

340B Drug Pricing Program Proposed Mega-Guidance Review Compliance Update

Region 1 HFMA
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Jeff Norman
Southwest Consulting
Associates

Verrill Dana_{LLP}
Attorneys at Law

Gary Rosenberg
Verrill Dana, LLP



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healthcare financial management association

Discussion Outline

- Background
- Key Changes
- Patient Definition
- Audit & Compliance
- Group Purchasing Organization (GPO) Prohibition
- Duplicate Discount
- 340B Health Survey
- HRSA Audit Statistics
- HRSA Audit – What to Expect
- Issues to Watch
- Closing Remarks
- Questions



Background

- Section 340B of the Public Health Service Act (42 USC 256b)
- Overseen by the U.S. DHHS, Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA)
- Requires drug manufacturers to give substantial discounts on covered *outpatient* drugs to certain providers (“Covered Entities” or “CEs”) that qualify for the 340B Drug Pricing Program based upon the patients served by the entity (i.e. low income/safety net individuals).



Background

- Purpose is to allow a CE to stretch scarce resources to reach more eligible patients and provide more comprehensive services
- Discount available to any outpatient, not limited to low-income patients
- But – there is no restriction on how a CE may use its additional revenue from the discounted drugs
- Savings to a CE typically 20% to 50%
- Government runs program but has no financial stake



Background

- Only covers prescriptions to outpatients
- Covers drugs dispensed in ED, clinics, surgery centers, dialysis, or prescriptions written for an eligible patient of a CE that is filled at the CE's own pharmacy or at a retail pharmacy that has a contract with the CE
- Satellite ("child site") must be included on a reimbursable line of the Medicare cost report



Background

- ACA and other legislative changes greatly expanded the definition of CEs.
- Currently about 20,000 CE sites, about double the number in 2001
- CEs include:
 - FQHCs
 - DSH hospitals >11.75%
 - CAHs
 - SCHs
 - free standing cancer hospitals
 - children's hospitals



Background

- Historically, very little formal guidance provided
 - Federal Register notices, guidance, FAQs, personal letters
- “mega-reg” idea was discarded last year after orphan drug suit confirmed HRSA’s limited statutory authority to promulgate regulations
- Mega-**guidance** published in 8/29/15 Federal Register
 - Comments were due 10/27/15
 - Unclear legal status of “guidance” – not legally binding but agency will enforce, then challenge in court



Key Changes in Guidance

- No 340B for discharge prescriptions resulting from inpatient stays
- No 340B for drugs given to outpatients that are included in a bill for inpatient services even if outpatient at the time drug was dispensed (e.g., 72-hour rule, observation days)
- No 340B for prescriptions written outside the hospital or child sites
 - Infusion orders written outside the hospital
 - Referrals, follow-up care, non-reimbursable hospital clinics, providers treating patients outside the hospital



Key Changes in Guidance

- No 340B for prescriptions written by providers who are not employees or independent contractors unless CE may bill for the service
- No 340B for Medicaid bundled drugs (but could use GPO for these drugs)



Patient Definition

Under this proposed guidance, an individual will be considered a patient of a covered entity, on a **prescription-by-prescription or order-by-order basis**, if **all** of the following conditions are met:

- 1.The individual receives a health care service at a facility or clinic site which is registered for the 340B Program and listed on the public database.
- 2.The individual receives a health care service provided by the covered entity (CE) provider who is either employed by the CE or who is an independent contractor for the CE, such that the CE may bill for services on behalf of the provider.
- 3.An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2) above.



Patient Definition

4. The individual's health care is consistent with the scope of the Federal grant, project, designation, or contract. (Ex. If a child site of an FQHC is limited in its scope of grant to treating pediatric individuals, then only individuals receiving pediatric care meeting the limitations specified in the child site scope of grant would be eligible to receive 340B drugs.)

5. The individual's drug is ordered or prescribed pursuant to a health care service that is classified as outpatient.

6. The individual's patient records are accessible to the CE and demonstrate that the CE is responsible for care.



Patient Definition – Operational Concerns

Operational Concerns:

- Seeing a physician in his/her private practice which is not listed on the public 340B database, even as follow-up care from a stay at a registered site, would not be eligible.
- Inpatients discharged with a prescription will no longer be eligible for 340B drugs.
- An individual receiving care provided by another health care organization that has an affiliation arrangement with the covered entity will not be considered a patient of the CE.
- Simply having privileges/credentials at a CE is not sufficient for 340B Program purposes.
- An individual would not be considered a patient of the CE whose only relationship to the individual is the dispensing or infusing of a drug.



Patient Definition – Operational Concerns

Operational Concerns:

- An individual is considered an eligible patient if his/her health care service is billed as outpatient to the patient's insurance or third party payor.
- Maintain auditable records that document changes in patient status due to insurer determinations - How the service is billed to the payor (payor billing policies vary significantly). How to track retro payer determinations?
- CE employees are not eligible to receive 340B drugs solely by being employees, but by being a patient as defined in this guidance.



Patient Definition - Legal Issues

- Terms and definitions are somewhat unclear and up to interpretation (i.e. may bill for services).
- Complex physicians arrangements need assessing.
- CEs should consider engaging counsel as a key component of the 340B oversight program, and potentially to serve on the compliance committee.



Audit and Compliance

Record Retention:

- Section 340B(a)(5)(C) of the PHSA requires a CE to permit the Secretary and certain manufacturers to audit entity records pertaining to the CE's compliance with 340B Program requirements.
- HHS proposes a record retention standard of not less than 5 years, including child sites and contract pharmacies.
- If HHS, during an audit, finds a pattern of failure to comply, HHS is not precluded from accessing existing records prior to the 5-year period.
- A CE's failure to provide records is grounds for termination from the 340B Program.



Audit and Compliance

Contract Pharmacy Documentation:

- A written contract must exist between the CE and contract pharmacy, and must include all locations of a single pharmacy company the CE plans to use and all child sites that plan to use the contract pharmacies.

Reminder - HRSA Recertification Attestation Language:

- (6) if the covered entity uses contract pharmacy services, you certify that the contract pharmacy arrangement is being performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and that the hospital has utilized an appropriate methodology to ensure compliance (e.g. independent audit, or other mechanism).



Audit and Compliance

Contract Pharmacy Compliance:

- The 2010 contract pharmacy guidance *recommended* annual audits of contract pharmacies; proposed guidance further clarifies the expectations of the recommendation.
- The expectation of an annual audit of each contract pharmacy location by an independent auditor.
- Additionally, a CE should compare its 340B records with contract pharmacy dispensing records at least quarterly to ensure neither diversion nor duplicate discounts have occurred.



Audit and Compliance

Contract Pharmacy Compliance:

- A CE should correct **any instances** of diversion or duplicate discounts found during either the annual audit or quarterly review and report corrective action to HHS.
- “By certifying compliance with all 340B Program requirements, a covered entity attests that it employs effective business practices to ensure and monitor ongoing compliance, including self-audits where appropriate; maintains accurate 340B database information; and notifies HHS in the event the entity is no longer eligible for the 340B Program or has violated any 340B Program requirement, subject to HHS audit.”



Audit and Compliance - Legal Issues

- Contract pharmacy contractual agreement must regularly be updated to detail child site changes.
- Attestations
- Guidance on self-reporting and disclosure – There is no materiality threshold!
- Do hospitals have the infrastructure in place for an effective compliance program that includes hospital compliance committee, internal audit, an external audit firm and legal counsel, if needed?



GPO Prohibition

To be eligible for the 340B program, CEs are subject to the GPO prohibition which states that to be eligible, these hospital covered entities do not “obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.”

A GPO may be used by CE to purchase drugs dispensed to inpatients or to purchase drugs that do not meet the definition of a covered outpatient drug.

Exceptions:

- Drugs used at off-site outpatient facility that are not listed on public 340B database.
- Inpatient whose patient status subsequently changed to outpatient by a 3rd party.
- Situations where the CE cannot access a drug at the 340B price or at wholesale acquisition cost (WAC) to prevent disruptions in patient care (must document).



GPO Prohibition

- GPO compliance is required for program participation.
- GPO violations are fairly common.
- Exclusion from the program is possible for systemic violations.
- Hospitals have 30 days from HRSA's final report to document its case.
- The Notice & Hearing process has been extended to cover GPO prohibition. Hospitals must demonstrate a GPO violation was an isolated error as opposed to systematic violation.



Duplicate Discount

Previously, CEs made the determination to carve-in or carve-out Medicaid FFS patients and notified the state of its decision. Under proposed guidance, Medicaid Managed Care (MCO) are included in the decision matrix:

- The CE may make a different determination regarding carve-in or carve-out status for MCO patients than it does for FFS patients.
- CE can make different decisions by CE site and by MCO.
- CEs should have mechanisms in place to identify MCO patients.
- CEs and States should work together on methods to prevent duplicate discounts.
- The use of Bank identification numbers, Processor Contract Numbers, and National Council for Prescription Drug Program (NCPDP) codes are important to identify MCO patients and 340B claims.
- Billing instructions are beyond the scope of the 340B Program.



Duplicate Discount - Operational Concerns

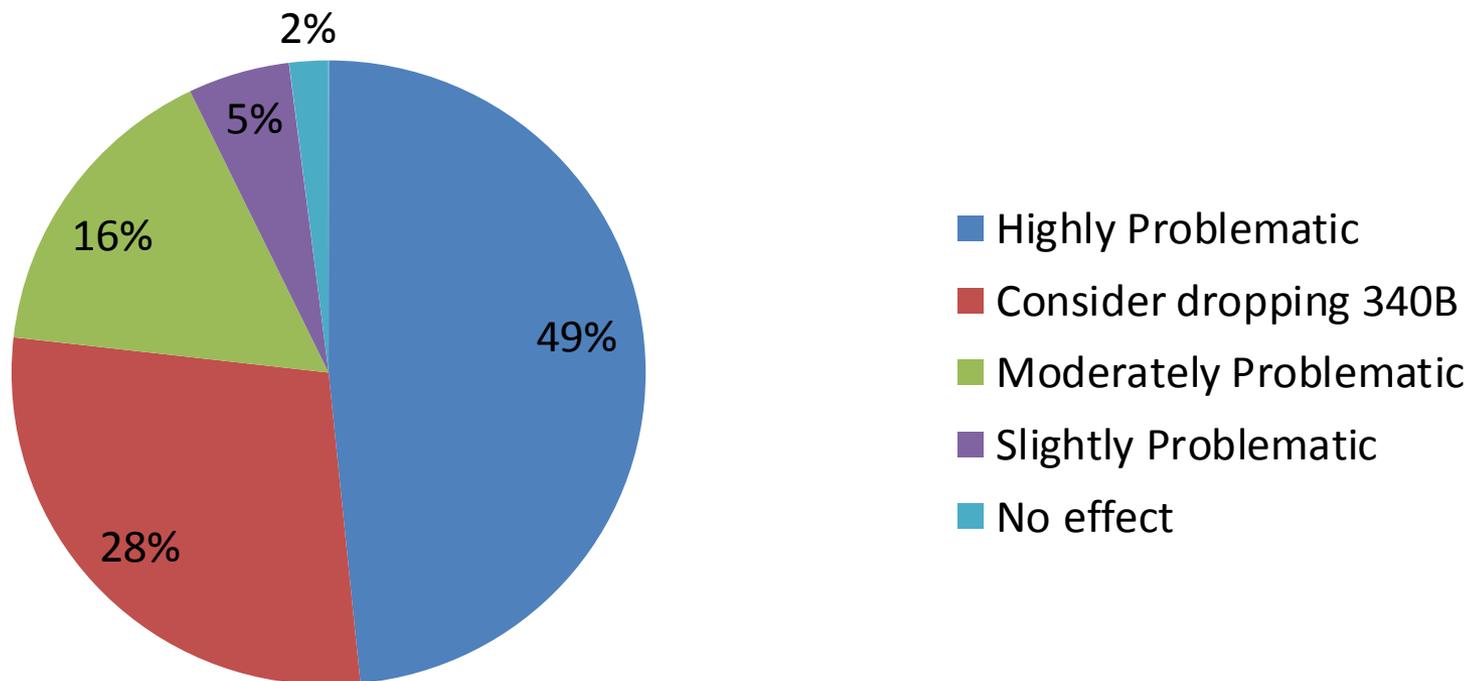
Implications:

- Added complexity of a decision tree and use/non-use of billing codes by states make MCO transitions ripe for duplicate discount violations.
- Understanding each state's billing limitations and your hospital/client risks are critical.



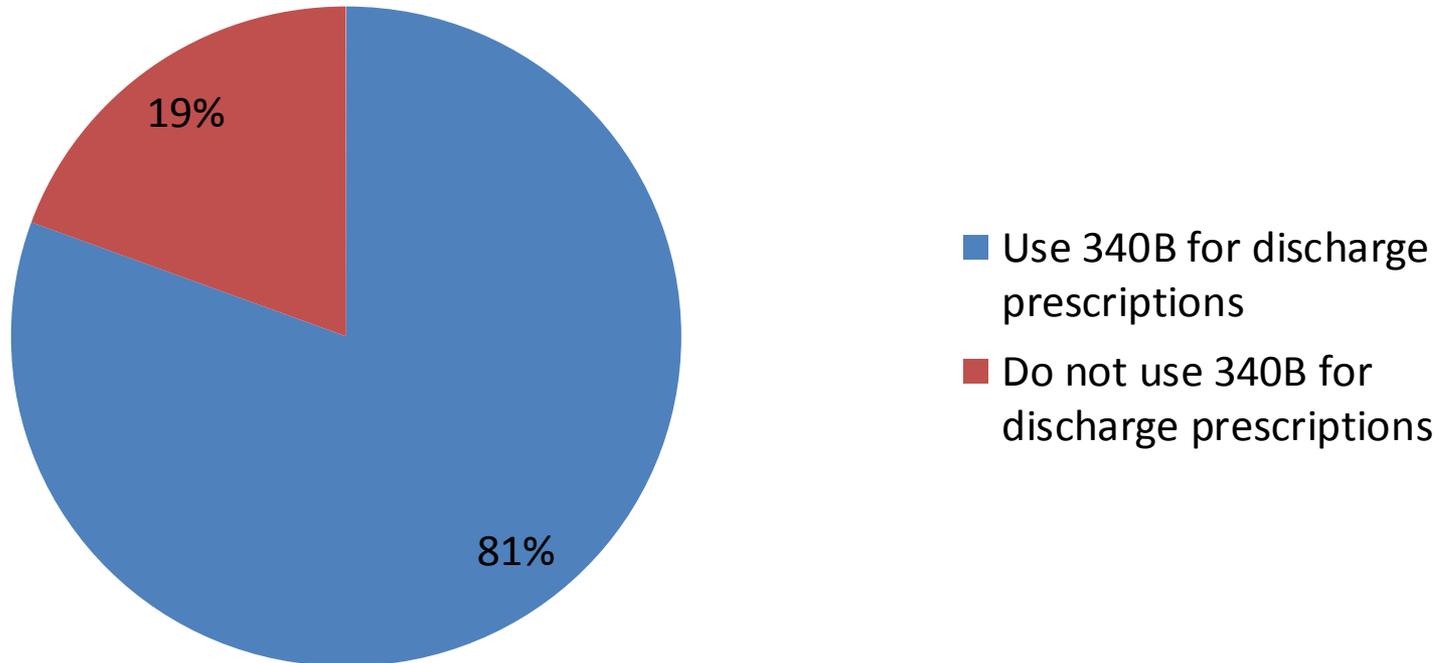
340B Health Survey of Health Members

HRSA's proposed Mega-Guidance would jeopardize over 75% of 340B hospitals



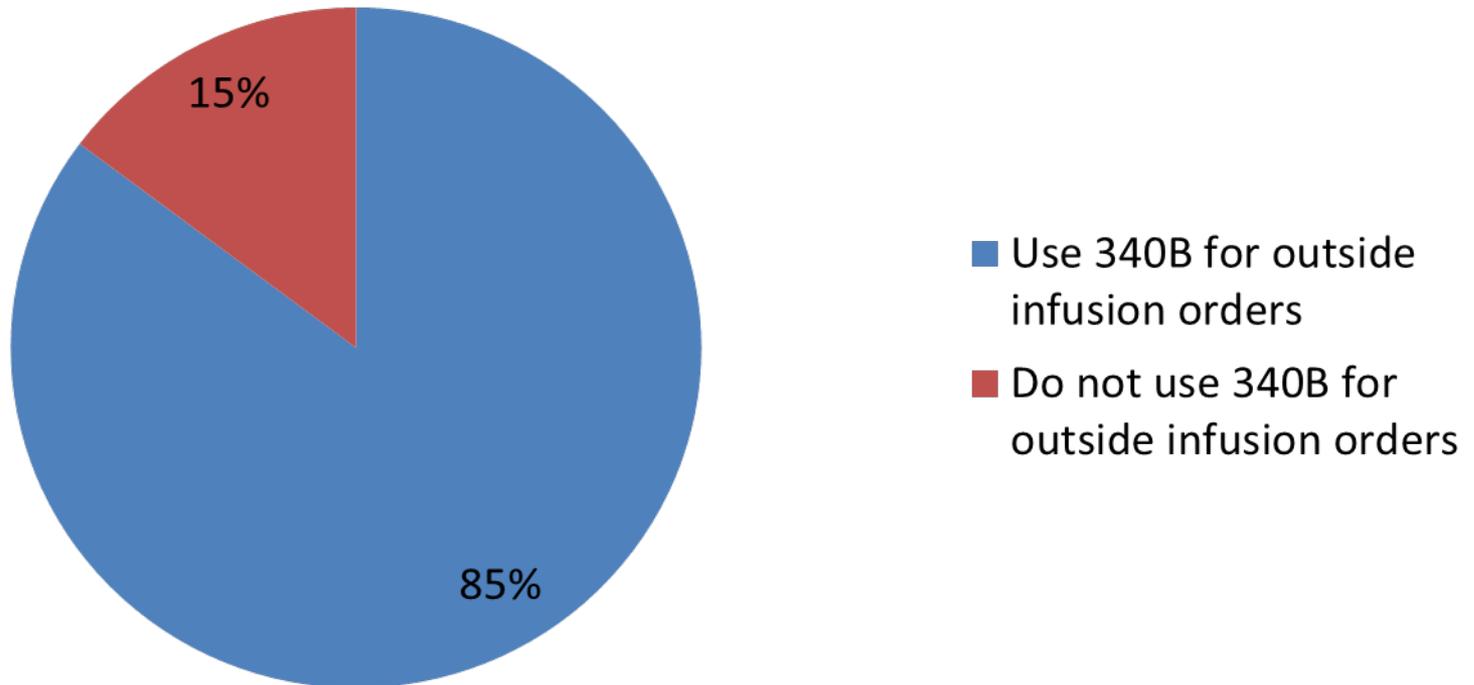
340B Health Survey of Health Members

Removing 340B for discharge prescriptions



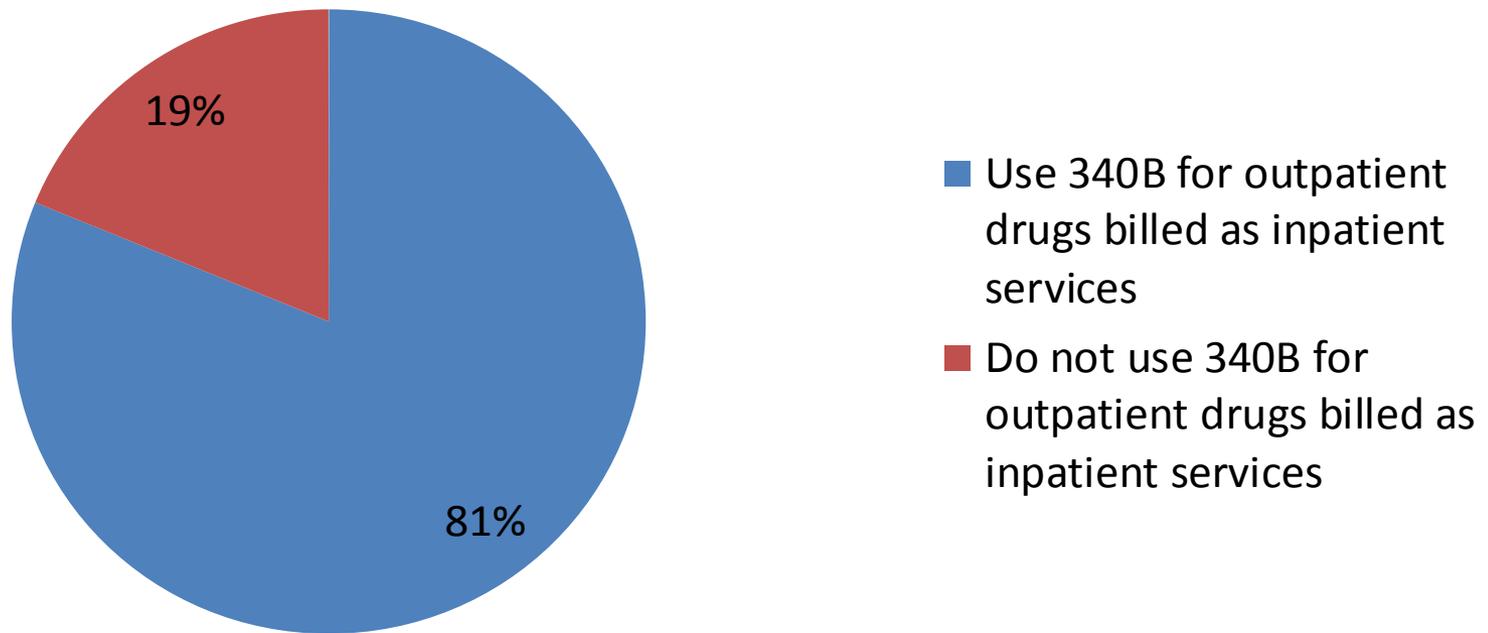
340B Health Survey of Health Members

Most hospitals use 340B for outside infusion orders



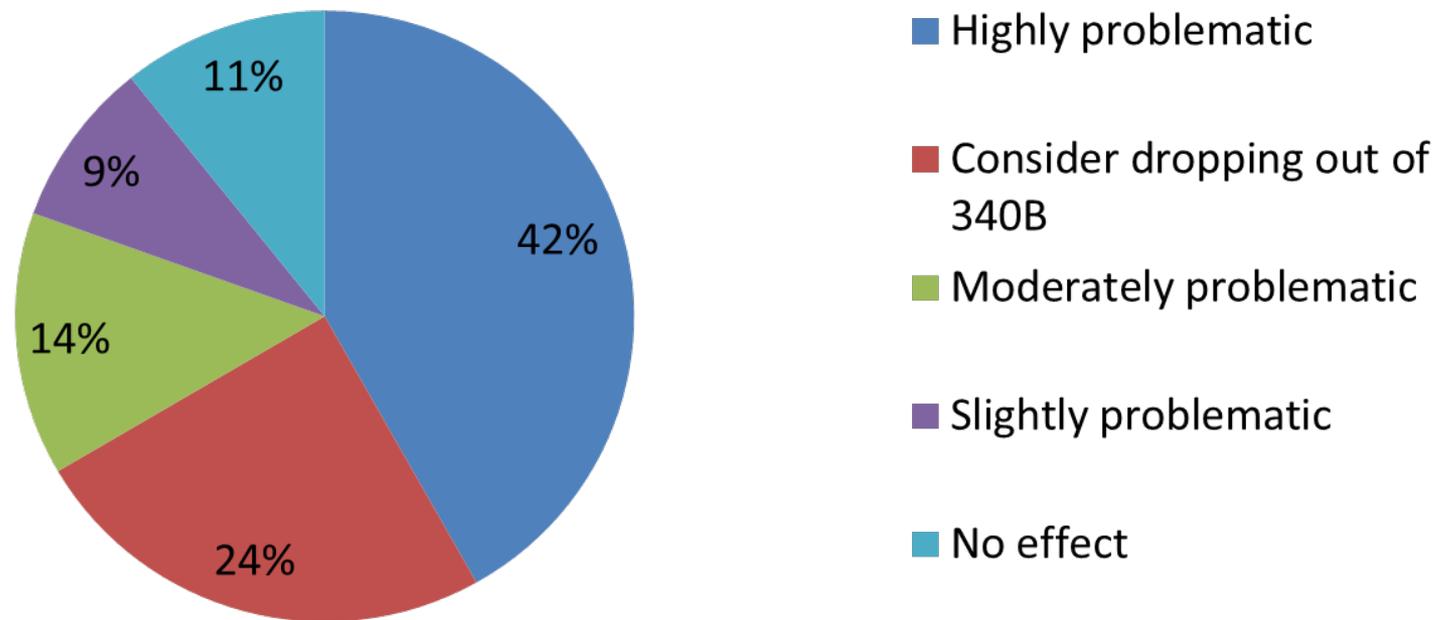
340B Health Survey of Health Members

Most hospitals use 340B for outpatient drugs billed as inpatient services



340B Health Survey of Health Members

Most hospitals would struggle if required to bill for all 340B transactions



340B Audit and Compliance Outline

- HRSA Audit Statistics
- HRSA Audit – What to expect
- Takeaways



HRSA Auditors

- There are roughly 19 HRSA Auditors
- Division of Financial Integrity (CPA/Auditing Background)
- Required to participate in 2 audits each month



HRSA Audit Stats (as of 03/31/2016)

Audit statistics since 2012:

- Over 500 on-site audits conducted
- Over 7,000 outpatient / sub-grantees
- Over 13,000 contract pharmacy locations

HRSA uses a risk stratification methodology so that entities with higher risk factors are more likely to be selected for an audit. Risk factors include:

1. Volume of purchases
2. Number of child sites
3. Number of contract pharmacies



HRSA Audit Stats

(Based on results published through 3/31/2016)

- 2012 51 audits
- 2013 94 audits
- 2014 99 audits
- 2015 190 audits
- 2016 23 audits



HRSA Audit Stats

(Based on FFY 2015/2016 audits published through 3/31/2016)

➤ DSH Hospitals	57%
➤ Critical Access Hospitals	15%
➤ Community Health Centers	13%
➤ Other Centers	10%
➤ Sole Community Hospitals	4%
➤ Children's Hospitals	1%



HRSA Audit Stats

(Based on FFY 2015/2016 audits published through 3/31/2016)

Audits Conducted

- 213 - Audits conducted (where results are published)
- 122 - at Medicare DSH hospitals (57%)

Audit Stats:

- 55 with no findings (26%)
- 140 with findings (74%)
- 82 with multiple findings (45%)



HRSA Audit Stats

(Based on FFY 2015/2016 audits published through 3/31/2016)

- 96 – Database errors (45%)
- 94 – Diversion (44%)
 - ❖ 78 hospitals had 340B drugs dispensed at contract pharmacies for prescriptions written at ineligible sites not supported by responsibility of care (37%).
 - ❖ 8 hospitals had drugs dispensed by ineligible providers
 - ❖ 14 hospitals cited for *inadequate controls* for preventing diversion
- 57 – Duplicate discounts (27%)
 - ❖ 45 hospitals had incorrect NPI number listed on Medicaid Exclusion File (MEF)
 - ❖ 10 hospitals billed Medicaid contrary to information on MEF.
- 17 – *GPO violations* (8%)
- 4 – *Failure to maintain auditable records*



HRSA Audit Stats

(Based on FFY 2015/2016 audits published through 3/31/2016)

Sample of sanctions:

- 120 – Repayment to manufacturer (56%)
- 20 – Contract pharmacies terminated
- 2 – Termination of covered entity
- 3 – Termination of ineligible site



HRSA Audit What to Expect



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HRSA Audits

➤ What to expect

- Engagement letter with data request
- Conference call to review data request and schedule the on-site audit
- Policies and Procedures
- Medicare Cost Report with Trial Balance
- Crosswalk Medicare Cost Report to Child Sites
- Contract Pharmacy Agreements



HRSA Audits

➤ What to expect

- 6 months of data (Hospital & Contract Pharmacy)
 - ❖ Specific data elements
- Pick 25-30 drug administrations from accumulation
- 5 high cost drugs
- Pick 25-30 prescriptions from Contract Pharmacy



HRSA Audits

➤ What to expect

- Medicaid Provider Enrollment Verification Letter
- UB04
- Listings
 - ❖ Provider (exclusive vs. non-exclusive)
 - ❖ All sites that purchase and/or provide 340B drugs, with their physical address
 - ❖ Contract Pharmacies with addresses
 - ❖ All accounts used to purchase drugs
- OPA database review



HRSA Audits

➤ What to expect

- Policy and procedure detailing:
 - ❖ Procurement process in each applicable setting
 - ❖ Inventory process in each applicable setting
 - ❖ Dispensing processes
 - ❖ If not detailing in P&P, need narrative
- Self-audit documentation.



HRSA Audits

➤ What to expect

- Room set-up
 - ❖ Enclosed room that locks (for up to 3 staff)
 - ❖ Internet access (up to 3 computers)
 - ❖ White board
 - ❖ Access to telephone, fax and copier
 - ❖ Computer & projector (we suggest 2)
- Someone to navigate EHR (we suggest 2)
- Parking spaces (likely 2)
- Access to financial and transactional documents as well as patient information related to 340B program.



HRSA Audits

- What to expect (on-site)
 - Opening conference
 - List of prescription samples for review
 - List of providers for proof of relationship at time of drug order
 - Tour of pharmacy (may talk to pharmacy buyer)



HRSA Audits

- What to expect (on-site)
 - Walk through process on white board
 - ❖ Inventory management
 - ❖ Split-billing
 - ❖ Contract Pharmacy
 - Ask questions about policies and procedures
 - ❖ Where in the policy does it identify the time the patient status is determined



HRSA Audits

- What to expect (on-site)
 - Record review
 - ❖ Location of encounter
 - ❖ Outpatient at time of drug administration
 - ❖ Provider
 - ❖ Payor



Other Best Practices

- Participate in industry meetings and training
- Prepare in advance to be audited
- Regularly update and vary self-audit practices
- Have annual external, independent audit conducted
- Ensure your 340B program has appropriate resources



Possible Impact of Section 603 on 340B Hospitals

- Bipartisan Budget Act of 2015
- November 2, 2015
- Continues trend to site-neutral payments
- Items and services after 1/1/2017 in new off-campus departments of a provider generally will not be paid under Medicare OPPS, but instead under other payment systems, e.g., ASC or PFS.



Section 603 Does Not:

- Eliminate provider-based status for on-campus or pre-existing or future off-campus departments
- Prevent a hospital from establishing or acquiring off-campus outpatient departments after 11/2/15
- Apply to services in a dedicated ED
- Apply to CAHs or RHCs
- Apply to departments that were billing under OPPS prior to 11/2/15



Unknowns:

- Waiting for CMS 2017 OPPS regulations
 - Under development on 11/2/15
 - Increase in square footage
 - Exposed existing services
 - Add new services
 - Change types of services
 - Renovate/replace facility
 - Change of Ownership
 - Relocation



Impact on 340B

- Should have no impact on grandfathered facility
- But – can services in non-grandfathered facilities still be included in reimbursable cost center on cost report, thereby eligible for 340B prescriptions?
- Will payment differences for grandfathered and non-grandfathered off-campus facilities be treated differently on cost reporting of costs and charges?



MedPAC Recommendations

- Medicare Payment Advisory Commission
 - Medicare pays ~ \$1.2 billion above 340B drug acquisition costs
- March recommendations to Congress included:
 - Medicare Part B payments to hospitals for 340B drugs be reduced by 10%
 - Savings from payment cut redistributed to hospitals based on uncompensated care on Worksheet S-10
 - OIG 2015 report advocated for shared savings between Medicare and 340B-covered entities





Jeff Norman
National Sales Manager

2805 Dallas Parkway, Suite 620
Plano, TX 75093
(972) 732-8100

jnorman@southwestconsulting.net

www.southwestconsulting.net



Gary Rosenberg
Verrill Dana, LLP

One Boston Place, Suite 1600
Boston, MA 02108
617-274-2846
grosenberg@verrilldana.com

www.verrilldana.com



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