and Group Number combinations are used by pharmacies, switches, and processors to electronically route and adjudicate pharmacy claims for prescriptions and typically identify pharmacy insurance programs.

Centers for Medicare & Medicaid Services (CMS)

The Centers for Medicare & Medicaid Services (CMS) is part of the Department of Health and Human Services (HHS). Some programs administered by CMS include: Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Marketplace.

Coordination of Benefits (COB)

Allows entities involved in claims processing to determine respective payment responsibilities including determination of primary payer and the extent to which other entities will contribute when an individual has more than one payer option. Payers may be mutually exclusive or supplemental.

Coordination of Benefits (COB) Claim

The mechanism for the pharmacy to bill multiple entities when there is more than one entity involved in the claims process. A COB claim allows payers supplemental to a primary payer to receive pertinent information about prior payer(s) coverage.

Copay Assistance or Manufacturer Coupon Programs:

These programs are generally funded by the drug manufacturer for the specific product being dispensed and are considered non-needs-based, where there are usually no income requirements for the patient to qualify for the program. These programs may or may not require the patient have a specific diagnosis to be eligible for the program. These programs may have per use, monthly or annual limits on the amount they will contribute/cover and are offered at the sole discretion of the manufacturer.

Information Reporting (N) Transactions

The Part D Transaction Facilitator transmits supplemental coverage information from payer-to-payer. The Part D Transaction Facilitator process is triggered by the submission of a transaction by a

pharmacy to a payer supplemental to a Part D Sponsor. The Information Reporting transactions Information Reporting (N1), Information Reporting Reversal (N2), and Information Reporting Rebill (N3) are used in this process and defined further in this document. These transactions are in the NCPDP ***Telecommunication Standard Implementation Guide***.

- **N1 - Information Reporting**
  This transaction is used to transmit a record of supplemental coverage information related to a Part D beneficiary's liability. Information Reporting (N1) is a transaction request and a response.

- **N2 - Information Reporting Reversal**
  This transaction is used to reverse a previously submitted N1 (Information Reporting) transaction. Information Reporting Reversal (N2) is a transaction request and a response.

- **N3 - Information Reporting Rebill**
  This transaction is an Information Reporting submission with an implied reversal. It is used by the Originator to cancel an Information Reporting transaction submitted that had been processed previously, and submit a new Information Reporting transaction in the same transaction. Information Reporting Rebill (N3) is a transaction request and a response.

Medicare Part D Sponsor

An entity that administers the Medicare Part D benefit through prescription claims processing, makes a decision regarding the level of reimbursement and sends the appropriate message or reject code back to the pharmacy/provider for action.

National Council for Prescription Drug Programs (NCPDP)

NCPDP is a not-for-profit, multi-stakeholder forum for developing and promoting industry standards and business solutions that improve patient safety and health outcomes, while also decreasing costs. The work of the organization is accomplished through its members who bring high-level expertise and diverse perspectives to the forum.

NCPDP Telecommunication Standard

The NCPDP Telecommunication Standard is used for the electronic submission of eligibility verification, claim and service billing, predetermination of benefits, prior authorization, information reporting, and controlled substance (general and regulated) transaction exchanges. The Telecommunication Standard is named in HIPAA and the Medicare Modernization Act.

Part D Transaction Facilitator

The Part D Transaction Facilitator is a federal contractor which is responsible, in conjunction with CMS, for establishing procedures for facilitating eligibility queries (E1 transactions) at point of sale (POS), identifying costs reimbursed by other payers (Information Reporting (Nx) transactions) and alerting Part D sponsors about such transactions, and facilitating the transfer of TrOOP-related data (financial information reporting (FIR) transactions) when a beneficiary changes plan enrollment during the coverage year.

Patient Assistance Programs

These programs are generally funded by foundations, charitable organizations, or drug manufacturers. If these programs are administered by a non-profit entity, they will have filed the

appropriate tax documents. These programs have qualification requirements (such as financial need, clinical, geographic or socio-economic status) patients must meet to be eligible for assistance.

11. Appendix C. History of Changes