340B | ORPHAN DRUG SOLUTIONS

FOR CRITICAL ACCESS HOSPITALS,
SOLE COMMUNITY HOSPITALS,
RURAL REFERRAL CENTERS,
AND FREESTANDING CANCER CENTERS

The 2015 PhRMA v. HHS Ruling:

What Rural Hospitals Need to Know

About Orphan Drug Discretionary Pricing

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EXECUTIVE SUMMARY

The Most Under-Recovered Revenue Lever in 340B

On October 14, 2015, the U.S. District Court for the District of Columbia ruled in PhRMA v. HHS that the orphan drug exclusion under Section 7101(b) of the Affordable Care Act applies to orphan-designated drugs in their entirety for the 340B expansion entities — Critical Access Hospitals (CAHs), Sole Community Hospitals (SCHs), Rural Referral Centers (RRCs), and Freestanding Cancer Centers — regardless of the indication for which the drug is being used.

The ruling reshaped how rural hospitals access savings on a defined and growing set of high-cost drugs. The mandatory 340B ceiling price no longer applies to orphan-designated drugs for these covered entities. But the ruling did not eliminate access to savings. It moved those savings into a different mechanism: manufacturer discretionary pricing.

Eleven years after the ruling, the majority of rural hospitals are still leaving discretionary pricing dollars unclaimed — not because the savings aren't available, but because the orphan drug carve-out has been treated as a closed door rather than the revenue lever it actually is.

> **THE BOTTOM LINE**
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> Across a 12-year practice working exclusively with rural hospitals on orphan drug revenue recovery, the average annual recovery per client engagement exceeds **$200,000**. A single Minnesota Critical Access Hospital engagement recovered **$247,000**. The findings rate across every engagement to date is **100%**.

What this paper covers

- What the 2015 PhRMA v. HHS ruling actually said — and what it didn't
- What “discretionary pricing” means in practice for rural hospitals
- The three most common ways rural hospitals under-recover orphan drug revenue
- A practical path forward for CFOs, Directors of Pharmacy, and 340B Program leads

SECTION ONE

Background: What the Ruling Actually Said

The Affordable Care Act of 2010 expanded the 340B Drug Pricing Program to include several new categories of covered entities — Critical Access Hospitals, Sole Community Hospitals, Rural Referral Centers, and Freestanding Cancer Centers — collectively known as the expansion entities.

Section 7101(b) of the ACA carved out an exception for these new expansion entities: drugs designated by the FDA as orphan drugs were excluded from mandatory 340B pricing.

The Health Resources and Services Administration (HRSA), which administers the 340B Program, interpreted this exclusion narrowly. HRSA's position was that only orphan drugs used *for their designated orphan indication* were excluded — meaning an orphan-designated drug used for a non-orphan indication would still qualify for 340B ceiling pricing at expansion entities.

The Pharmaceutical Research and Manufacturers of America (PhRMA) challenged this interpretation. On October 14, 2015, the U.S. District Court for the District of Columbia ruled in PhRMA's favor.

The court's holding

The court found that the statutory text excluded orphan-designated drugs categorically. Once a drug carries an orphan designation, it is excluded from mandatory 340B pricing at the four expansion entity categories **regardless of the indication for which it is prescribed or dispensed**.

This was a significant expansion of the exclusion. It also meant that diagnosis-based carve-ins were no longer a path to capturing savings on these drugs for expansion entities.

> **WHAT THE RULING DID — AND DID NOT — DO**
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> **It did:** Confirm that orphan-designated drugs are categorically excluded from mandatory 340B pricing at CAHs, SCHs, RRCs, and Freestanding Cancer Centers.
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> **It did not:** Prohibit manufacturers from offering voluntary discounted pricing on these drugs. It did not eliminate the revenue opportunity. It moved that opportunity into a discretionary pricing channel — one that requires a different approach to capture.

SECTION TWO

What Discretionary Pricing Actually Means

After the 2015 ruling, the conventional wisdom in many rural hospital pharmacies calcified around a single, costly assumption: *if mandatory 340B pricing doesn't apply to orphan drugs at our facility, then there's nothing to capture*.

That assumption misreads how the post-ruling market actually operates.

Manufacturers of orphan-designated drugs are not required to offer 340B ceiling pricing to expansion entities. They are, however, permitted to offer voluntary discounted pricing — and many of them do. This pricing goes by several names in the industry: discretionary pricing, voluntary 340B pricing, 340B-like pricing, sub-WAC pricing, or program-specific discounts.

The mechanism is simple in concept and complex in execution. A manufacturer determines, on a drug-by-drug and program-by-program basis, whether to extend a discount to expansion entities — and at what level. The discount can range from modest to substantial. The discount is offered on the manufacturer's terms, often through specific channels, and typically requires the covered entity to identify itself, request the pricing, and integrate it into the purchasing pathway.

None of this happens automatically. A rural hospital that does not actively engage with this channel will, by default, pay closer to WAC for the same orphan-designated drugs, while a more engaged peer hospital is acquiring at meaningfully discounted prices.

The revenue framing

Discretionary pricing is, at its core, a **revenue recovery** opportunity. The 340B Orphan Drug Solutions practice is built entirely on this framing. Every engagement begins with the question: *what discretionary pricing is currently available to this specific hospital, on this specific drug portfolio, that is not being captured?*

The answer is almost always the same: more than the leadership team realized.

> THE PRACTITIONER'S VIEW
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> *"Discretionary pricing is not a loophole. It is not a workaround. It is a legitimate, manufacturer-sanctioned pricing channel created in the wake of the 2015 ruling — and it is the single most under-utilized revenue lever in rural hospital pharmacy economics today."*
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> **— Rev. Dr. Lisa Nezneski, PharmD, BCPS**

SECTION THREE

Three Ways Rural Hospitals Under-Recover

Across a decade-plus of engagements with Critical Access Hospitals, Sole Community Hospitals, Rural Referral Centers, and Freestanding Cancer Centers, three patterns of under-recovery surface repeatedly. Most engagements involve all three.

1 Incomplete Orphan Drug Identification

Most pharmacies maintain a list of orphan drugs based on what they remember purchasing, what their wholesaler flagged at some point, or what was identified during the program's initial setup years ago. That list is almost never current.

The FDA grants new orphan designations on a rolling basis. Existing drugs receive line item extensions — new indications, new dosing, new pediatric formulations — that may carry orphan status. A hospital that is not actively tracking these movements is, by definition, working from an incomplete portfolio.

2 Failing to Engage the Discretionary Pricing Channel

Even when a hospital has correctly identified the orphan drugs it purchases, the next step — actually securing discretionary pricing from manufacturers — is rarely executed consistently. The work is fragmented across multiple manufacturers, multiple contact channels, and multiple drug categories. It does not align with the operational rhythm of a busy pharmacy department.

The result: hospitals that have technically identified their orphan portfolio still purchase those drugs at standard pricing because no one has the bandwidth to negotiate the discretionary pricing that would otherwise be available.

3 No System for Capturing Savings at the Point of Purchase

Even when discretionary pricing has been secured, the savings only materialize if the purchasing pathway routes the orphan drug acquisition through the discounted channel. Split-billing software has to be configured correctly, purchasing staff has to know which drugs go through which channel, and there has to be a feedback loop that catches missed opportunities for credit and rebill. Hospitals frequently lose recovered savings at this last mile — because the operational scaffolding was never built to support the pricing they negotiated.

SECTION FOUR

The Path Forward

A rural hospital with mature 340B operations can still be under-recovering orphan drug revenue by six figures annually. The gap is not a function of pharmacy capability. It is a function of specialization. Orphan drug discretionary pricing requires a dedicated, continuous, manufacturer-by-manufacturer practice — and that is rarely what a generalist 340B program is built to deliver.

A focused engagement typically follows four steps:

One. A case-mix and orphan purchase analysis to identify what the hospital is actually buying — and what should be classified as orphan-designated but currently isn't.

Two. A customized orphan drug list built around the hospital's specific portfolio, maintained with automated quarterly updates and monthly alerts on newly-approved drugs.

Three. Direct manufacturer engagement to secure discretionary pricing on the drugs the hospital actually purchases, with credit and rebill review for missed opportunities going back as far as the manufacturer permits.

Four. Split-billing software integration and pharmacy staff job aids so the savings actually materialize at the point of purchase — and stay captured quarter over quarter without the team having to spin their wheels.

ABOUT THE AUTHOR

Rev. Dr. Lisa Nezneski, PharmD, BCPS is the founder of 340B Orphan Drug Solutions, a consulting practice working exclusively with Critical Access Hospitals, Sole Community Hospitals, Rural Referral Centers, and Freestanding Cancer Centers on orphan drug revenue recovery. Her 12 years of dedicated orphan drug focus follow a 40-plus year career in pharmacy and healthcare. She is a regular attendee at the 340B Coalition Conference and is a published author.