340B Aware and Beware

Being aware of the complex and ever-changing 340B Drug Pricing Program rules helps covered entities maintain integrity and drive program value. Successful 340B programs focus on three fundamental objectives; ensuring compliance, optimizing savings and controlling skyrocketing costs of pharmaceuticals. It's a three-legged stool analogy, where all of the legs must be in balance in order to stand solidly over time. To effectively navigate the complex dynamics of the 340B Program and address challenges as they arise, it is important to select the right partner — a partner who truly understands all of the nuances of this complicated program.

1 Controlling Costs

Covered entities that own a pharmacy(s) which serves both inpatients and outpatients, bear the important burden of ensuring that drugs are purchased on the correct account - wholesale acquisition cost ("WAC"), group purchasing organization ("GPO") and 340B. And, importantly, that they must ensure that HRSA's "GPO Exclusion" rule is not violated. To assist in this important cost and compliance issue, many covered entities turn to split-billing vendors to assist them. Most split-billing vendors will boast that they can also easily manage a contract pharmacy network, and often seek the exclusive right to do so. Nothing could be further from the truth. It is important for a covered entity to be aware of the distinctions between these two essential, but very different lines of service.

Split-billing solutions allow the covered entity to separate 340B eligible prescriptions from non-340B eligible prescriptions after the prescriptions are dispensed. The split-billing solution attempts to do this by gathering information on all patient charges from the covered entity's information systems. It uses this information to ensure that inventory for the internal pharmacy(s) is purchased on the appropriate account. The ability to lower the overall cost of pharmaceutical purchases while remaining compliant is the goal, and the program performance is only as good as the quality and accuracy of the data. This means the split-billing solution must work seamlessly in the covered entity's information environment.

Choosing a split-billing vendor is not a decision to be taken lightly. By choosing the right split-billing solution, a covered entity can be reassured that the overall cost of pharmaceuticals it purchases is being optimized, 340B Program integrity is being maintained and diversion prevented. In addition, pharmacy personnel are freed to focus on patient care.

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Optimizing Program Savings

Optimizing 340B Program savings through a contract pharmacy network is a win-win-win strategy for the covered entity, its patients and the pharmacies. For the covered entity, a contract pharmacy network enables it to capture an increased number of prescriptions written by its providers to its outpatients — thus generating increased 340B savings. Patients receive increased access to pharmacy care, and pharmacies enjoy a closer relationship with the covered entity and higher dispensing fees. In addition, a contract pharmacy network enables covered entities to construct a more efficient program for its uninsured patients. Contract pharmacy networks provide the opportunity for covered entities to achieve HRSA's stated intent for the 340B Program — to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

> For covered entities, the 340B Drug Pricing Program facilitates the extension and expansion of services to the most vulnerable and needy patients, thereby improving patient health and ultimately lowering healthcare expenditures.

Establishing an optimized contract pharmacy network, requires a 340B administrator focused on all aspects of the program. An administrator who understands that each covered entity is unique and requires a custom solution. The 340B administrator must start with ensuring the proper registration of all clinics and pharmacies. From there it must obtain all data feeds in whatever format the covered entity can provide. Next it must analyze the data to identify the key community retail pharmacies and specialty pharmacies, where patients are filling their prescriptions. Then it must build the contract pharmacy network that optimizes the capture rate of 340B eligible prescriptions. Finally, it must continually work with the covered entity to ensure that every aspect of the program is being optimized. A successful contract pharmacy network should provide the following.

- High performing retail and specialty pharmacies
- A customized strategy to contract with limited and exclusive specialty pharmacy networks
  - This will help ensure that specialty prescriptions previously locked out of a 340B program by health plan's PBMs and their captive specialty pharmacies can be captured in the program
- Dedicated and engaged customer service, focused on optimizing the program
- Completely transparent, real-time program reporting and analysis
  - Including the ability to monitor and self-audit every prescription
- Pricing that is both transparent and completely aligned with the covered entity

There is lot of confusion in the market regarding program cost versus program value. Many 340B administrators will promote a 'per claim', 'per click' or 'per pharmacy' program fee structure. Be aware of the many hidden fixed fees associated with these approaches. In many of these arrangements the program savings may not exceed the fixed fee requirements, leaving the covered entities 340B program at a financial loss. A successful 340B administrator should be willing to provide a pricing methodology that aligns with the success of the program and puts the 340B administrator's fees at risk, based on overall program performance. It's a simple, transparent and aligned approach if you think about it.

So while many if not all of the split-billing software companies offer to provide a contract pharmacy component as an "add-on" to their primary offering, keep in mind that these are two very important albeit very distinct program offerings. Each with different requirements which provide different value propositions for the covered entity that should never be part of a single buying decision. Covered entities need to maximize cost reduction and optimize revenue opportunities.

3 Compliance

What does a covered entity need to be aware of when it comes to HRSA audits? Since 2012, the number of covered entities audited by HRSA has increased each year. Covered entities that have never been audited before may receive notice in the near future notifying them of an impending audit. Legal experts have warned it is not a matter of "if" but "when" a covered entity may be chosen to undergo an audit.

> Prioritizing the 3 fundamental 340B elements will lead you towards a 340B program manager that offers the most comprehensive services available. Ensuring the highest level of program integrity and optimizing the amount of 340B savings generated.

Over 75% of the audits conducted by HRSA have resulted in negative findings, with over 43% identifying two or more discoveries. Over half HRSA's audits have resulted in the covered entity incurring penalties, potentially requiring repayment to manufacturers. So far this year, 28 covered entities have undergone HRSA audits, with seven entities required to repay manufacturers due to diversion or duplicate discounts. Four entities were terminated from the program for working with contract pharmacies without written contracts in place. This is why it's imperative for a covered entity to choose a 340B administrator who surpasses the current industry standards in the ability to ensure program integrity and compliance. Subject to the rules of participation. covered entities are allowed to provide 340B drugs only to those individuals who are 'patients' of the covered entity. Currently, with the lack of specificity in regards to the criteria defining eligibility, covered entities must be aware of and beware of providing 340B prescriptions to individuals who do not meet the program's requirements. 340B administrators who are capable of providing covered entities with the tools needed to have real-time access to eligible prescriptions as well as potentially eligible prescriptions offer program optimization as well as self-auditing capabilities in today's environment.

According to the statute, when an eligible entity voluntarily decides to enroll in the 340B program, it accepts responsibility for ensuring compliance with all provisions of the 340B program, including all associated costs. Beware of 340B administrators that guarantee

100% compliance: check their history of audit occurrences and outcomes. Only a skilled 340B administrator, with a successful track record in navigating the ever-changing challenges of the 340B program can successfully guide you through the complex and highly regulated, evolving federal drug discount program.

Prioritizing the three fundamental 340B elements will lead you towards a 340B administrator that offers the most comprehensive services available ensuring the highest level of program integrity and optimizing the amount of 340B savings generated.

When it comes to participation in the 340B Drug Program some words of advice. Be aware and beware.

About the Author

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Jim Love joined Wellpartner as President in December 2011 and was named Chief Executive Officer in April 2012. Prior to joining Wellpartner, Mr. Love had significant healthcare experience in both operations and investment banking. He spent the early part of his career in the investment banking division of Merrill Lynch & Company where he led the healthcare group and provided both strategic and financing advice to a wide range of companies including Johnson & Johnson, Hospital Corporation of America, Medco, and Biogen Idec. Mr. Love left Merrill Lynch to serve as Executive Vice President of Synetic Inc. (and its successor company Medical Manager, Inc.) a publically traded healthcare information technology company, where he was responsible for all finance and administrative functions. During his tenure at Synetic, Mr. Love led the efforts to raise both debt and equity capital, acquire several businesses, and ultimately merge the company with WebMD. After the merger with WebMD, Mr. Love returned to the investment banking business, at the Bank of Montreal, where he rebuilt the firm's commercial and investment banking healthcare effort, and at Madison Williams and Company, where he was a senior investment banker.

Mr. Love received an A.B. degree from Brown University, and a M.B.A degree from New York University.

Wellpartner: Who We Are

As your strategic partner, we're committed to providing a complete 340B service suite that creates value, and gets it right.

Wellpartner is the authority in 340B program management offering innovative technology and the broadest set of 340B services. By staying ahead of industry changes, Wellpartner provides a seamless, easy-to-use solution for covered entities currently or considering participating in the 340B Drug Program.

Our experience is your advantage. Our processes are finely-tuned towards achieving the best results for our customers, whether it is contracting, providing our URAC-accredited specialty pharmacy services, ensuring program compliance, aligning specialty network access, maximizing claims capture, or driving program value. Wellpartner is focused on excelling at these tasks, since we share the same goal as our covered entity customers — to preserve resources, in order to serve those who need it most.

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