Federal Policy Updates
340B & More

Kansas Community Care Network

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What I’ll Discuss

General Federal Policy outlook

- Federal Funding – COVID and base grant
- Medicaid
- Telehealth
- Workforce
- Good Faith Estimates

340B - The elephant in the room
Federal COVID funding

- Expect a high level of after-the-fact Federal oversight, especially on Provider Relief Funding.

- The HRSA Uninsured Claims Fund is highly unlikely to be resuscitated.
  - Replacement doses of monoclonal antibodies are available for uninsured patients.

- The one-time funds that CHCs received under the American Rescue Plan Act (aka H8F or ARPA COVID funding) must be used by the end of March 2023.
  - This funding won’t be replaced.
Here comes another funding cliff

• 70% of each CHC’s base grant from BPHC is financed from “mandatory funding” that Congress approves a few years in advance.
  • The 70% is roughly $4 billion per year.
  • The other 30% comes from “discretionary” funding that Congress approves annually through the base grant.

• CHC’s pre-approved mandatory funding ends next September.
  • Advocacy will be needed to get Congress to renew this funding.
  • Don’t be surprised if it takes Congress until 2024 to fix this.

• CHC base grants haven’t been adjusted for inflation since 2015 – so at least 20% below current costs.
Medicaid:

Every downside has an upside...
Medicaid Enrollment – During and Post PHE

• At the start of the COVID Public Health Emergency (PHE), Congress made a deal with states: “For the duration of the PHE, the Feds will pay a higher share of your Medicaid bills if you don’t drop anyone from coverage.”
  • It has now been 2.5 years since anyone on Medicaid has had their eligibility redetermined.

• Once the PHE ends, states will have 14 months to conduct eligibility redeterminations on all Medicaid enrollees.
  • Many states will seek to do it faster.

When will the COVID PHE end?
Nobody knows for sure, but definitely not until at least mid-January, and likely not until at least mid-April.
Post-PHE Medicaid redeterminations

- Experts predict that **up to 15 million** people will lose Medicaid due to the post-PHE redeterminations – many for administrative reasons.
  - This will lead to more uninsured patients at CHCs – both existing patients who lose Medicaid, and other newly-uninsured patients.

- Two strategies that CHCs can employ now:
  - Encourage your patients to ensure Medicaid has their current contact information.
  - Work with your state to minimize bureaucratic barriers.
Telehealth

• Under current law, COVID-era Medicare telehealth rules will remain in place for 151 days after the PHE ends.
  o This likely means at least through next Sept.
  o These flexibilities include:
    ▪ payment for medical* visits provided to Medicare patients
    ▪ no in-person visit requirements for behavioral health visits.

• We expect Congress to eventually make the payment permanent – but more reports of fraud could complicate matters.

* CMS has already ensured that CHCs will be reimbursed – at the Medicare PPS rate – for behavioral health visits provided via telehealth, on a permanent basis.
Workforce

- CHCs around the US report that workforce issues are one of the biggest challenges they face.

- COVID has exacerbated these challenges by:
  - Contributing to burnout
  - Federal vaccine requirements (not expected to be lifted under this administration)
  - *Rapid increases in compensation.*

- There are no “silver bullets” in the works in DC.
Good Faith Estimates

• “Phase One” rules have officially been in effect since this past January.
  • CHCs report they are extremely burdensome with minimal ROI.

• We are waiting on a revised regulation that may lighten the load on CHCs a little.

• Meanwhile, new rules are currently scheduled to go into effect this coming January – but could be delayed.

We are unaware of any CHCs that have been audited around their GFE compliance.
Three phases of implementation

- There are two deadlines relative to uninsured patients, and eventually there will be a third for insured patients.
- **For now, just focus on Phase One.**

<table>
<thead>
<tr>
<th>Phase</th>
<th>GFEs for:</th>
<th>Requirements on Providers</th>
<th>Effective Date</th>
<th>CMS will start enforcing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ONE</strong></td>
<td>Uninsured &amp; “self-pay” patients</td>
<td>GFE must include charge info for services/items provided by the CHC</td>
<td>Jan. 1, 2022</td>
<td>Jan. 1, 2022</td>
</tr>
<tr>
<td><strong>TWO</strong></td>
<td></td>
<td>GFE must include charge info from outside providers</td>
<td>Jan. 1, 2022</td>
<td>Jan 1, 2023 (note one-year delay)</td>
</tr>
<tr>
<td><strong>THREE</strong></td>
<td>Insured patients</td>
<td>Providers must send GFE info to insurance companies of insured patients</td>
<td>CMS has <strong>postponed</strong> these requirements <strong>indefinitely</strong>, citing technological issues.</td>
<td></td>
</tr>
</tbody>
</table>
GOAL: Make a Good Faith Effort on Good Faith Estimates
While we wait for the revised regulation...

- Public notices re: availability of GFEs
- P&Ps
- Upon request
- Expected charges of $400 or more.
Toolkit on the Good Faith Estimate Requirements

• All of today’s information – and much more – is available in the Good Faith Estimate “Toolkit” at shorturl.at/dzK LW

• The Toolkit is updated regularly as new questions arise and information becomes available.
  – Templates P&Ps are now included.

• It contains FAQs, implementation flowchart, etc.

• shorturl.at/dzKLW
Why Jim Macrae is “very concerned”

• Mandatory funding (70% of our base grant) expires on Sept. 30, 2023

• ARPA COVID funding ends March 31, 2023

• The looming end of the COVID Public Health Emergency – and impact on Medicaid enrollment

• Workforce challenges

• Washington Post article

• 340B
Sometimes, even if I stand in the middle of the room, no one acknowledges me.
340B
Legislatively, the 340B program is not on stable footing.

- HRSA can’t enforce anything unless the statute gives them explicit regulatory authority in that area— and the 340B statute rarely gives them that authority.

- HRSA admitted this – with regards to contract pharmacies -- in recent letter to Congress.
Court cases have – and will continue – to highlight these weaknesses.

• 2014: Lawsuit around orphan drugs and HRSA authority.

• 2018-19: First Genesis lawsuit around contract pharmacy restrictions.

• On-going: Second Genesis CHC lawsuit is around patient definition.
340B

Where Are We Now?
Nationally, 340B savings are larger than 330 base grants

- On an average per-patient basis, 340B savings contribute **16% more** to CHCs’ bottom line than their base 330 grant.
  
  - In comparison, the mandatory funding cliff is 70% of the base 330 grant.
### 340B savings are more vulnerable than 330 base funding

<table>
<thead>
<tr>
<th>330 Base Grants</th>
<th>340B Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject to the actions of one organization: Congress</td>
<td>Subject to the unregulated actions of many organizations, none of whom are publicly accountable. (Ex: drug makers, PBMs)</td>
</tr>
<tr>
<td>we know years in advance when funding will run out.</td>
<td>Major &quot;hits&quot; arrive regularly, with little notice; we never know what's coming next, or when.</td>
</tr>
<tr>
<td>BPHC has creative options to “keep us whole” while Congress works on a long-term fix.</td>
<td>There's no mechanism to make us whole for losses.</td>
</tr>
</tbody>
</table>
Every CHC should ask itself:

• Does our CHC’s focus on compliance and advocacy mirror:
  • this 116% to 70% ratio for 340B savings vs. 330 mandatory grant funding?
  • that 340B savings are even more vulnerable than the 330 mandatory funding?

• Are our CHC’s finance staff adequately focused on 340B?
  • The finance staff are the ones who will need to “pick up the pieces” as 340B savings diminish.
PhRMA’s perspective on 340B

• PhRMA just experienced a major loss in the Inflation Reduction Act (IRA), which:
  • Requires Medicare to negotiate the price of some drugs
  • Requires manufacturers to rebate Medicare if they raise drug prices faster than inflation.

• Given 340B’s size and rapid growth, PhRMA is now turning its full attention to 340B.
  - Two weeks before Congress passed the IRA, PhRMA took out a full-page ad in the Washington Post arguing that 340B benefits big hospitals and chain pharmacies, not patients.
Recent ads in well-read DC news sources

By 2026, #340B is projected to be the largest federal drug program. If critical reforms to transparency, oversight and accountability aren’t prioritized now, vulnerable patients will continue to be left behind. More here: https://bit.ly/3AcNhmf
Every time a PBM pays for a 340B drug, they see it as a loss for their bottom line.

- Because they can’t get the manufacturer rebate on that drug.
- That’s why they engage in two types of pick-pocketing:
  - Direct: Cover the 340B drug, but then take the 340B savings from the CHC.
  - Indirect: Prevent patients from receiving 340B drugs.
Pick-pocketing may be in a lull, but it’s NOT gone.

• As public attention has focused on pick-pocketing over the last 18 months, PBMs have generally become less obvious about their practices.
  o 22 states (including VT) have passed anti-pickpocketing laws.
  o The Federal anti-pickpocketing bill – PROTECT 340B – has 111 House cosponsors.

• Nonetheless, it is clear that PBMs still have their eyes on our 340B savings.
  • Re: state laws, they have fought tooth-and-nail to be allowed to require that 340B drugs be identified (aka: modifier.)
  • The newest pick-pocketing trend: refusing to cover drugs purchased under 340B.
Contract Pharmacy Restrictions

- Eight manufacturers now restrict shipments of 340B-priced drugs to CHCs’ contract pharmacies.

- The additions of Gilead, Merck, and Boehringer-Ingelheim are having significant impacts on CHCs:
  - A 3-month course of a Gilead brand-name Hepatitis C drug yields $60,000 in 340B savings.
  - Merck makes a lot of high-volume drugs for CHCs.
  - Boehringer-Ingelheim became CHCs’ fallback for many diabetes drugs once Eli Lilly and Sanofi blocked shipments. Novo Nordisk is now the only manufacturer of diabetes drugs that has not imposed contract pharmacy restrictions on CHCs.
To provide data to 340B-ESP, or not?

• All manufacturers except Astra-Zeneca will *(theoretically*) resume shipments to contract pharmacies if the CHC submits claims data to 340B-ESP.

• The increasing costs of not providing data are causing many CHCs to reconsider whether to do so.

• Our concerns about providing the data are as – or more – real than ever.
  • *They include legal, logistical, and win-the-battle-lose-the-war concerns.*

• However, the cost of not providing the data are growing.
Toolkit to help CHCs make an informed decision re: 340B-ESP.

• To help CHCs make this difficult decision, there is a new Toolkit on Responding to Contract Pharmacy Restrictions at shorturl.at/aefJ4
  • The Toolkit was prepared by Colleen with extensive help from Tim Mallett, Sue Veer, and many others; it was also reviewed and approved by NACHC.

• The Toolkit includes:
  • General info on restrictions
  • Strategies to mitigate the impact of restrictions
  • Info about providing data to 340B ESP, including legal and logistical issues.

• The Toolkit is a living document, and will be updated regularly. Please send any suggestions or corrections to colleen@fachc.org
Some strategies CHCs are using to cope

1. Increased reliance on in-house – e.g., raising capture rates, building new pharmacies, creative arrangements.
2. Switching patients from restricted Rx to clinically-equivalent ones that are still available.
3. Become a specialty pharmacy (or even your own wholesaler?)
4. Pleading your case directly to the manufacturer, to request an exception.
5. Advocate (including telling HRSA – repeatedly – of your inability to get 340B pricing)
6. If all else fails:
   • Direct the patient to a different CHC with an in-house pharmacy
   • Find creative delivery methods.
The realities of submitting data to 340B ESP

• CHCs (and other 340B providers) who have recently begun submitting data regularly refer to the process as a “nightmare.”
  ○ Maybe the situation will improve with time?

• For example:
  ○ 340B-ESP will tell the manufacturer that you started submitting data. But that info needs to trickle down to your wholesaler, your contract pharmacy, etc. – NOT an automatic or fast process.
  ○ Ensuring this happens requires extensive monitoring and tracking.
  ○ Each manufacturer can set their own rules around replenishment, which drugs to report on, etc – and can change them without your awareness.
### An Example

<table>
<thead>
<tr>
<th>Wholesaler:</th>
<th>Mckesson</th>
<th>ABC</th>
<th>Cardinal</th>
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<tbody>
<tr>
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<tr>
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<tr>
<td><strong>Gilead Harvoni (61958180501)</strong></td>
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<tr>
<td>Accumulations</td>
<td>Yes</td>
<td>Yes</td>
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</tr>
</tbody>
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*Note: The table above represents a sample of information related to different pharmaceuticals and their pricing and accumulation statuses.*
If manufacturers succeed in setting the 340B rules, we should expect...

1. Even more (most?) drug makers restricting CHCs’ contract pharmacy shipments.
   - Legally, it’s clear that there are no immediate downsides to doing so.
   - Drug makers who don’t impose restrictions are at a competitive disadvantage to those who do.

2. Restrictions/ data demands being extending to in-house pharmacies.

3. Efforts to restrict 340B drugs to uninsured patients only.

4. A potential switch to a rebate model. This also hinges on a court ruling.

5. More private insurers refusing to cover 340B drugs.
Congress is the only path forward

• **The Administration** – including the White House – is out of “arrows in its quiver” under the current statute.

• **The Courts:**
  • Best case scenario – the cases drag on, and eventually make their way to the Supreme Court.
  • Worst case scenario – the Appeals Courts decide in favor of drug makers.

• **State laws** – States lack the authority to block all pick-pocketing. Also, PhRMA is betting that they are not enforceable.

• **Manufacturers** – We continue to reach out to them but are not optimistic that this will lead to broad-scale relief.
Ornaments and Christmas Trees

Possible ornaments
• PROTECT 1.0
• PROTECT 2.0 (includes contract pharmacy protections)
• Comprehensive, multi-stakeholder proposal
• 340”C” (aka the ACCESS Act”)

Possible trees
• FY2023 “Omnibus” Appropriations package
• Medicare payment fixes for doctors, etc.
We need to be heard on Capitol Hill

- PhRMA and PBM are all over the Hill – in droves – telling their side of the 340B story.

- We need to be heard as often, and as loudly – and bring the patient perspective to the debate.

- Repetition/ frequency of contacts matters!
We’re in the middle of a messaging war

“No actual patients are being hurt by the restrictions on contract pharmacy.”

“340B spending keeps going up, so how could providers or patients possibly be hurting?”

“The courts are handling 340B issues – Congress shouldn’t get involved.”

“340B savings doesn’t help underserved patients; it just makes providers & chain pharmacies richer.”

“340B exploits communities of color.”

“340B should just be replaced with a discount card for uninsured patients.”

“340B is rampant with fraud and abuse, and it’s up to the drug makers and PBMs to stop it.”
The message can be simple – just three key points

1. 340B savings are essential to the financial sustainability of our CHC.

2. The threats to 340B are severe and getting worse, and patients are being harmed. Give specific examples!

3. Only Congress can fix these issues.
The number of “touches” matters.

• We recommend frequent outreach to your Senators and House members, via as many different voices and points-of-contact as possible.

• There are many ways to “touch” your members.
  • Phone calls to staff and members.
  • Emails and snail-mail letters to staff and members. Template points are in the PROTECT 340B toolkit.
  • Tweets that tag your member at #protect340B.
  • Social media posts
  • Get local media coverage re: the value and threats to 340B.
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