

## > Delivering the Highest Level of 340B Expertise

# Protect Your 340B Program & Minimize Your Compliance Risk



Visante's focus is to help covered entities prepare for a HRSA 340B Program audit. Our stem to stern assessment reduces financial risk and identifies compliance issues that jeopardize your 340B Program.

## 340B Drug Discount Program Consulting Service Options

- **Comprehensive 340B Program Assessment and Integrity Audit Readiness Review:** Visante assesses all types of covered entities, and every 340B requirement specific to each type of entity, to identify potential compliance problems. Our goal is to help you receive a positive audit result and protect your program.
- **Contract Pharmacy Independent External Audits:** Visante has conducted audits of more than 1,000 contract pharmacies for virtually every type of covered entity, including review of more than 100,000 individual contract pharmacy transactions. This means we provide our clients with a wealth of experience to help guide programs to full compliance.
- **Split-billing Setup, Implementation Assessment & Correction:** Visante has extensive experience in working with all split-billing vendors to uncover and correct setup and implementation errors. Understanding, maintaining, and optimizing these complex software systems requires internal expertise frequently lacking within the covered entity workforce.
- **Internal Audit Support Services:** HRSA's proposed 340B Drug Pricing Program Omnibus Guidance (Mega-Guidance) requires covered entities to conduct routine internal audits of all contract pharmacies *at least quarterly*. Visante offers a subscription service for ongoing quarterly audit support to conduct these internal audits on behalf of the covered entity and provide documentation, as well as identify compliance breaches. These services support ongoing compliance.
- **On-Site HRSA Audit Support:** Visante offers on-site support for covered entities during HRSA audits. Frequently, clients have requested Visante consultants to be on-site while HRSA auditors are present. When Visante has conducted an integrity audit readiness review prior to a HRSA audit, our consultants can help covered entities manage a successful audit.
- **340B Program Optimization:** Visante often uncovers additional savings opportunities for covered entities. Assisting covered entities to expand their 340B program while remaining fully compliant is an important element of our service offerings.
- **Annual Check-up for Recertification:** Visante will annually review your program for full compliance, and assist covered entities with the recertification process. An annual check-up is an excellent method to support the attestation process. Our consultants have assisted covered entities of all types to recertify and remain compliant.
- **Online Training & Subscription Service:** Visante offers remote online training of new employees, refresher programs for keeping covered entities up-to-date with 340B Program changes, and HRSA auditor's interpretations and latest audit findings to help guide covered entities through the complexity of the 340B Program.

### 340B Omnibus "Mega" Guidelines Will you be prepared?

- ✓ Internal Audits of Contract Pharmacies *at least* Quarterly
- ✓ New Facility Eligibility Criteria
- ✓ New Patient Eligibility Criteria
- ✓ New Provider Eligibility Criteria
- ✓ New Location Eligibility Criteria
- ✓ New Auditable Records Requirements
- ✓ Audit documentation preparedness

## Our experience removes the guesswork

Visante's 340B team consultants are all graduates of the APEXUS 340B University and highly experienced in 340B Program compliance. We understand the complex issues of the 340B Program and the nuances that can mean substantial savings or compliance risk that may lead to financial penalties and/or removal from the program.

## Experts at understanding individual program needs

Our consultants each have 10 or more years successfully managing 340B programs nationwide. We have seen many programs and understand how to work with a vast array of programs. We can help you make the most of your unique 340B program.

### CASE STUDY

#### Improper split-billing system means millions lost

For one large community hospital, improper set up of a split-billing system resulted in \$2-3 million lost in eight short months. The system incorrectly excluded its pediatric hospital from the 340B Program.

Visante quickly identified this missed opportunity for savings. Our experience led us to investigate the incidence of orphan drug prescribing in this pediatric hospital.

***Operational efficiency is key to maximizing 340B programs.***

## Be confident by being prepared

Visante 340B team members are current with all of HRSA's Office of Pharmacy Affairs (OPA) regulations and Government Accountability Office (GAO) recommendations and regularly share these updates with our clients. We help prepare our 340B clients for upcoming audits by reviewing their compliance with these regulations and guidance statements, including a comprehensive review of all required documentation.

### NEW HRSA EXPECTATION: ANNUAL INDEPENDENT EXTERNAL AUDIT OF CONTRACT PHARMACIES

HRSA/OPA expects ALL covered entities to conduct quarterly internal audits and annual external INDEPENDENT audits of ALL contract pharmacies. Visante's expertise will help you fulfill these expectations and provide support to your 340B Program to help ensure integrity, while providing internal audit options to achieve and maintain compliance.

***"Risks are amplified with continual changes to 340B regulations, and annual recertification brings opportunity for further scrutiny and even personal risk for hospital administrators."***

— Kristin Fox-Smith, Vice President, Visante

» We welcome the opportunity to assist you. To find out more, visit [visanteinc.com](http://visanteinc.com) or call (866) 388-7583.

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