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Patient Assistance Programs Off Limits?

Not Anymore... The Proposed Rule Seeks to Include Them in Best Price!

The Medicaid Program proposed rule published on June 19, 2020 ("CMS-2842-P" or the "Proposed Rule") includes several proposed revisions to program regulations, each of which present different legal, strategic, and operational challenges for manufacturers.

At Riparian, our mission is to empower our clients by delivering innovative solutions that provide efficiency, clarity, and accelerated insights. With that in mind, we identified a number of questions that manufacturers may want to consider as they socialize the revisions in the proposed rule within their organization and formulate potential comments to submit to CMS (due by 5 p.m. on July 20, 2020). In this first article in our series on the Proposed Rule, we address the revision affecting the exclusion of certain manufacturer-sponsored patient assistance programs from the determination of Best Price, and some of the key questions that will need to be addressed in order to assess the potential impact of including manufacturer-sponsored patient assistance program discounts in Best Price.

Proposed Revision to Best Price ("BP") Exempt Transactions

The Medicaid Program Final Rule excludes from BP the following types of manufacturer-sponsored patient assistance programs that inure to the benefit of patients:[1]

- Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.
- Manufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer, and the pharmacy, agent, or other entity does not receive any price concession.

[1] See §447.505(c)(8) through §447.505(c)(12).

- Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.
- Manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession.
- Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other entity does not receive any price concession.

In the proposed rule, CMS indicates that the use of a PBM accumulator program by health plans results in a manufacturer-sponsored program (e.g., copay assistance) being inured to the benefit of the plan, rather than to the patient in its entirety. CMS includes numeric examples to demonstrate this viewpoint; when a manufacturers' copay assistance is not applied to the deductible of the patient, the copay results in a benefit to the health plan, rather than to the patient.

Based on this reasoning, CMS proposes revising the BP exclusions listed above – i.e., to narrow the scope of such exclusions only to the extent that the manufacturer "***ensures*** the full value of the assistance or benefit is passed on to the consumer or patient." [emphasis added]

Inclusion of Patient Assistance Program Discounts in Best Price

In the event the proposed revision to the BP exclusions is finalized as is, we anticipate that the "first line" approach for many manufacturers will be to revise the parameters of their patient assistance programs so that they may continue to be exempt from consideration in BP. However, in the event there are certain patient assistance programs that cannot be revised in a way that fully satisfies CMS' criteria, there are a number of key questions that will need to be addressed in order to establish a methodology to calculate net price(s) relating to such patient assistance programs for BP consideration.

Question 1: What is the amount of discount to be included in BP?

CMS includes numeric examples in the proposed rule that illustrate the amount of payment made by a health plan, patient, and manufacturer under two scenarios: 1) copay assistance program with no PBM accumulator program, and 2) copay assistance program with PBM accumulator program.

In providing these numerical examples, CMS suggests that the health plan (rather than the patient) benefits from the manufacturer sponsored copay assistance program when it uses a PBM accumulator program, and therefore should be a BP-includable discount. However, in the second of the two scenarios, a portion of the copay assistance is arguably a discount to the patient, which would make that portion of the discount exempt from BP. This idea is presented in the following tables – the first of which is based on CMS' numeric example of a copay assistance program with PBM accumulator program, with the following assumptions:

- Drug cost (monthly): $2,500
- Patient Deductible: $2,500
- Copayment Assistance Program Maximum: $10,000

Table 1 – Copay Assistance Program with PBM Accumulator Program[2]

	Jan	Feb	Mar	Apr	May	Jun-Dec	***Total***
Total Cost	$2,500	$2,500	$2,500	$2,500	$2,500	$2,500 per month	***$30,000***
Manufacturer Pays	$2,475	$2,475	$2,475	$2,475	$100 copay max reached	$0	***$10,000***
Patient Pays	$25	$25	$25	$25	$2,400 deductible reached	$500 per month	***$6,000***
Plan Pays	$0	$0	$0	$0	$0	$2,000 per month	***$14,000***

Table 2 – No Copay Assistance Program

	Jan	Feb	Mar	Apr	May	Jun-Dec	***Total***
Total Cost	$2,500	$2,500	$2,500	$2,500	$2,500	$2,500 per month	***$30,000***
Manufacturer Pays	$0	$0	$0	$0	$0	$0	***$0***
Patient Pays	$2,500 deductible reached	$500	$500	$500	$500	$500 per month	***$8,000***
Plan Pays	$0	$2,000	$2,000	$2,000	$2,000	$2,000 per month	***$22,000***

[2] Expanded from CMS' TABLE 2—COPAY ASSISTANCE PROGRAM WITH PBM ACCUMULATOR PROGRAM example in the proposed rule.

Table 3 – Difference Between No Copay and Copay with PBM Accumulator Program

	Jan	Feb	Mar	Apr	May	Jun-Dec	***Total***
Patient Pays	-$2,475	-$475	-$475	-$475	$1,900	$0 per month	***-$2,000***
Plan Pays	$0	-$2,000	-$2,000	-$2,000	-$2,000	$0 per month	***-$8,000***

Table 3 demonstrates that in a scenario where a PBM accumulator program is used, the full value of the Copayment Assistance Program Maximum is not realized by the health plan (i.e., only $8,000 of the $10,000 is realized by the health plan in this specific example). This illustration suggests that there is a reasonable basis for bifurcating the patient assistance dollars spent by the manufacturer – such that only a portion should be included for BP consideration.

Question 2: How should the discount be applied?

Fundamentally, patient assistance programs are designed to help those in need obtain their medicines – at no cost or very low cost – so they don't have to make the difficult choice between getting their prescriptions filled and other basic needs (e.g., buying food, paying for rent and utilities). In general, patient assistance programs function in a manner such that there is a higher initial outlay by the manufacturer (as demonstrated in Table 3) until the patient meets their deductible, at which point the manufacturer's financial contribution decreases as the patient's health plan begins paying for a greater share of the cost.

Arguably, the intent of the assistance program is to enable the patient to continue to fill their prescriptions for the entirety of the plan year. This intent may be a reasonable basis for evaluating the BP-includable patient assistance discounts in a manner similar to the treatment of bunded sale arrangements[3] – because the discount from the manufacturer is conditioned upon the expectation that there will be ongoing purchases of the drug for the entire plan year, as illustrated by Table 4.

[3] Bundled sale is defined as "any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit national drug code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.

(1) The discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.

(2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle."

Table 4 – Copay Assistance Program[4]

	Jan	Feb	Mar	Apr	May	Jun-Dec	***Total***
Total Cost	$2,500	$2,500	$2,500	$2,500	$2,500	$2,500 per month	***$30,000***
Manufacturer Pays	$2,475	$475	$475	$475	$475	$475 per month	***$7,700***
Patient Pays	$25	$25	$25	$25	$25	$25 per month	***$300***
Plan Pays	$0	$2,000	$2,000	$2,000	$2,000	$2,000 per month	***$22,000***

If the treatment is akin to a bundled sale arrangement, the manufacturer discount would be allocated to sales over the full plan year (or time the expected duration of treatment). Such an approach would generate net prices for BP consideration that are more similar quarter over quarter, rather than very low net prices in the early part of a plan year and then significantly higher prices in the latter part of the plan year.

A potential methodology framework may look something like the following:

Net Price = WAC less Effective Discount Rate

Effective Discount Rate = Total Copay Assistance Program Discounts attributable to a BP-Eligible Customer (e.g., Provider) for the Plan Year ÷ Total Cost of the Drug for the Plan Year

If this approach were to be applied using the discount amount attributable to the health plan as calculated in Table 3, the Effective Discount Rate would be 26.67% (i.e., $8,000 ÷ $30,000).

Question 3: Is it reasonable to calculate net prices based on discounts attributable to a health plan in aggregate for all patients (vs. on a patient-by-patient basis)?

Expanding on the concept in Question 2, if there is a reasonable basis for treating the discounts attributable to health plans as a type of bundled sale arrangement, there may also be a reasonable basis to calculate a single net price resulting from patient assistance program discounts for each health plan as a whole, rather than on a patient-by-patient basis. Taking an aggregate approach would likely generate a net price that would not be as low as it would be under a patient-by-patient approach – especially if there are patients that stop taking the drug, causing "sales" to the health plan to cease once the amount of the manufacturer benefit decreases.

[4] Expanded from CMS' TABLE 1—COPAY ASSISTANCE PROGRAM WITH NO PBM ACCUMULATOR PROGRAM example in the proposed rule.

Question 4: Do BP-eligible patient assistance program discounts need to be "stacked" on top of managed care rebates and non bona fide admin fees?

In general, manufacturers stack two (or more) discounts when they are paid to the same customer and the discounts are associated with (or could reasonably be connected to) the same unit of a covered outpatient drug. Patient assistance program discounts ought to be subject to a stacking evaluation process or decision tree to determine whether or not the "same customer" and "same unit" conditions necessitate patient assistance program discounts to be stacked with other discounts paid to health plans (e.g., managed care rebates and non bona fide admin fees).

Concluding Thoughts

The use of accumulator programs is likely to experience continued growth in adoption as PBMs continue to tout them as cost saving measures for health plans. The questions and considerations addressed in this article are specifically focused on some of the immediate questions that may arise in order to develop a methodology for including patient assistance program discounts in BP in the event CMS' proposed revision to the BP exemption criteria go into effect. It is worth noting that methodology considerations are just the tip of the iceberg; there are many additional operational considerations that will need to be carefully evaluated – including data, processes, systems, and additional resources needed to actually implement a calculation methodology. Further, the considerations presented in this article are not meant to comprehensively address the implications of the proposed revision to BP, but rather, as an aide to facilitate discussions with key stakeholders and legal counsel.

As a separate matter, to mitigate the potential impact that PBM accumulator programs may have on BP, manufacturers may be forced to explore alternative means to continue to support patient access to much-needed drugs. These alternatives may include providing prepaid debit cards and/or rebates directly to patients, and/or adjusting managed care rebates to PBMs/ plan sponsors to offset the benefit they receive by using an accumulator program.

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Proposed Final Rule for "Medicaid Drug Rebates and Third-Party Liability Requirements"

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