

Developing a Peak Performance Culture for 340B

A Map for 340B Leadership



Sherri D. Faber, RPh, MHA, 340B ACE
President & CEO
340B Compliance Partners



July 13, 2021

Disclosure

I declare no conflict of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holding, and honoraria.

340B Strategy- Balancing Act

Compliance



This Photo by Unknown Author is licensed under [CC BY-SA](#)

Expansion



This Photo by Unknown Author is licensed under [CC BY-SA-NC](#)

Explore the Path to a Top-Performing 340B Program

Objectives:

- ❖ Self-educate
- ❖ Establish Team & Critical Leaders
- ❖ Highlight 340B Importance and Create the Ultimate Culture
- ❖ Empower with Tools and Resources

Self-Educate

- Lay the foundation: Can't lead what you do not understand
- Covered Entity type of registration
- Basics of split-billing and contract pharmacy
- Participate in your state associations with advocacy



“To stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

- HRSA (2019)

Solid Foundation



Know the Basic Rules

Conflicts of interest

Patient definition

Carve-IN vs Carve-OUT

Policies & Procedures

Backbone
of your
program



Proper Program Oversight

Continuous readiness

Shared vision

Key personnel trust

Covered Entity 340B Type

- ❖ Registration type i.e. FQHC, CAH, DSH, Ryan White
- ❖ Recertification time of year
- ❖ Stipulations for your “group” – Orphan Drug Exclusion, Electronic Handbook, GPO prohibition
- ❖ Terminology – parent, child site/associated site, entity-owned pharmacy, MEF, Carve-IN, Carve-OUT

Basics of Split-billing and Contract Pharmacy

- ❖ Terminology
- ❖ Flow of money
- ❖ TPA logic
- ❖ Assignments of oversight for financial and maintenance

State Organizations and Advocacy

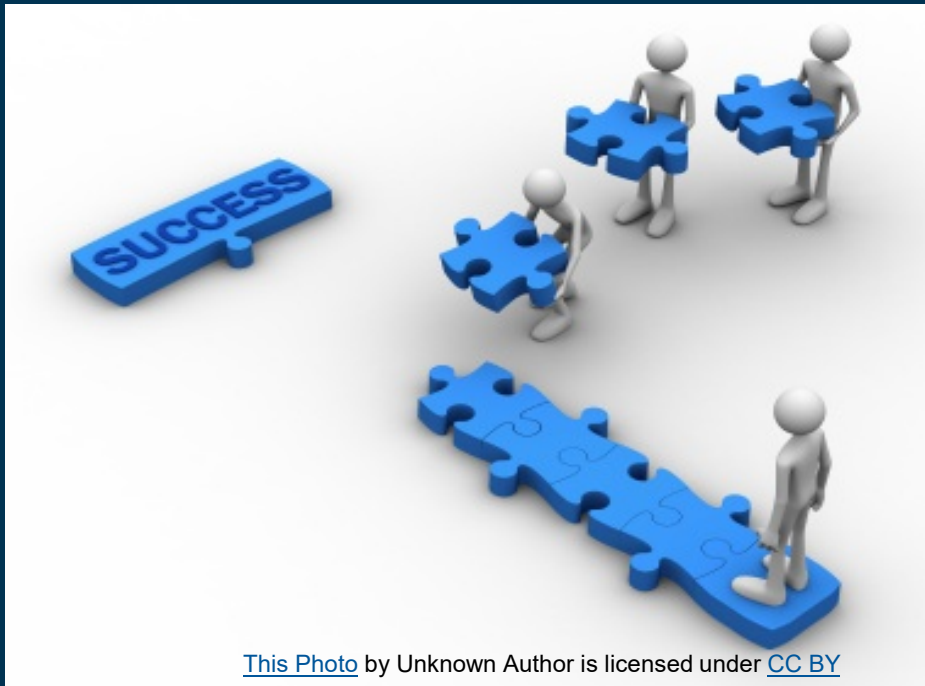
- ❖ Hospital Associations i.e., American Hospital Association 340B Advocacy Alliance, America's Essential Hospitals, Children's Hospital Association
- ❖ Rural Health Associations i.e., National Rural Health Association,
- ❖ Advocacy Groups i.e., 340B Health, Ryan White Clinics for 340B Access, Association of Medical Colleges, ASHP, APhA

Establish Team & Critical Leaders

- Multi-disciplinary approach
- SSS (Silos Stifle Success)
- Detail-oriented team members
- Set high expectations
- Routine meetings with minutes

Multi-disciplinary Team

Learn your role and do it well



[This Photo](#) by Unknown Author is licensed under [CC BY](#)

- ❖ Members by title in P&P with role and responsibilities
- ❖ Minimal education requirements for team
- ❖ Covers many departments:
Billing, finance, medical affairs, legal, IT, pharmacy, administration

SSS (Silos Stifle Success)

Pharmacy silo

Finance silo

Other departments to be routinely included

Critical Leaders (detail-oriented)

- ❖ **Authorizing Official**
- ❖ **Primary Contact**
- ❖ **Establish Roles and Responsibilities**
- ❖ **Know your 340B Coordinator**
- ❖ **340B Priority if Coordinator wears many hats**
- ❖ **IT and file submission**
- ❖ **Medical Affairs/Credentialing- provider file**

Set High Expectations

- ❖ **Staff will see program as important if you do**
- ❖ **Performance Indicators**
- ❖ **Internal Quality Assurance Plan Design**

Routine Meetings with Minutes

340B Oversight Committee

- ❖ Frequency of meetings
- ❖ Agenda content
- ❖ Material Breach discussion
- ❖ Quality Assurance Reports and Follow-up
- ❖ Minutes to capture approvals and decisions
- ❖ Incorporate education

Highlight 340B Importance and Create Ultimate Culture

- Directors Meetings/Standing Agenda item with Quality Team
- Patient Impact
- Incorporate into 3- or 5-year plan
- Individual, measurable goals for frontline staff
- Deliver Message of Compliance First, Compliant Expansion Next

Leadership Meetings



340B VISIBILITY



ACCOUNTABILITY



INCLUSION OF
TEAM

Patient Impact

Direct Patient
Benefit

Equipment or
Services

Account for
Savings and
Revenue for
HHS/CMS

Strategic Plan



Demonstrates importance

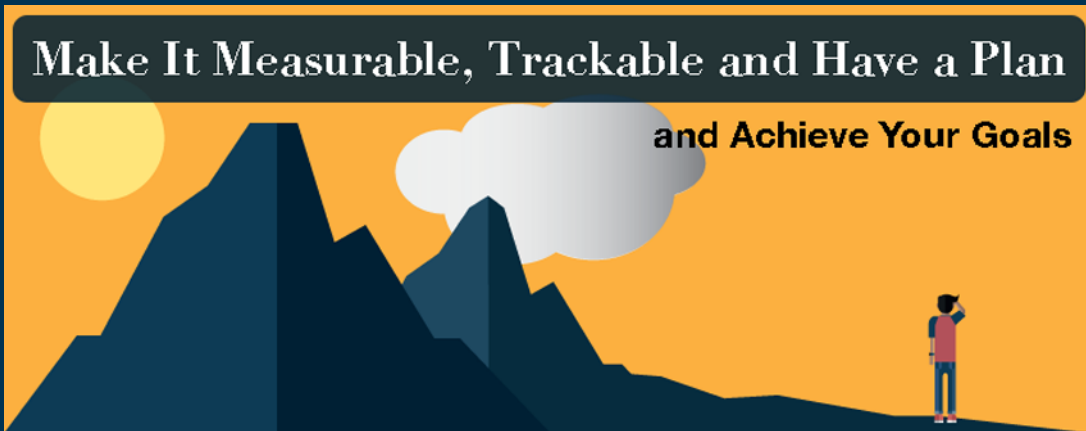


Keeps program on radar



Forces more re-evaluation and performance of program with software and viability of relationships with pharmacies

Measurable Goals



[This Photo](#) by Unknown Author is licensed under [CC BY-SA-NC](#)



Staff need direction and targets for evaluations



Periodic check-ins with monthly reports to gauge



Facilitates oversight

Messaging

Lead by
example

Compliance is
KEY

Risk of losing
program
entirely

Ongoing
evaluation of
expansion
opportunities

Empower with Tools and Resources

- TPA selection
- Certifications and Conferences
- Evaluate labor needed
- Annual Independent Audit

TPA Selection



Available
Data



Real time
capture and
look back
capabilities



Compliant
functionality at a
granular level



Transparency



Partnership
versus set it
and forget it

Certifications and Conferences



- ❖ Highly trained staff
- ❖ ACE and ongoing education
- ❖ Exposure to other programs and networking online and live

Evaluate the Labor Needed

(contract for pieces if necessary)

Data Maintenance	Quality Assurance	P&P Upkeep	Reporting and Education for staff
mapping	Mixed-Use analysis	Annual review	340B Committee
Price file review	Contract Pharmacy Analysis	Process changes	Quality
Files crossing	Financial analysis	Regulatory changes	Update leadership
HCPCS units	OPAIS database accuracy		Stakeholder education
Modifiers/pricing tables/CMS status drugs	Trends of errors		
BIN/PCN/Group #s Medicaid	Material Breach		

Annual Independent Audit

❖ INDEPENDENT

1. Unbiased to analyze TPA function
2. Review wholesaler pricing updates
3. Approach to patient definition

❖ Value-added

❖ Thorough

❖ Actionable reports

❖ Participate as though HRSA audit



Aim high for that Peak
Performance Culture
and accept nothing less

References

Apexus 340B Prime Vendor Program. *340B Tools*. Retrieved from <https://www.340bpvp.com/education/340b-tools/>

Federal Register / Vol.75, No. 43 / Friday, March 5, 2010 / Notices. Retrieved from <https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf>



Thank you!

Rebecca Runyan
Senior Sales Executive
Maxor 340B
(615) 714-6330
rirunyan@maxor.com

Questions?

Sherri D. Faber, RPh, MHA
President & CEO

Pharmacy Consultants, Inc.

DBA: 340B Compliance Partners

sfaber@340BCompliancePartners.com

(304) 964-3903