THE PATIENT ACCESS PARADOX:

How New Regulations Intended to Improve Product Affordability May Unravel Manufacturers' Advancements in Patient Outcomes

New CMS Rule Could Prioritize Drug Pricing Before Clinical Decision-Making and Increase Patients' Financial Burden

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Introduction: New Ruling Challenges Current Patient Access Strategies

On June 17, 2020, the Centers for Medicare and Medicaid Services (CMS) published a Final Rule stating that the benefits of co-pay coupons and vouchers are provided entirely to the consumer. Historically, manufacturer-sponsored co-pay coupons and vouchers ensured the full value of their affordability programs accrued to the enrolled patient by paying for the cost of the drug and counting toward the patient's deductible.

However, Pharmacy Benefit Managers (PBMs) have been reluctant to accept co-pay cards in recent years. While the co-pay card can shield the patient from the high out-of-pocket (OOP) costs of a medication, they may actually cost the PBM more because the co-payments paid by manufacturers use up patient deductibles faster, thus shifting the prescription cost to the plan. As a result, PBMs implemented "accumulator programs" in which the contribution of the manufacturer is not applied to the patient deductible. When the co-pay benefit maximum is reached, the patient receives a significantly higher bill. This would increase the patient's OOP costs and the overall financial burden, making it extremely difficult (if not impossible) for patients to afford treatments.

The CMS position on the new ruling is that "manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure the benefit goes exclusively to the consumer or patient." Therefore, manufacturers will need to establish criteria in the co-pay coupons such that 100% of the benefit goes to the patient, or those coupons will not be Best Price (BP) excluded. The co-pay would be considered a price concession to the PBM and would then be AMP (Average Manufacturer Price) and BP eligible. This change would require significant modifications in government pricing (GP) reporting systems, as well as the ability for manufacturers to identify and track Accumulator Programs for determination of GP calculation inclusions/exclusions.

While the intent of the final rule seems to help the patient, CMS makes the manufacturer responsible for determining whether a PBM has implemented an accumulator program, which is difficult (if not impossible) to discern and track.

A Turning Point for Pharma: The Impact on Manufacturers

Now more than ever, manufacturers are trying to drive patient adoption in a competitive market while simultaneously adapting to global trends in regulations and pricing that are already causing a decrease in fill rates and treatment adherence. Despite all the advancements manufacturers have made in recent years, the industry is at risk of digression when the Final Rule goes into effect.

FINAL RULE: POSSIBLE IMPACTS ON MANUFACTURERS

- If co-pay programs impact best price, affordability programs may become too costly to maintain, causing manufacturers to shut down or amend existing programs.
- Without co-pay programs, many patients will be unable to afford prescribed drugs.
- Patients will seek alternative medications, upending progress in their treatment journey.
- Manufacturers will have no clear understanding of changes made to patients' treatment journeys.
- It would have a dramatic effect on gross-to-net and BP. If a PBM "adjusts" one patient, it could have a material impact on BP-assessed programs (e.g., Medicaid).
- Current solutions in the marketplace will not satisfy this rule, which would create a need to update or change most co-pay programs in the market.
- There would be an increased need to launch new methods or mechanisms for payment and processing of co-pay programs.
- Manufacturers' desire to modify contracting with payers and PBMs would need to include identification of accumulators or a formulary exclusion of accumulators.

The Final Rule also adds more responsibility to manufacturers, including reconciliation between manufacturers and PBMs, as well as rethinking PBM contracting strategies. Manufacturers will have to gain access to accurate government pricing calculations and develop advanced enrollment processes to understand patients and formulary plans. Among all the changes the Final Rule does outline, it does not explain how the co-pay benefit should be counted – relying on manufacturers to figure out this next step.

Risking Access: The Real Impact on Patients

When the Final Rule goes into effect on January 1, 2023, the patient experience will be quickly upended, dramatically affecting adherence and outcomes. Patients cannot be expected to understand the complexities of the Final Rule or its effects. Rather, the patient will face a blindsiding new charge that their insurance doesn't cover. In this moment, the patient will have to choose between their finances or their health – and for some patients, their only choice will be to discontinue treatment.

When patients lose access to co-pay cards and vouchers, their treatment affordability becomes extremely restricted, and the role of providers becomes even more difficult. Not only will provider office staffs be faced with new questions from confused patients about their prescription coverage, but the price of a drug will become more important than clinical decisions, as well. How can a provider prescribe a drug that a patient can't afford? They won't. With limited affordable treatment options, prescribers will try to find generic alternatives. Or even worse, patients will choose to go untreated. The added confusion and affordability complications caused by the Final Rule will stress the entire healthcare ecosystem, putting an end to product access as we know it.

Proactively Responding to the Final Rule: Launch Your Pilot Program Now

In January 2023, co-pay programs will be put to the test, consequently examining how well your brand can adapt to the Final Rule changes to meet patient and provider needs. Our recommendation: Don't wait – start solutioning a patient-centric approach to access and affordability now.

Creating the right solution for your program will require piloting solutions that provide the education and insights to drive the future configurations of your programs. The right solution will have to meet all patient preferences, and patient and provider engagement will have to become even more personalized as manufacturers guide consumers through their program and process changes. Failing to pilot now could result in a lower best price, noncompliant co-pay program and an increase in untreated patients down the road.

THE FINAL RULE WILL RESULT IN ...

- Limited access to life-changing medications.
- Increased financial burden on the patient.
- Stymied progress in technological advancements in patient engagement and adherence.
- A decline in the commercialization of specialty medication.
- Complex and convoluted patient access and affordability.

Bearing the Storm: Preparing Today Will Lead to Improved Programs Tomorrow

If manufacturers don't efficiently solve Final Rule challenges to their co-pay programs, the ripple effects of this regulatory change will restrict access to life-saving medications and create a perfect storm in patient care. By starting to amend co-pay programs now, manufacturers have a new opportunity to realign their programs with patient and provider needs while building a deeper relationship with patients.

January 1, 2023, might seem like the distant future, but between piloting, solutioning and re-strategizing, there's much work to be completed. Fortunately, manufacturers don't have to find the right solution alone. Co-pay programs require investments and resources that affect the entire company, which is why EVERSANA™ is taking a holistic approach to the CMS Final Rule. With our strong capabilities in research and consulting, we stay ahead of the commercial and regulatory trends that will impact the future of patient access.

EVERSANA's deep bench of experts is here to help you figure out solutions to this industry change from all angles: global pricing, access, affordability, patient services and more. As the leading provider of global services to the life sciences industry, our integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers.

Contact us today for more information on the implications of the Final Rule and how we can help you pilot a new affordability program to ensure your patients maintain access to your innovative therapy.