This presentation has been designed to discuss compliance needs, proposed changes and best practices for covered entities in the 340B Drug Pricing Program.

This presentation should not be relied upon as legal advice.
AGENDA

• 340B Drug Pricing Program Overview
• Compliance Considerations
  ▪ Registration
  ▪ Recertification
  ▪ Diversion
  ▪ Duplicate Discounts
  ▪ Contract Pharmacy Arrangements
• Independent Audit Expectation
• HRSA Site Visits and 340B Audits
• Mega Guidance
• Success Stories
• Questions
OVERVIEW OF BKD FQHC EXPERTISE

• Operate in 15 states with 35 offices
• 12th Largest CPA firm in the country

- Audit / Tax
- Reimbursement Strategies
- 340B Agreed Upon Procedures Engagements & Consulting
- Medicaid PPS
- Fee Schedule Development
- Financial & Grants Management Consulting
- Cost Reporting
- Coding & Billing
- Operations Management
- Strategic Positioning
340B PROGRAM OVERVIEW

• Federally mandated drug pricing program
• Part of Public Health Service Act, section 340B & Medicaid rebate program
  ▪ Drug manufacturers must provide front-end discounts on covered outpatient drugs purchased by covered entities
• Provides discounts on outpatient drugs purchased by “safety net” providers for eligible patients
  ▪ Intended to provide financial relief to facilities that provide care to medically underserved
• Average savings of 25 - 50% for eligible covered entities on outpatient drugs
• Purpose of savings

Provide discounts on drugs to patients
Expand services by provider to patients
Provide services to more patients
THE EVOLUTION OF 340B

1992
340B was started with the Public Health Services Act

1994
Audit guidelines established. Patient definition clarified. Contract pharmacy process established.

1996
Guidance on outpatient clinics released by HRSA

2000
HRSA guidance on contract pharmacies allowing multiple relationships. ACA expands eligibility to include 5 new entities

2010
Medicaid duplicate discount prohibition Carve-in/Carve-out

2011
Orphan drug exclusion

2012
HRSA begins audits and Recertification process established

2013
GPO prohibition guidance HRSA issues final rule on orphan drug exclusion

2014
Federal judge invalidates HRSA’s orphan drug regulation

2015
On August 28, 2015, HRSA released 340B Omnibus Guidance (Mega Guidance)

Future
- Compliance
- Independent Audits – Quarterly
- Auditable Records
340B PROGRAM COMPLIANCE

- Eligibility
- Diversion
- Registration
- Duplicate Discounts
- Contract Pharmacy
- Orphan Drugs
- Group Purchasing Organization
**COMPLIANCE - ELIGIBILITY**

- Federally Qualified Health Centers
- Ryan White HIV / Aids Program Grantees
- Hospitals
  - Disproportionate Share Hospitals
  - Critical Access Hospitals
  - Children’s Hospitals
  - Rural Referral Centers
  - Sole Community Hospitals
  - Free Standing Cancer
- Specialized Clinics
  - Black Lung Clinic
  - Comprehensive Hemophilia Diagnostic Treatment Centers
  - Title X Family Planning Clinics
  - Sexually Transmitted Disease Clinics
  - Sole Community Hospitals
  - Tuberculosis Clinics
COMPLIANCE – REGISTRATION

• Registration
  – Covered entity must register with HRSA
  – Each eligible entity location that plans to use 340B drugs (clinic or offsite outpatient department) must be separately registered
  – Information should be collected by the authorizing official during the annual recertification process
Recertification process for all covered entity types is required annually or covered entity will be removed from the Program.

Authorizing official must attest to seven statements.
COMPLIANCE – RECERTIFICATION PROCESS

1. **All** information listed on the 340B Program database for the covered entity is complete, accurate & correct;
2. The covered entity meets **all** 340B Program eligibility requirements;
3. The covered entity is complying with **all** requirements & restrictions of Section 340B of the Public Health Service Act and any accompanying regulations including, but not limited to, the prohibition against duplicate discounts and diversion;
4. The covered entity maintains **auditable records** pertaining to compliance with the requirements above;
5. If the covered entity uses **contract pharmacy services**, the that contract pharmacy arrangement will be performed in accordance with the OPA requirements and guidelines;
6. The covered entity acknowledges its responsibility to contact OPA as soon as possible if there is any change in 340B eligibility and/or breach by the covered entity of any of the foregoing;

7. The covered entity acknowledges that if there is a breach of the requirements described in paragraph (3) that the covered entity may be liable to the manufacturer of the covered outpatient drug that is subject of the violation, and, depending on the circumstances, may be subject to removal from the list of eligible 340B entities.

IS YOUR AUTHORIZING OFFICIAL READY TO ATTEST TO THESE 7 QUESTIONS?
Diversion

- Drugs can only be used on an outpatient basis for covered entity’s patients as defined by HRSA
- Use for other individuals constitutes prohibited diversion
- Focus on defining “patient” & “covered entity”

What is “covered entity”?  

- Where services are provided
- Physicians must be employed or under a contractual or other arrangement
- Entity should have a listing of approved 340B physicians
COMPLIANCE – DUPLICATE DISCOUNTS

• Duplicate discounts
  – 340B laws prohibit application of both 340B price discount (front end) and payment of pharmacy rebate to state Medicaid (back end) on same drug claim
  – General options for covered entities
    • Carve-out Medicaid - from 340B drug purchases
    • Carve-in Medicaid - requires verifying Medicaid exclusion file is accurate
  – Medicaid managed care
COMPLIANCE – DUPLICATE DISCOUNTS

• Medicaid duplicate discount
  – Some states have been slow to establish and communicate Medicaid billing requirements and potential modifiers
  – Transition to Medicaid managed care has created confusion
  – Contract pharmacies should not “Carve-in” unless arrangement with state Medicaid exists
  – Recommendation – Engage in ongoing dialogue with Medicaid pharmacy directors of the states where you file claims—a “win-win” solution may be available

THE RESPONSIBILITY FOR AVOIDING DUPLICATE DISCOUNTS IS ON THE COVERED ENTITY!!
CONSIDERATIONS FOR HOSPITALS

• Prescription has to come from reimbursable part of hospital included on the Medicare cost report

• Freestanding clinics prescriptions cannot be included in 340B program

• DSH Hospital Only:
  – Gets complicated when carving out MCD because you have to have inventory @ WAC and replenish at 340B
COMPLIANCE – CONTRACT PHARMACY

• Contract Pharmacy
  – HRSA allows providers to enter into arrangements with multiple contract pharmacies to dispense 340B drugs to qualifying patients of providers
  – Covered entity is responsible for compliance & must monitor contract pharmacies
  – HRSA recommends independent audits
COMPLIANCE – CONTRACT PHARMACY

• OIG on Contract Pharmacy Arrangements in the 340B Program
  – February 2014 – Memorandum Report:
    Contract Pharmacy Arrangements in 340B Program, OEI-05-013-00431
  – Report stated that it “creates complications” in preventing diversion &
    duplicate discounts
  – Report noted that some covered entities do not
    1. Offer 340B discounts to uninsured patients at their
      contracted pharmacies
      1. What is the requirement?
    2. Provide sufficient oversight of contract pharmacies
    3. Many do not engage outside independent auditors to review them
COMPLIANCE - CONTRACT PHARMACY

• HRSA defines a contract pharmacy as a pharmacy that is not covered by the covered entity or child site.

• Under contract pharmacy arrangements, both Medicaid FFS and Medicaid MCO dispensations will be excluded from the 340B Drug Program unless a well-documented plan from the covered entity, managed care company and state Medicaid agency clearly states how duplicate discounts will be mitigated. The plan must be submitted to and approved by HRSA.
INDEPENDENT AUDIT EXPECTATION

• Mega Guidance emphasizes the continued importance and expectation of an annual independent audit being performed.
• HRSA is proposing standards for audits and quarterly reviews of contract pharmacy arrangements to ensure that compliance efforts result in
  – Early identification of problems
  – Implementation of corrections
  – Corrective action plans
  – Prevention of future compliance issues
• Maintain auditable data for a period of not less than 5 years
INDEPENDENT AUDITS – HRSA’S VIEW

HRSA believes that covered entities that do not regularly review and audit contract pharmacy operations are at increased risk for compliance issues.

Annual audit of each location will provide covered entities with a regular opportunity to review and reconcile 340B patient eligibility information.

Covered entity should compare 340B prescribing records with contract pharmacy’s dispensing records at least on a quarterly basis to prevent diversion.

Conducting these audits using an independent auditor will ensure the pharmacy is following all 340B program requirements and provide the covered entity with ability to timely report any violations if applicable.

- Regular opportunity to review and reconcile 340B patient eligibility information
- Prevent diversion

- Diversion
- Duplicate discounts
INDEPENDENT AUDIT – AGREED UPON PROCEDURES

- We will compare eligible 340B locations as listed on the HRSA Office of Pharmacy Affairs database to a listing of sites utilizing Covered Entity’s 340B program provided by the Health Center and note whether there are any differences. We will also agree each 340B site to a listing of sites within scope of the HRSA Notice of Grant Award.

- We will obtain lists of patients receiving 340B eligible drugs during the period from January 1, 20xx to December 31, 20xx. We will select 75 patients from the lists and agree them to the medical record at the Health Center.

- We will obtain the medical records of the patients selected in item #2 and agree the services that were provided to the patient to the scope of eligible services for which funding was awarded to the Health Center.
INDEPENDENT AUDIT – AGREED UPON PROCEDURES

• From the patient's medical records viewed in item #3 above, we will compare the prescribing physician to the list of eligible employed or contracted providers determined by the Health Center's policies and procedures related to the 340B Drug Pricing Program.

• We will obtain a listing of all contract pharmacy locations for the Health Center and agree the location of each contract pharmacy to the approved location list maintained on the HRSA Office of Pharmacy Affairs website.

• We will obtain the Health Center’s financial class records for the patients selected in item #2 to determine if the patient accounts were billed to Medicaid or Medicaid Managed Care organizations.

• If Medicaid or Medicaid Managed Care was billed in item #6, we will compare the amount billed for pharmacy claims to instructions received from Medicaid for proper treatment for avoidance of a duplicate discount.
INDEPENDENT AUDIT – AGREED UPON PROCEDURES

• We will obtain the Health Center’s policy and procedures documentation for the 340B Drug Pricing Program and compare the medical records of the patients selected in item #2 to the definition of covered patients eligible for participation in the 340B program as outlined in the Health Center’s policy and procedures documentation and report patients that do not meet the stated eligibility criteria.

• We will clerically test four monthly reconciliation reports for amounts owed to the Health Center and amounts owed to the Contract Pharmacy.

• We will agree the reimbursement received for the patients selected in Item #2 (contract arrangement patients only) to remittance advices and cash receipts listings and agree this total to the amount remitted to the Health Center from the Contract Pharmacy.
INDEPENDENT AUDIT – AGREED UPON PROCEDURES

• We will select 20 individual drugs from a detailed listing of replenishments, and report items that are included in the detail in excess of quantities included in dispensing reports.
COMPLIANCE – CONSEQUENCES OF NOT COMPLYING

- Repayment of discount to manufacturer
- Removable from 340B Program
- Possible Civil Monetary Penalties for knowing & intentional violations
- Potentially false claim liability (ripe for qui tam actions?)
COMPLIANCE – HRSA AUDITS 2015 AND BEYOND

2015 audits
- 86 now publicly available & final
- 46 have public letters to manufacturers
- 23 had no adverse findings

- Audits initially had a collaborative/educational tone but the tone has changed when HRSA began instituting punitive penalties to ensure compliance
- $6 million in new funding for program integrity efforts approved as part of the 2014 Omnibus spending bill
- OPA expects to perform twice as many audits in FY 2015 as it did in FY 2014
- HRSA will continue to focus on contract pharmacy arrangements, diversion, duplicate discounts and 340B database records

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COMPLIANCE – HRSA AUDITS 2015 AND BEYOND

2016 audits

- 152 now publicly available & final
- 83 have public letters to manufacturers
- 57 had no adverse findings

- Audits initially had a collaborative/educational tone but the tone has changed when HRSA began instituting punitive penalties to ensure compliance
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Why is contract pharmacy oversight non-compliance so low?
HRSA SITE VISIT PREPARATION

• Be prepared to share your organization’s 340B policies, procedures, and other related documents in order to document they address the following

A. Patient Definition

• Individuals provided access to 340B drugs purchased by the covered entity have an established relationship with the patient as documented by the covered entities maintaining records of that individuals healthcare.

• Individuals provided access to 340B drugs purchased by the covered entity have received healthcare services from a healthcare professional who is either employed by the covered entity or under contractual or other arrangements (e.g., referral for consultation) such that responsibility for care provided remains with the covered entity; i.e., 340B prescriptions are only made available that receive services that are either provided directly by the covered entity/or through formal written referral arrangements.

• 340B drugs purchased/dispensed by the covered entity to such individuals are consistent with the service or range of services for which grant funding was approved.
B. **Duplicate Discount**
   - The covered entity has the ability to prevent duplicate discounts for patients covered under Medicaid and who receive a 340B drug

C. **Contract Pharmacy**
If the covered entity dispenses 340B drugs to patients through a contract pharmacy services model the covered entity should be prepared to provide the following
   - The written contract between the covered entity and the contract pharmacy
   - Policies, procedures, and/or other documents as to how the contract pharmacy will prevent diversion
   - Policies, procedures and/or other documents as to how the contract pharmacy will prevent duplicate discounts
   - How the covered entity provides oversight (e.g., annual audit or other mechanism) of the 340B drugs dispensed by the contract pharmacy
MEGA GUIDANCE - TIMELINE

- August 28, 2015 – Proposed guidance released by HRSA
- October 27, 2015 – Comments on proposed guidance were due
  - 1000+ comments submitted
  - Mega Guidance is proposed guidance & not formal regulation. HRSA does not have formal rule-making authority; however, HRSA can issue interpretation & guidance. Guidance is currently proposed & may never be final interpretation
- September 2016 – Final guidance is expected to be published
- January 2017 – Mega Guidance withdrawn by new administration – Future is uncertain....
- Covered entities should challenge current process and be preparing for impact if/when final guidance is finalized
• Current – 3 prong test
  ▪ The covered entity must have an established relationship with the individual, maintaining records of the individual’s healthcare
  ▪ The individual must receive healthcare services from providers who either are employed by the covered entity or maintain contractual or other arrangements (e.g., referral for consultation) such that the covered entity is responsible for the care provided
  ▪ The healthcare services that the individual receives from the covered entity are consistent with the services for which the entity has received grant funding or federally qualified health center look-alike status. Disproportionate share hospitals are exempt from this requirement
MEGA GUIDANCE – PATIENT DEFINITION

• Proposed – 6 prong test
  ▪ Services must be provided at a facility that is both registered for the 340B program and listed on the public 340B database.
    • Ensuring child sites are registered will be a critical compliance element
  ▪ The individual’s healthcare is consistent with the scope of the federal grant, project, designation, or contract.
  ▪ The covered entity has access to the individual’s patient records, which show that the covered entity is responsible for care.
  ▪ Services must come from a provider who is either employed by a covered entity or is an independent contractor for the covered entity, which may bill for services on behalf of the provider.
    • Referral prescriptions will only be 340B eligible if eligible provider has written prescription
  ▪ The drug that the individual receives must be ordered or prescribed by the covered entity provider as a result of the service already described.
  ▪ The drug is ordered or prescribed based on a healthcare service classified as outpatient.
    • Historically a patient who was in ER or observation and later admitted as an inpatient was eligible for 340B drugs up to time of admission
    • Prescription must be written or ordered while patient is classified as outpatient based on payer billing rules
MEGA GUIDANCE – INPATIENT DISCHARGE PRESCRIPTIONS

• Discharge prescriptions from an inpatient stay will no longer be considered 340B eligible dispensations.
• Only drugs billed as part of an outpatient visit will be 340B eligible.
• These discharge prescriptions are often filled under meds-to-beds program or subsequently through contract pharmacy relationships.
• Common for patients who cannot afford their medications to receive it via a charity care process at discharge.
• CMS has recognized the importance of medication adherence and teaching at discharge and include it as part of Core Measures of Success.
• HRSA Audit Findings
  - Prohibiting 340B for certain inpatient discharge prescriptions.
• An individual would not be considered a patient of a covered entity whose only relationship to individual is dispensing or infusion of a drug
• Dispensing of or infusion of a drug alone, without a covered entity provider-to-patient encounter, does not qualify an individual as a 340B-eligible patient
• If covered entity has an infusion center that services patients that do not have written orders from qualified locations, then the impact of the proposed guidance will have an impact on 340B savings
Covered entities are now able to make a determination for both Medicaid Fee for Service & Medicaid Managed Care Organizations when determining to carve in or carve out Medicaid.

Prevention of duplicate discounts remains requirement of covered entity.

Under contract pharmacy arrangements both Medicaid FFS and Medicaid MCO dispensations will be excluded from 340B Drug Pricing Program.

Covered entities should have mechanisms in place to identify Medicaid MCO patients.

Urges covered entities, state Medicaid programs and Medicaid MCOs to work together on a process to identify 340B claims.

Alternate mechanisms to supplement the 340B Medicaid Exclusion File.

Critical for covered entity to maintain dialogue with state Medicaid agencies to prevent duplicate discounts.
SUCCESS STORIES

• $300,000 please
  - Setting up 340B program & refining with 340B Administrator

• $1,200,000 please
  - Understanding 340B Program & refining practices to increase revenues

• $1,200,000 fine & $2,000,000 profits?
  - Bringing a covered entity into compliance
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QUESTIONS?
THANK YOU!
FOR MORE INFORMATION

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