



What Drugs Are Not Eligible For 340B Savings?

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Introduction

Although the 340B Drug Pricing Program was created to provide significant prescription drug discounts to eligible providers, a surprisingly low percentage take advantage of their legal right to use it.

As a leading provider of 340B program-management services, we believe the primary reasons for that low percentage are **1) Lack of understanding of the program's potential benefits, 2) Lack of administrative bandwidth to ensure full compliance — not to mention apprehension over the consequences of non-compliance, and 3) Unfounded concerns that drug-manufacturer restrictions have made the 340B program too costly and complicated to expect any reasonable ROI for eligible health systems.**

Introduction

Since late 2019, VytlOne has supported the 340B programs of 33 health systems and 38 health centers. Altogether, we've generated nearly \$1 billion in pharmacy-related savings for our clients. Since the 2020 advent of manufacturer restrictions, while the average 340B hospital's revenues have decreased significantly, the 340B revenue of every hospital we serve has increased.

That said, the 340B program certainly has its share of complications — and the answer to the question posed in this resource's headline is equally complicated. Which is why we'll start with a review of what drugs are eligible for 340B savings.

General drug criteria for 340B eligibility

1)

The covered entity has a relationship with the patient and maintains records of care.

2)

The services are provided by a healthcare professional who is either employed by, or contracted with, the covered entity.

3)

The responsibility for care rests with the covered entity.

General drug criteria for 340B eligibility

4)

The services are within the scope of project for grantees and designees.

5)

The service must be more than just dispensing.

6)

The drug is administered in an eligible outpatient location or dispensed by the covered entity's 340B contract pharmacy.

General drug criteria for 340B eligibility

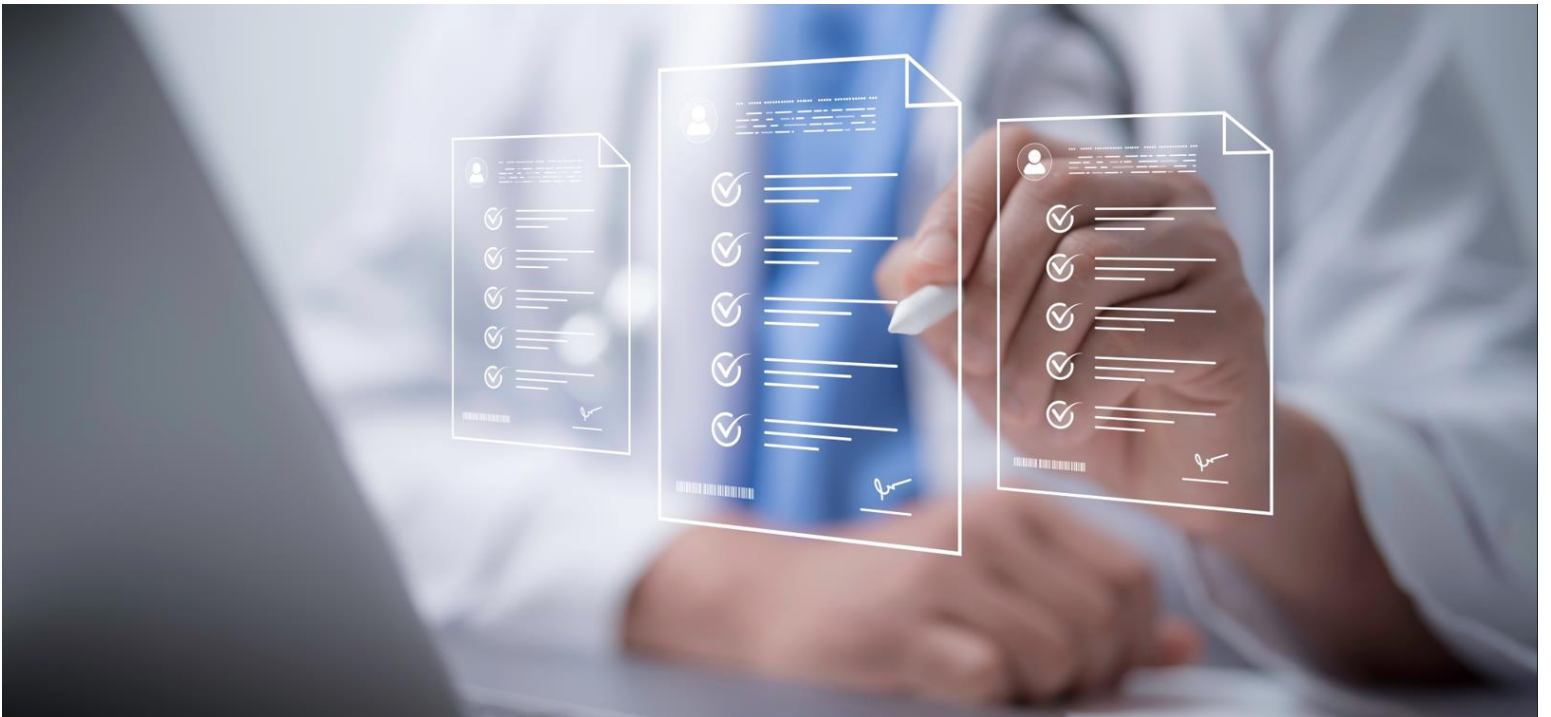
Manufacturers' responsibilities

Manufacturers that want outpatient drug products of theirs to be billable to Medicaid and other CMS programs have to make those drugs eligible for the 340B program — or, as otherwise stated, subject to a 340B ceiling price.

NOTE: The term Outpatient Drug includes all outpatient prescription drugs, and can include some testing supplies and over-the-counter products that are sometimes billed as prescriptions.

The eligible drug catalog list, which can be different for various covered entities, includes over 30,000 separate NDCs, or National Drug Codes. [Click Here](#) to see a list of drugs reported by manufacturers under the Medicaid Drug Rebate program — all of which are subject to 340B ceiling prices.

Making the most of 340B prescribing options for patients



There are Good, Better and Best medications within virtually every medication class. At hospitals with 340B programs and pharmacies managed by VytlOne, we support providers by matching patients in need with 340B-eligible medications. When the best available medications aren't covered by hospitals' 340B programs, our pharmacists can ask our 340B team to access our own regularly-updated database of National Drug Codes for the best available medications eligible for 340B savings.

Unlawful 340B restrictions imposed by drug manufacturers

Since the June, 2020 launch of 340B ESP, the drug manufacturing industry has been imposing unlawful restrictions on a broad range of 340B-eligible prescriptions. 340B ESP is operated by Second Sight Solutions, a privately-owned corporation created and run by a man with a long history of accepting money to promote the drug industry's interests.

HRSA has publicly confirmed that the site has no legal right to impose its restrictions on covered entities. And yet, the drug industry continues to do just that —with virtual impunity. At latest count, there were 24 manufacturers imposing restrictions — either through 340B ESP, or independent of the website.

Unlawful 340B restrictions imposed by drug manufacturers

The two primary, and most punitive, 340B restrictions imposed by drug manufacturers are **1)** Limiting the number of eligible contract pharmacies they'll recognize and honor in any given entity's network, and **2)** Limiting the location of eligible contract pharmacies they'll recognize and honor to pharmacies within a 40-mile radius of a 340B hospital's primary campus.

The good news for 340B-eligible health systems is, VytOne has overcome many of the manufacturers' restrictions. To learn how, [Click Here](#).

Overcoming 340B restrictions on specialty pharmacy prescriptions



Not surprisingly, a significant number of 340B-eligible prescriptions restricted by the manufacturers are specialty pharmacy drugs — for the simple reason that 340B specialty pharmacy drugs tend to be significantly more expensive (and, therefore, more costly to manufacturers) than retail-pharmacy prescriptions.

Overcoming 340B restrictions on specialty pharmacy prescriptions

As we pointed-out in the article "[The Case for Onsite Specialty Pharmacies in 340B Hospitals](#)," there is a workaround for 340B hospitals forced to select a single pharmacy for manufacturers' 340B pricing — and it is perfectly legal in many states. Hospitals can operate specialty pharmacies alongside their retail pharmacies, as long as the two operations are physically in their own spaces (working under separate Pharmacists-In-Charge), and there is no procedural, functional or personnel overlap between the two.

Overcoming 340B restrictions on specialty pharmacy prescriptions

In some states, you can combine specialty and retail together, but the retail operation is subject to the heavy policy and process requirements of specialty accreditation — which is an exceptionally demanding burden for a retail pharmacy. Regardless of the state laws governing your health system, VytlOne can help health systems understand and navigate the best options for dealing with state regulations, maximizing available space, and meeting patient needs.

Overcoming 340B restrictions on specialty pharmacy prescriptions

As we noted in [another article](#), one excellent way of overcoming many manufacturer restrictions on 340B pricing for specialty medications is by partnering with those manufacturers. Specialty drugs are often manufactured under “pseudo-approved” status, and require ongoing usage and outcome data to support the manufacturers’ efficacy claims and justify Medicare / Medicaid reimbursement. This is exactly the kind of data that your onsite specialty pharmacy can provide them in prescribing, dispensing and monitoring 340B-eligible specialty drugs for your patients.

Overcoming 340B restrictions on specialty pharmacy prescriptions

VytlOne can help your health system build and operate its own specialty pharmacy — AND help you pay for it from your 340B-program revenue. To learn more, refer to the articles below:

[Use Your Hospital's Retail Pharmacy 340B Drug Savings To Build A Specialty Pharmacy](#)

[Why 340B Hospitals Should Now Build Their Own Specialty Pharmacies](#)

[Why A 340B Hospital Should Own A Specialty Pharmacy. Why Not.](#)

[Best Practices For A 340B Hospital Looking To Build An Onsite Specialty Pharmacy](#)

General exceptions to 340B drug eligibility



There are a few exceptions, which include vaccines and Orphan Drugs (which are, by definition, medications specifically developed to treat rare diseases or conditions — and drugs that have only recently been granted New Drug Status by the FDA).

Eligible drugs frequently not submitted for 340B savings

While narcotic medications are included among 340B eligible drugs, covered entities often choose to exclude them from their programs — due, primarily, to the complexity of procuring this class of medication for replenishment. That procurement complexity adds-up to significant time-and-effort costs. And as we've noted in a previous post, what's the point of utilizing 340B for specific medications when the time-and-effort costs exceed the savings generated?

About 340B Orphan Drugs

For the following covered entities utilizing the 340B Program, covered outpatient drugs do not include any drugs designated by the Secretary under Section 526 of the Federal Food, Drug, and Cosmetic Act for rare diseases and conditions:

- Free-standing cancer hospitals
- Rural referral centers
- Sole community hospitals
- Critical access hospitals

About 340B Orphan Drugs

Exceptions to the rule above

The orphan drug exclusion does not apply to 340B-eligible entities which are:

- Enrolled under sections 340B(a)(4)(A) through 340B(a)(4)(L) of the PHSA
- Children's hospitals described in section 340B(a)(4)(M)

BROAD, SIMPLIFIED SUMMARY of the exceptions above: Covered entity types that can purchase orphan drugs at 340B prices are disproportionate share hospitals (DSHs) and children's hospitals.

Keeping current with orphan drug manufacturers / sponsors

HRSA recognizes that an orphan drug's sponsor — listed on the FDA orphan drug list — may not be the current manufacturer for an orphan drug. Which is why HRSA encourages 340B stakeholders to work, in good faith, to resolve any potential disputes that may result from the use of its list. HRSA posts an updated list of orphan drugs on a quarterly basis, to ensure that covered entities have the information they need to comply with orphan drug exclusions. To determine if a specific drug has been designated an Orphan Drug, visit the FDA [Search Database](#).



VytlOne is here to help, if you have questions.

There are so many ways to optimize your 340B drug program savings & benefits, and overcome manufacturer restrictions while still minimizing the likelihood of noncompliance. For more information, contact:

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