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340B Pharmacy Program Best Practices

Matthew Hutt
Partner
AAFCPAs

Courtney McFarland
Manager
AAFCPAs

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Agenda

1. **The Program and the Requirements**

2. **Program Compliance and Integrity (Best Practices)**
   - Internal Controls
   - Policies and Procedures
   - OPA Database Maintenance
   - Internal or External Audits

3. **Contract Pharmacies**
   - Management
   - Measuring Success

4. **Maintenance of the Program**

The Program and Requirements

- In 1992, section 340B of the Public Health Service Act introduced the 340B Drug Pricing Program with the intent of permitting covered entities *"to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services".*

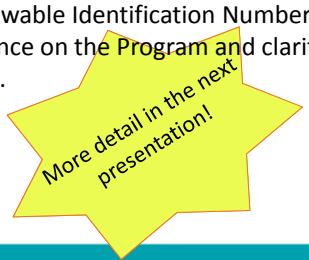
- Covered entities are eligible to purchase certain outpatient drugs at or below statutorily defined discount prices (340B drugs) thereby allowing them to achieve substantial savings on drug expenses.

- The Affordable Care Act expanded access of the Program to certain safety net providers including Federally Qualified Health Centers. FQHCs are able to provide these discounted drugs at their internal pharmacies or they are able to contract with a pharmacy to dispense drugs on their behalf.

The Program and Requirements

- The Office of Pharmacy Affairs (OPA) administers and regulates the Program in order to ensure the intent and integrity of the Program. *The **FQHC is responsible** to create and maintain policies, procedures and records, of both in-house and contract pharmacies, to prove compliance with all requirements of the Program.*

- In August, 2015, the Department of Health and Human Services issued a Renewable Identification Number (0906-AB08) providing further guidance on the Program and clarifying certain compliance requirements.



The Program and Requirements

Covered entities are subject to audit by the producer of the drug (the Manufacturer) or the Federal Government at any time during their participation in the Program.
Compliance findings generally fall into two categories:

1. **Non-systemic:** Where the covered entity appears to maintain auditable records proving compliance, however, they are unable to provide documentation regarding specific transaction(s). This type of finding typically results in repayment to the Manufacturer for all ineligible scripts, but does not result in the revocation of participation in the Program.

2. **Systemic:** Where the covered entity is found to have in-auditable, inaccurate or insufficient records and/or procedures. This type of finding typically results in revocation of participation in the Program and repayment to manufacturers.

All findings are made publically known and available. Re-instatement into the Program is possible after revocation; however a detailed corrective action plan is required.

The Program and Requirements

Though there are multiple compliance requirements of the Program, there are **two main prohibitions** :

1. **Diversion:**
   The resale of 340B drugs to a person who is not a patient of the covered entity.

   Diversion may also occur by dispensing 340B drugs for a service or scope of service which is not covered by the Program, or the Federal grant which triggers eligibility to participate in the Program.

The Program and Requirements

2. **Duplicate Discount:**

When a Manufacturer is required to pay discounts or rebates under both the Program and the Medicaid Drug Rebate Program. Duplicate discounts occur when the covered entity bills Medicaid contrary to information included in the Medicaid exclusion file.

OPA 340B Database Reporting

The Program and Requirements

2. **Duplicate Discount (Continued):**

Initially, the Rebate Program was limited to Medicaid Fee For Service (FFS) drugs only, however, section 2501(c) amended the Social Security Act to specify that covered outpatient drugs dispensed by Medicaid Managed Care Organizations (MCOs) are not subject to a rebate if also subject to a discount under section 340B of the Act.

The determination of certain MCOs and their Medicaid inclusion is often difficult and should be carefully monitored.

The Program and Requirements

2. **Duplicate Discount (Continued):**

   Contract pharmacies are not issued a 340B provider number and are therefore excluded from providing 340B drugs to eligible patients.

   For this reason, all contract pharmacies must be carve-out (Medicaid patients are never dispensed 340B drugs) unless there is a specific agreement and contract with the State, the covered entity and the contract pharmacy allowing such distribution.

It is the **covered entity's responsibility** to notify OPA, HRSA of this arrangement

The Program and Requirements

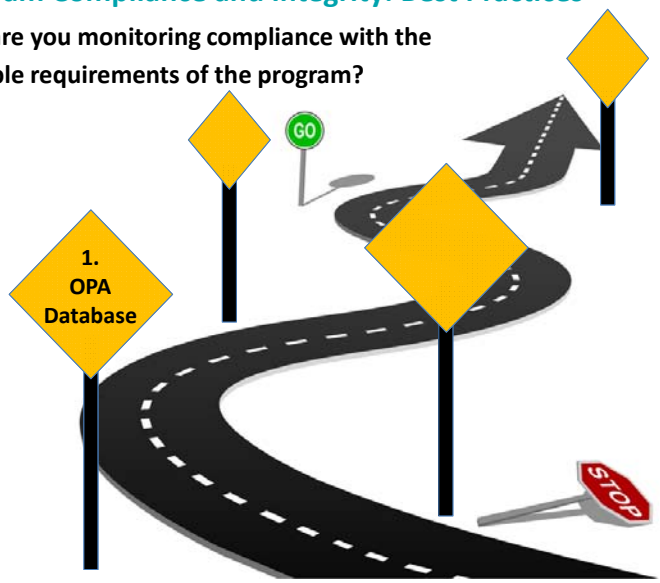
2. **Duplicate Discount (Continued):**

   Massachusetts State Policy (130 CMR 406.000(D)(2)(a) allows a covered entity to contract with a MassHealth pharmacy provider to dispense 340B drugs, however:

   - The subcontracts must be in writing
   - Ensure continuity of care
   - Specify that the 340B-covered entity pays the pharmacy
   - Specify that the payment constitutes payment in full for 340B drugs provided to MassHealth members
   - Be consistent with all applicable provisions
   - Subject to MassHealth approval

Program Compliance and Integrity: Best Practices

How are you monitoring compliance with the multiple requirements of the program?



Program Compliance and Integrity: Best Practices

Step 1 **OPA Database Maintenance**

1. Keep all contact information up to date and accurate
   - Best practice to have two separate people as authorizing official and primary contact
2. Keep all changes in scope of services or service locations up to date and accurate
3. Keep status of Medicaid billing and all NPI numbers up to date and accurate
4. Recertify annually, and update the database as changes occur

Additional for contract pharmacy arrangements

5. Review listed authorized pharmacies monthly for reasonableness
   - Non-mail order pharmacies that are out of the State of the covered entity pose a greater risk of non-compliance with the program due to patient definition.

Program Compliance and Integrity: Best Practices

Program Compliance and Integrity: Best Practices

Step 2 **Policies and Procedures**

Policies and Procedures surrounding the compliance and management of the program should be written and must address the following:

1. A summary of all operating sites (including contract)
2. Name of the person responsible for maintaining compliance with the Program
3. The scope of services/grants under which scripts are eligible
4. Software:
   - What software is used to manage inventory?
   - How are price changes monitored and updated?
   - Who is the key contact for software issues and updates?
   - Consider obtaining a Service Organization Control Report attesting to the adequacy of controls surrounding your data.

Program Compliance and Integrity: Best Practices

Step 2 **Policies and Procedures (Continued)**

5. Preventing **Diversion**: Patient Definition
   - When is a patient considered eligible?
   - If a patient has not been seen by a covered entity prescriber in over 1 year, does the prescription qualify?
   - What about a referral prescription? Does the covered entity have complete care of the patient or the specific prescription?
   - How often, and how are changes in covered entity eligible prescribers communicated to the pharmacy locations?
   - Insurance status: Carve- In accepting Medicaid, or Carve-Out
   - Any moonlighting prescribers? Risk for diversion.

Program Compliance and Integrity: Best Practices

Step 2 **Policies and Procedures (Continued)**

More detail in the next presentation!

6. Preventing **Duplicate Discounts**: Medicaid Billing
   - Do you accept Medicaid?
   - Are MCOs specifically excluded? If not, which MCOs are still processed?
   - Include specific spot checks of data to ensure no Medicaid claims are being erroneously processed.

7. Who is responsible for updating the OPA database? How often is it monitored and who approves changes?

8. Physician Administered Drugs: How are these monitored and tracked? These drugs are under the same compliance regulations.

Program Compliance and Integrity: Best Practices

Step 2 **Policies and Procedures (Continued)**

9. Who is responsible for training pharmacy staff? What training materials are provided and who updates pharmacy staff on changing 340B rules, trends, compliance and changes in patient definition or scope of services?

10. **Financial**:
    - How are pharmacy transactions recorded in the general ledger?
    - Who reviews monthly activity and approves recording the activity?
    - How are price changes recorded in the general ledger?

Program Compliance and Integrity: Best Practices

Step 2 **Policies and Procedures (Continued)**

11. **Inventory reconciliation and counts:**
    - If offering retail and 340B drugs, details on how the inventory is separated
    - Documentation of annual physical inventory
    - Best Practice: Quarterly reconciliation of 340B inventory (see right)

Beginning 340B Inventory Balance	$
Purchases during the Period	$
Dispensed Drugs during the Period	$
Returns	$
Other Adjustments	$
Ending 340B Inventory Balance	$

Program Compliance and Integrity: Best Practices

Step 2 **Policies and Procedures (Continued)**

12. The timing, extent and frequency of self-audits, or external audits
    - Best Practice: At least annually. All results should be documented
    - Need documentation of what is considered a material non-compliance; and the process for self-reporting
13. Policies and procedures should have documented approval by the Board or Directors and/or C-Suite (CEO, COO, CFO and etc)

Program Compliance and Integrity: Best Practices

Step 2 **Policies and Procedures (Continued)**

Additional for Contract Pharmacy Arrangements:

1. Review and conclude on internal controls at the contract pharmacy
    - Obtain a Service Organization Control Report attesting to controls of the prescription data.
    - The covered entity is responsible for compliance with the program, if there is an issue with the internal mechanisms determining eligibility, it is the covered entity's compliance issue.
2. Procedures for and timing of monitoring the OPA database for new or unusual locations
3. Results of, and procedures for performing internal or external audits (Best Practice: at least annually)

Program Compliance and Integrity: Best Practices

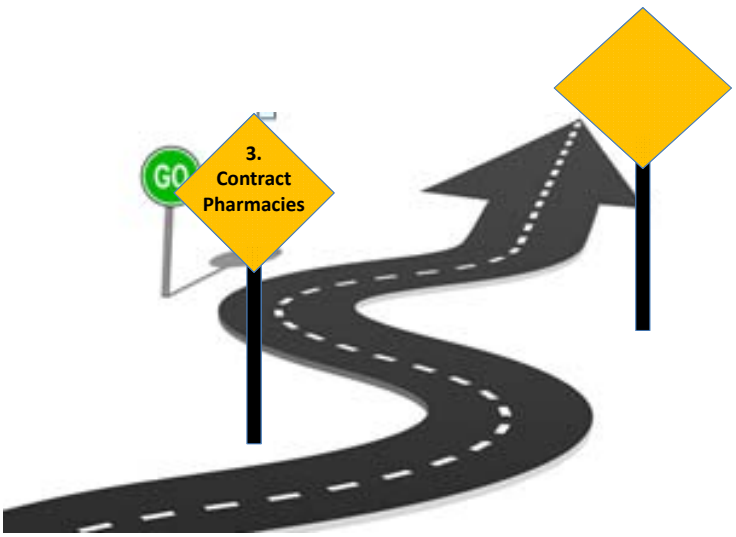
Step 2

Policies and Procedures (Continued)

Additional for Contract Pharmacy Arrangements:

4. Documentation of how sales data is reviewed for reasonableness (Best Practice: monthly)
5. Documentation of how changes in patients, prescribers and scope of services is communicated to the contract pharmacy
6. How fees and remediation costs are monitored and tracked in order to preserve the intent of the Program (see later slides)

Contract Pharmacies: Management and Measuring Success



Contract Pharmacies: Management and Measuring Success

A couple of small reminders!

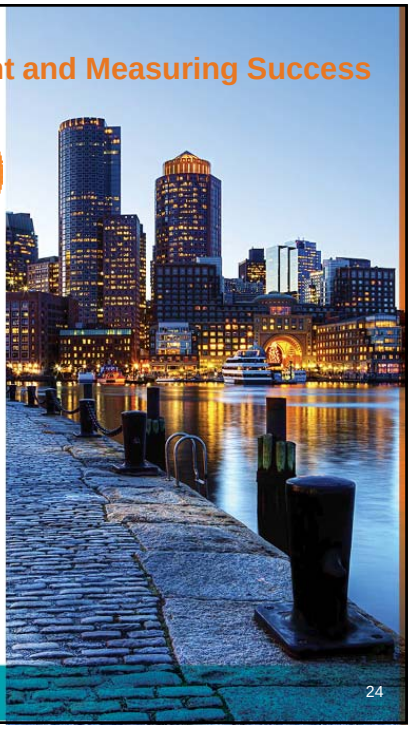
1. The covered entity is responsible for compliance with the Program
2. The Program is designed to *"to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services".*

Contract Pharmacies: Management and Measuring Success

1. Meet with a representative of your contract pharmacy and understand:

Step 3

- How is eligibility determined?
- How is data flowing between you and the contract pharmacy?
- How soon is data updated on the contract pharmacy side after changes or updates are made by you?
- Understand the process of processing claims
- How is it determined that the lowest price drug is purchased?
- Understand fees and remediation requirements
- Be sure you have the most up to date contracts for all participating locations
- Understand if Medicaid claims are processed



Contract Pharmacies: Management and Measuring Success

2. **Program Integrity** - Perform monthly or quarterly reviews of the following:

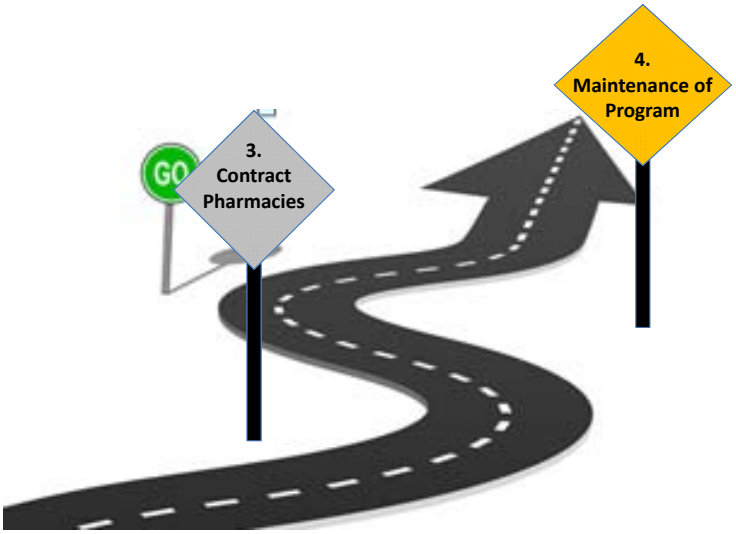
Step 3

- Total gross profit
- Total processing fees
- Total remediation costs
- Total value of all reversed claims (for errors)

Consider:

- Is there an automatic stop on processing claims where the fee is higher than the potential revenue? If not, why?
- Are the fees paid typical for the industry? Are the fees high enough to threaten the integrity of the Program?
- Renegotiate contracts where necessary. The covered entity isn't the only one profiting!

Maintenance of the Program



Maintenance of the Program

Step 4

With proper policies and procedures in place, maintenance of the Program is simplified, but minimum requirements are as follows:

1. Perform frequent self audits, or have an external audit done.
   - Document findings and corrective actions
2. Seek out training to stay up to date with changing requirements and trends.
   - Join the email list for HRSA 340B updates

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Maintenance of the Program

Step 4

3. Document how savings from the 340B program are re-invested back into the covered entity.

Informally:

- Show total net profit of the program and compare to non-funded or under-funded programs run by the covered entity (such as a residency program, or under-funded social program)
- Show profits set aside for future capital expansion and improvements

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Maintenance of the Program

Step 4

3. Document how savings from the 340B program are re-invested back into the covered entity.

Formally:

- Complete a formal worksheet documenting total savings and the distribution of the savings throughout the covered entity.
- Template available if interested!

Slides & CPE!

For access to the slides & CPE, please complete the attendance sheet including your email address and all information will be made available to you.

To receive CPE credit: You must fill out the evaluation form and sign-in & sign-out on the sheet provided

Thank You!

For more information, visit: www.aafcpa.com