340B: Policy and Administrative Updates

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The Big Picture

- 340B is getting a lot of attention – from the Hill, the Administration, payers, and Rx manufacturers.
- While no significant changes have officially been made under the Trump Administration, there is a lot of talk.
- Even without legislative changes, policies and practices we thought were “set in stone” may now be revisited.
Topics

1. Regulatory Updates
2. Pricing and Reimbursement Updates
3. Operational Updates
4. Reliable T/TA Resources
5. 340B on the Hill
6. Key Take-aways
Regulatory Updates
Status of “Mega-Guidance”

- Assumed dead
  - Never finalized under Obama
  - Trump Administration isn’t moving on it
    - Hard to finalize even if they wanted, due to:
      - Lack of clear authority
      - Requirement to rescind two regs for each new one.

- Likely to be “overtaken by events”
In January, Obama team issued final reg that:

- Makes “penny-pricing” policy official.
- Permits HRSA to impose Civil Monetary Penalties (CMPs) on drug manufacturers who knowingly overcharge 340B providers.
  - Currently no way to:
    - Verify what the ceiling price should be.
    - Make manufacturers comply with pricing rules.
Penny Pricing/CMP reg to go into effect Oct. 1

- Trump Administration delayed effective date twice
  - Asked for fourth round of public comments
  - Currently scheduled to go into effect, as written under Obama, on October 1, 2017.

- Delay will have minimal impact, due to current difficulty confirming ceiling prices.
Reg on Dispute Resolution Process?

- Obama Administration issued a draft regulation on “Administrative Dispute Resolution”
  - A binding process to resolve disputes between providers and manufacturers
  - Draft issued last August, NACHC submitted comments

- No sign of movement; likely overtaken by events.
Pricing and Reimbursement Update
Ceiling Price Database

- HRSA is expected to launch a database with ceiling price info late this summer
  - Required by ACA; about 5 years overdue

- At present, no reliable source of data re: ceiling prices
Changes in Medicaid Reimbursement

• Important changes occurring nationwide re: how Medicaid reimburses for Rx purchased under 340B.
  • Significant financial impact for health centers.
• Your PCA has likely been involved in these state-level policy discussions
Medicaid Payment for Fee-for-Service (FFS) Drugs

- Federal regulations require that for Rx paid under FFS, State Medicaid agencies must pay only:
  - The 340B ceiling price or the Actual Acquisition Cost (if lower), plus
  - A professional dispensing fee.
- Effective 4/1/17, but states have until 6/30/17 to finalize their plans.
Medicaid Payment for Managed Care Drugs

- States are **not required** to keep the 340B savings for drugs dispensed under managed care.
  - Different from FFS policy.

- But **they aren’t prohibited from keeping them** either.
Medicaid Managed Care and 340B

• Different states have different approaches, e.g.,
  • Taking all the savings (340B + sub-ceiling savings)
  • Taking only 340B savings (FQHC keeps sub-ceiling savings)
  • Prohibiting contract pharmacies under 340B
  • Allowing health centers to keep all savings
• This is a key area for educating your state officials.
Third Party Insurance

- A growing number of third-party insurers are reducing payment for Rx purchased under 340B.
  - Includes Medicare Part D plans.
  - Again, FQHCs have no legal protection to stop them – but that doesn’t mean there’s nothing you can do!
Operational Updates
Latest Compliance Alerts

- Pay close attention to contract pharmacies
  - Annual independent audits HIGHLY recommended
  - Check your contracts carefully
  - Remember – YOU are 100% responsible for their compliance.
- If a contract pharmacy closes, be sure to get all your compliance records BEFORE they are sealed.
Good News on 340B Registration!

Health center sites have been receiving much longer windows to register – leading to shorter delays in becoming eligible.
Traditional Registration Timelines*

- New service sites and contract pharmacies can only register on HRSA’s 340B database during four two-week windows each year.
  - The first two weeks of January, April, July, October.

- Applicants became eligible to start participating in 340B on the first day of the following quarter (Jan.1, April 1, July 1, Oct. 1)

* Still applies to all types of providers except FQHCs.
New Registration Windows for FQHC Sites

• Since January 2017, health center sites have had until the 9th day of the third month of each quarter to register and become eligible on the first day of the following quarter.

• The current quarter is an exception, because HRSA needs to take the registration database offline to launch the ceiling price database.
### Anticipated New Registration Timelines

<table>
<thead>
<tr>
<th>To be eligible starting on</th>
<th>Registration must be completed by</th>
<th>New FQHC sites</th>
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<tbody>
<tr>
<td></td>
<td>Old system (still applies to new contract pharmacy sites and non-FQHC providers)</td>
<td></td>
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<tr>
<td>April 1, 2018</td>
<td>Jan. 14, 2018</td>
<td>March 9, 2018</td>
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<tr>
<td>July 1, 2018</td>
<td>April 14, 2018</td>
<td>June 9, 2018</td>
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<tr>
<td>Oct. 1, 2018</td>
<td>July 14, 2018</td>
<td>Sept. 9, 2018</td>
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<tr>
<td>Jan. 1, 2019</td>
<td>Oct. 14, 2018</td>
<td>Dec. 9, 2018</td>
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* Earlier than usual because HRSA needs to shut down the registration system for several weeks to bring the Ceiling Price database on-line.
How to Register during the Extended Window

- Wait until your site is “active” in EHB.

- Contact the 340B call center (Apexus) to request a “one-time registration link.”
Please note!

- Your site must be active in EHB in order to register.
- Relocations of existing pharmacies should now be handled as “changes of address” - not new sites requiring a new registration.
- These extended deadlines apply ONLY to FQHCs – no other covered entities. So HRSA will not announce them broadly.
- As of 6/19/2017, these extended deadlines are “anticipated”, not firm.
What about Contract Pharmacies?

- These extended timeframes apply to new FQHC sites, but *not to new contract pharmacy arrangements*.
- When you register a new site, you may register all contract pharmacies that it will work with at the same time.
- However, these extended timeframes do *not* apply to registrations for brand new contract pharmacy arrangements.
Reliable TA Resources
NACHC’s 340B Manual for Health Centers

- Consolidated resource of all info we could find to help FQHCs navigate the 340B world
  - Contains input from auditors, lawyers, Pharmacy Directors, Apexus, FQHC C-Suite, policy people, etc.
- Available for immediate download
  - Google “NACHC 340B Manual” or click here
  - $249 for NACHC members
Other Reliable TA Resources

A. Apexus
   - HRSA-approved TA provider
   - Now officially collaborating with NACHC
   - 340B University before the CHI will be FQHC-focused

B. Gervean Williams – NACHC’s in-house lead on 340B T/TA
   - gwilliams@nachc.org

C. Sue Veer from Carolina Health Centers
   - Under contract with NACHC to do 340B T/TA
   - Doing state-specific trainings around the country
   - Answering lots of individual questions
340B on the Hill
Attention Keeps Growing

- More and more lawmakers and interest groups are talking about 340B.
- “340B is...
  - a major reason behind rising drug prices.”
  - not benefitting low-income patients.”
  - exploding in size due to contract pharmacies.”
  - killing community-based oncology practices.”
Rumors re: Potential Bills

- No bills addressing 340B have been offered yet this year. However:
  - Rep. Chris Collins (R-upstate NY, biotech investor and entrepreneur) is drafting legislation specific to 340B.
  - Sen. Bill Cassidy (R-LA) is drafting a bill on drug pricing, which may include 340B.
- These bills are expected to focus on hospitals – e.g., which are eligible, how savings must be used.
- NACHC is working hard to ensure FQHCs aren’t “collateral damage.”
President’s FY18 Budget

The President’s proposed budget for FY 2018 states:

“HHS will work with Congress to develop a legislative proposal to improve 340B Program integrity and ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations. This proposal would provide regulatory authority.”
Latest News

- E&C Letter to HRSA
  - Concerns raised include:
    - “the 340B program’s rapid growth without additional and proportional oversight”
    - HRSA’s failure to track how much providers earn from 340B, or how they use the savings
    - Duplicate discounts
    - Diversion (giving a 340B drug to an ineligible patient)
    - Audits -- Not enough are being done; not enough follow-up for those that are done
  - Drug Pricing Related Hearings
What’s NACHC doing?

- Monitoring Hill activity very closely.
- Working in coalition with other 340B providers.
- Educating the Hill and HRSA re:
  - the importance of 340B to health centers
  - “one-size-fits-all” changes to the program will likely hurt us.
- Working with health centers on what they should be doing.
What Should Health Centers Be Doing?

- Ensure that you are complying with all requirements.
  - Pay particular attention to:
    - Contract pharmacies
    - Diversion (giving 340B Rx to non-eligible patients)
    - Duplicate discounts
  - Be able to demonstrate how 340B benefits your patients.
Key Takeaways

1. The mega-guidance is dead.
2. Be prepared for private insurers to try to keep 340B savings.
3. Keep a close eye on your contract pharmacies!
4. Health centers may have longer windows to register new sites for 340B eligibility.
5. There are lots of TA resources to support your 340B program.
6. There’s lots of talk about possible Congressional action on 340B – but nothing definite yet.
7. Be able to demonstrate how 340B benefits your patients.
Questions?

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