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# KEY TAKE-AWAYS

1. Since the “minibus” spending bill (which has already passed the House and is expected to pass the Senate this afternoon) extends Section 330, NHSC, and THC funding only through December 31, it is effectively a short-term patch. The big battle over long-term funding is expected to come during the lame duck session, when a large bill addressing many health care provisions (e.g., Medicare telehealth coverage, PBM reform) is expected to move. Hopefully the CHC/NHSC/THC increases in the minibus will become the new “floor” for negotiating increases this December. *See pages 3-4.*
2. Claims linking 340B to illegal immigration are escalating and spreading. For example, the [National Review](https://www.nationalreview.com/news/state-of-the-union-ad-to-blame-biden-for-murder-of-laken-riley-call-out-dangers-of-health-care-for-illegal-immigrants/) described the program as a “$340 billion program to provide health care for illegal immigrants”, and similar arguments are being used to pressure the Virginia governor to veto the bill banning contract pharmacy restrictions against CHCs, even though the legislature recently approved it by overwhelming margins. *See page 4.*
3. There’s been extensive activity this week around state 340B bills advanced by PCAs. Unfortunately, Arizona and Idaho’s bills around contract pharmacy restrictions (CPRs) look dead for this session, but Kentucky’s and West Virginia’s CPR bills both passed a full chamber with strong margins. Also, South Dakota enacted a new bill to strengthen its 2019 pick-pocketing bill. *See page 7.*
4. A twelfth manufacturer has announced contract pharmacy restrictions on CHCs – with two new twists. First, the manufacturer has only one drug, and it’s still awaiting FDA approval. Second, to have access to 340B pricing for this drug at even a single contract pharmacy (CP), the CHC must agree to submit data to ESP. As the new product will be considered a “specialty” drug, many CHCs with in-house pharmacies will still need to rely on a CP to access the drug. CHCs must designate their single CP site by March 22 in order to have it effective by April 1. *See page 6.*
5. Two updates regarding Federal 340B legislation:

* Colleen comments on the discussion draft of the Senate 340B reform bill and RFI will be shared early next week, along with several templates that PCAs can adapt for their own use if desired. The two most important points will be:
  + Ensuring access to specialty drugs via multiple, out-of-area contract pharmacies.
  + Ensuring that all CHCs can fill all specialist and discharge all prescriptions for their eligible patients.

Apologies in advance for the length of the full comments, but as with all things 340B, *the devil is in the details*. *See page 5.*

* The ASAP 340B bill is expected to be formally introduced in Congress soon. Vacheria at NACHC shared a high-level overview with PCAs this week. *See page 6.*

1. Once the minibus is passed, Certified Community Behavioral Health Care (CCBHC) services will become an optional Medicaid benefit in all states. *See page 9.*

# CAPITOL HILL UPDATES

### Summary of Section 330, NHSC, and THC-GME funding in House “minibus” bill.

Here is a summary of the additional funding provided to these three programs in the minibus that has been approved by the House and being voted on today by the Senate. For each category of funding, the percentage increase varies based on whether you spread the new funding over 9.7 months (starting March 8, 2024), or 15 months (starting October 1, 2023), as follows:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **New funding provided in House minibus through 12/31/2024** | **Increase when calculated over** | |
|  | **9.7 months** (3/8/24 - 12/31/24) | **15 months**  (10/1/23 - 12/31/24) |
| **Section 330** | $ 3,592,328,767 | 10% | 7% |
| **NHSC** | $ 297,013,699 | 18% | 12% |
| **THC-GME** | $ 164,136,986 | 59% | 39% |

We are attaching a spreadsheet that provides more details on each of these calculations.

### Other health issues addressed included – or excluded – in the minibus.

The minibus:

* Establishes Certified Community Behavioral Health Clinic (CCBHC) services as an optional Medicaid benefit in all states.
* Partially offsets the reduction in Medicare payments to doctors that went into effect in January. (These reductions applied only to doctors paid under the fee schedule, so not to FQHCs.)
* Eliminates (as opposed to further delay) the $8 billion in cuts to DSH hospitals that were enacted under the Affordable Care Act in 2010.
* Requires states to suspect, rather than terminate, coverage for justice-involved Medicaid enrollees.
* Extends funding for Special Diabetes Programs
* Extends some opioid-related programs enacted under the SUPPORT Act.

These policies were paid for in part by striking $2.2 billion from the Medicare Improvement Fund and $5.1 billion from the Medicaid Improvement Fund.

Notably, the minibus does not address PBM reform or hospital site-neutral policies, and nor does it fully reauthorize the Pandemic and All-Hazards Preparedness Act. Reports suggest that the PBM reforms were left out due to a disagreement between House and Senate GOP leaders on extending some provisions into the commercial market.

### This week’s funding bill sets up a major “lame-duck battle” over many health issues, including CHC/ NHSC/ THC funding.

Many stakeholders see this week’s funding bill as simply the first step in a two-step effort to obtain long-term funding increases for Section 330, the National Health Service Corps, and Teaching Health Centers. Observers expect a large health-related bill to pass in December, (during the lame-duck period after the November election and before the new Congress is sworn in), and plan to push for substantial increases then. At a minimum, a lame-duck package will need to address Medicare telehealth, as many COVID-era policies (including payment to FQHCs for medical services provided via telehealth) expire December 31. Supporters of other stalled policy initiatives – such as PCM reform and hospital site neutrality – are also eyeing the lame duck package.

# POLICY & REGULATORY UPDATES

*Policy and regulatory updates are organized alphabetically by topic area.*

## 340B & Pharmaceuticals

### Claims linking 340B to illegal immigration expand and escalate.

Articles and ad linking 340B to illegal immigration continue to spread, following the release two weeks ago of a [30-second TV ad on Fox News](https://www.youtube.com/watch?v=hAIBteXFZ3U) linking 340B to border crossings, money laundering, taxpayer dollars, and assaults on police. This week:

* An [article in the National Review](https://www.nationalreview.com/news/state-of-the-union-ad-to-blame-biden-for-murder-of-laken-riley-call-out-dangers-of-health-care-for-illegal-immigrants/) prominently describe 340B as a “$340 billion program to provide health care for illegal immigrants”, while announcing that the ad described above would be aired during the State of the Union address.
* In Virginia, this argument is being used to try to convince the Governor to veto the bill banning contract pharmacy restrictions against CHCs, which was approved by the state legislature by overwhelming margins. Multiple conservative media outlets are now [reporting that](https://wset.com/amp/newsletter-daily/gov-youngkin-pressured-to-reject-bill-that-may-subsidize-illegal-immigrant-healthcare-governor-richmond-southern-border-money-illegals-migrants-health-hospitals-340b-constitution):

“A major portion of likely Virginia GOP primary voters say they would not support Gov. Glenn Youngkin if he signed a controversial bill that could bolster healthcare benefits for illegal migrants.”

* Mike Pence’s former Communications Director tweeted that “Joe Biden and the Democrats continue to give our taxpayer money to illegal aliens. The 340B program directly funnels money to illegal aliens.”
* An [article in Breitbar](https://www.breitbart.com/2024-election/2024/03/04/poll-gop-voters-extremely-motivated-laken-rileys-murder-subsidized-health-care-illegal-immigrants/)t stated:

“it was exposed recently by [Real Clear Politics](https://twitter.com/philipwegmann/status/1755271664214913387?s=42&t=s5Lt9kahx_TV-WAj0END8w) that healthcare providers in states like New York are now using the 340B program to subsidize “costs of care for [the] undocumented….  Despite polling revealing the unpopularity of the issues, legislatures in both Virginia and Mississippi are considering legislation to strengthen the 340b program in their respective states, thus expanding health care access to illegal immigrants.”

PCAs who encounter these arguments can push back by pointing out that whoever is making these arguments is woefully ill-informed about the 340B program. It is neither taxpayer funded, nor money laundering. Rather, it is paid for by big PhRMA, in exchange for Medicare and Medicaid covering their drugs, and the method of retaining 340B savings was established by Congress in 1993. Given how ill-informed – or intentionally misleading – these people are, why would you trust anything they say?

If necessary, you could add that CHCs are required by Congress to care for all residents of their service area.

### Draft comments on Senate 340B RFI and discussion draft bill coming early next week; two key points to emphasize.

Colleen is finishing up her full comments on the discussion draft of the Senate comprehensive 340B reform bill (called the SUSTAIN 340B bill) and accompanying RFI, which are ***due by Monday April 1***. She will share them early next week for PCAs’ and CHCs’ consideration, along with templates of varying lengths. Colleen thinks the two most important points to emphasize in these comments are:

* ***Ensuring access to specialty drugs via multiple, out-of-area contract pharmacies.*** According to the latest data, over 50% of 340B savings are attributable to specialty drugs. Most PBMs and insurers strictly limit which pharmacies can dispense these drugs, and a single insurer may have 10-12 different specialty drug pharmacies, each limited to a single category of drugs (e.g., Hepatitis C, auto-immune, HIV.) Therefore, *any limits on the number or locations of contract pharmacies are effectively limits on specialty drugs – meaning limits on CHCs’ 340B savings* – and therefore should not be allowed.
* ***Ensuring that CHCs can fill all specialist and discharge all prescriptions for their eligible patients.*** One of the most controversial topics in 340B reform discussions is whether covered entities (CE) should be allowed to use 340B drugs to fill their patients’ specialist and discharge prescriptions (meaning prescriptions written by providers who aren’t associated with the CE.) In the case of CHCs, this includes prescriptions written by specialists, and by hospitals when a patient is discharged from an in-patient stay or ER visit.

The various manufacturers Colleen has spoken with feel strongly that CHCs should not be permitted to use 340B for these prescriptions – particularly the specialist prescriptions – because CHC providers do not bear the medical/ legal liability for them. They also insist that an exception should not be made for CHCs, because once an exception is made, it will open a Pandora’s box.

Colleen’s response is that *CHCs already are an exception, and therefore we merit an exception. Among all CE types, CHCs are the only ones that are required by statute to provide pharmacy services to all their patients, regardless of their ability to pay*. All other CE types have the option to not provide pharmacy services to their low-income patients; CHCs do not. Therefore, we merit an exception.

### ASAP 340B bill expected to be introduced soon/ shortly; general concepts have been shared, while many details remain TBD.

The comprehensive 340B reform bill drafted by ASAP (the NACHC/ PhRMA Coalition) is expected to be officially introduced in Congress in the near future. This week, NACHC staff shared high-level information about the bill’s provisions with PCAs; please contact Vacheria for that information. As with all things 340B, the “devil is in the details”, so as we suggest with many legislative issues, please review the contents of the bill before determining your level of support.

### Another drugmaker imposes contract pharmacy restrictions on CHCs – with two new twists.

Last Friday, a newly-formed drug maker named Liquidia announced 340B contract pharmacy restrictions on all 340B covered entities (CEs) , including CHCs. Compared to previous restrictions, this announcement has two new twists.

* The single drug that it will apply to -- Yutrepia, a new inhaled version of Treprostinil – has ***yet to receive approval from the FDA.***
* CEs who are unable to dispense the drug from an in-house pharmacy may register a single contract pharmacy (CP) site to access Yutrepia. (As it will be a “specialty” drug, many CHCs with in-house pharmacies will not be eligible to dispense it, and therefore will have to rely on a CP site.) However, ***to access even one CP site, the CHC must agree to submit data to ESP.***

While we don’t know when Yutrepia will receive FDA approval and be available for sale, ***Liquidia advises all CEs to designate the single CP site on ESP by March 22***, in order for that selection to be in effect as of April 1.

The addition of Liquidia brings the total number of manufacturers with contract pharmacy restrictions to twelve. [For a detailed list, see Tab 2 of the CHC Resource Spreadsheet.](https://docs.google.com/spreadsheets/d/1DfM-aU42TMaByT5YPOo0DAVWgT6CyIAo67j4FWj9dho/edit?usp=sharing)

### Lots of action on state 340B bills – KY & WV CPR bills approved by full chambers.

This has been a very active week for 340B bills that PCAs are advancing at the state level. Both Kentucky’s and West Virginia’s bills about contract pharmacy restriction (CPRs) were approved by strong margins by a full legislative chamber, while South Dakota strengthened its original 2019 law banning PBM pickpocketing. Here are some specifics:

* Arizona’s bill to ban contract pharmacy restrictions (CPRs) is on life-support, as it must be added to the official legislative agenda by next Wednesday in order to be considered this session, and it’s not there yet.
* **Kentucky**’s bill was approved by the full Senate this morning, 32-5. The PCA is now pushing to have the bill transferred over to the House, and hopefully passed this session.
* Idaho’s bill failed to advance out of a House Committee, after extensive lobbying by manufacturers led to confusion about the program works and its impact.
* Missouri’s bill received its second House hearing on Wednesday.
* Rhode Island introduced a pair of companion bills addressing both contract pharmacy restrictions (CPRs) and pick-pocketing. The original sponsors included 3 Democrats (including the Senate Majority Leader), a Republican, and an Independent.
* **South Dakota’s** governor signed a law that expands on the state’s 2019 pickpocketing law, by adding explicit examples of prohibited PBM activities, and strengthening enforcement authorities.
* Virginia’s bill is facing pushback from conservative groups linking 340B to illegal immigration. While it passed the state legislature with overwhelming margins (340-0 in the Senate, 92-5 in the House), [opponents pressuring the governor to veto it](https://wset.com/amp/newsletter-daily/gov-youngkin-pressured-to-reject-bill-that-may-subsidize-illegal-immigrant-healthcare-governor-richmond-southern-border-money-illegals-migrants-health-hospitals-340b-constitution)
* **West Virginia’s** bill just passed the House this morning, 96-1, and has until tomorrow night to get through the Senate before the legislature adjourns for the session. Fingers crossed.

*For more information on state laws and bills around 340B, see* [*Tabs 3A and 3B here*](https://docs.google.com/spreadsheets/d/1DfM-aU42TMaByT5YPOo0DAVWgT6CyIAo67j4FWj9dho/edit?usp=sharing)*.*

*For resources to help with advancing a state contract pharmacy bill,* [*see here*](https://docs.google.com/document/d/1aI6XbOFCOpgLLjsngNsk8nAnDQPj-TGKnGJaWMvSyzk/edit?usp=sharing)*.*

### ALEC issues a list of 340B “Myths and Facts”

This week, ALEC (the American Legislative Exchange Council, a group of conservative state legislators and private sector representatives) issued a [document regarding three “340B Myths vs. Facts”](https://alec.org/article/myths-vs-facts-340b-drug-discounts-and-price-fixing/). Their three “myths” are:

* 340B discounts go to patients.
* Contract pharmacies are part of the 340B program.
* 340B transactions are documented, monitored, and transparent.

The articles tag line reads “Imposing 340B mandates and regulation at the state level are, at best, misguided, and, at worst, potentially unconstitutional.” And concludes “The 340B program has no method in place to ensure the discounts from the program are helping uninsured or economically disadvantaged patients.” PCAs and CHCs can push back on this argument by citing the statutory and regulatory rules that require CHCs to invest every penny of 340B savings into activities that expand access for underserved populations. (For more on these requirements, see pages 5-6 of the [PCA Toolkit for State Contract Pharmacy Bills](https://docs.google.com/document/d/1aI6XbOFCOpgLLjsngNsk8nAnDQPj-TGKnGJaWMvSyzk/edit?usp=sharing). The ALEC article was also added to the toolkit at page 27.)

## BIDEN ADMINSITRATION

### Health care highlights from the State of the Union speech.

During his hour-plus State of the Union Address last night, President Biden advocated for the following health-related policies:

* Making permanent the enhanced Affordable Care Act subsidies that were established during COVID and expire at the end of 2025.
* Expanding Medicare drug negotiations to 500 drugs over the next decade.
* Expanding the $2,000 cap on drugs and $35 cap on insulin to all type of health care plans. (Currently, they apply only to Medicare.)
* Protecting access to in vitro fertilization and abortion**.**

### New regulation bans religious discrimination in federally-funded social services.

Last Friday, HHS (along with 8 other Federal Departments) issued a final rule banning discrimination based on religion in federally-funded social services. The rule directs religious organizations that receive Federal funding to inform beneficiaries who may use their services that:

* they cannot be discriminated against on the basis of religion or a refusal to hold a religious belief, and
* they cannot be required to attend or participate in any explicitly religious activities offered by the organization, unless they want to.

These organizations are also required to hold their religious activities separate in time or location from the activities supported by direct federal financial assistance. This rule reverses the prior Trump administration’s policy, which stopped requiring religious organizations to tell beneficiaries about their rights and to refer them to alternative providers upon request.

## BPHC

### President’s FY2025 budget will propose expanding CHC hours, behavioral health services, and NAPs; will not mention base increases.

President Biden’s FY2025 budget for HHS and HRSA will be released next week, and while it will advocate for increased funding for Section 330, observers are convinced that it will not propose using these funds for base increases. As in previous years, the budget is expected to propose that new funds be dedicated to:

* Expanding behavioral health services
* Increasing hours of operations
* New Access Points
* Other smaller service expansions (e.g., for cancer screening, HIV).

## EXPANDING ACCESS

Circuit Court appears poised to overturn ACA rule that insurers must cover preventive services; case will likely go to SCOTUS.

A panel of judges in the Fifth Circuit seems likely to affirm the lower court ruling that the ACA requirement that insurers cover preventative care services recommended by the U.S. Preventative Services Task Force (USPSTF) violates the Constitution’s Appointments Clause. The case has implications not only for the USPSTF’s recommendations but also contraceptives and vaccinations recommended by the CDC’s Advisory Committee on Immunization Practices. Regardless of how the Circuit Court rules, the decision is likely to be appealed to the US Supreme Court (SCOTUS) during its 2024-25 term.

## MEDICAID

### CCBHC services are now an optional Medicaid benefit in all states.

As discussed above, the “minibus” that included CHC funding through the end of 2024 and prevented a partial government shutdown on March 9 also contained language making Certified Community Behavioral Health Care (CCBHC) services an optional Medicaid benefit in all states.

## HIT

### Patients and providers continue to reel from cyberattack, and call HHS’ response inadequate.

Three weeks after the cyber-attack on Change Inc. -- the subsidiary of United Health that processes 15 billion claims, prior authorizations, and insurance verifications each year – patients and providers a continuing to reel from the attack. For CHCs and their underserved patients, one of the most direct impacts is that many prescription discount cards still can’t be processed, forcing the drug back to its regular price. Also, the inability to get claims paid in a timely manner is causing major cash flow crunches.

On Tuesday, [CMS offered some relief](https://www.hhs.gov/about/news/2024/03/05/hhs-statement-regarding-the-cyberattack-on-change-healthcare.html), including:

* Encouraging Medicare and Medicaid programs to remove or relax prior authorizations during the outage and to consider giving health care providers advance funding.
* Allowing hospitals – but no other providers – to request advance payments from their Medicare Administrative Contractors (similar to what was done in the early days of COVID.)
* Allowing Medicare providers to submit paper claims, and request exceptions or extensions.

Many national groups railed against CMS’ announcement, calling the list of flexibilities inadequate to fully relieve financial burdens on patients and providers. Both the American Medical Association and the Medical Group Management Association are advocating for advance payments to outpatient providers.

# FUNDING OPPORTUNITY

### $350,000 grants available to help CHCs integrate behavioral health services via telehealth; deadline in 2 weeks (3/22)

HRSA’s Office of Telehealth has released a new [Notice of Funding Opportunity](https://grants.gov/search-results-detail/349061?utm_campaign=OATannouncements20240307&utm_medium=email&utm_source=govdelivery) designed to assists providers “in integrating behavioral health services into primary care settings using telehealth technology through telehealth networks.” HRSA will make roughly 25 awards of up to $350,000 each. The deadline is Friday March 22 (two weeks from now.)

*For info on this and other funding opportunities currently open to CHCs and/or PCAs, see*

*Tab 6 of the* [*CHC Resource Spreadsheet.*](https://docs.google.com/spreadsheets/d/1DfM-aU42TMaByT5YPOo0DAVWgT6CyIAo67j4FWj9dho/edit?usp=sharing)