

Federal Policy & Legislative Updates Resources

Tennessee Primary Care Association

October 8, 2021



Steve Carey
Legislative & Strategy Advisor for PCAs
scarey@potomacstrategic.com
703-395-1241

Colleen Meiman
National Policy Advisor to State & Regional PCAs
colleen@fachc.org
301-906-5958

What We'll Cover

- Capitol Hill Updates
- Federal Vaccine Mandate on Health Care Providers
- 340B
- Other Administration Updates
- Resources for Federal Policy Issues



Capitol Hill Updates





Health Care provisions being considered for reconciliation bill

- Health care provisions be considered for this bill include:
 - Adding dental, hearing, and vision benefits to Medicare
 - Permanently raising the subsidies available for ACA/ Marketplace plans
 - Expanding Medicaid in non-expansion states.
 - Expanding Medicaid coverage for Home and Community-based services.
- The original House leadership proposal for this bill included \$10 billion for CHCs for capital needs, and over \$6 billion for workforce programs.



Drug pricing reform likely to have unintended downsides for CHCs

- These health care provisions are expected to be paid for by reforms to drug pricing policies – up to \$700 Billion worth.
- It goes without saying that CHCs strongly support efforts to make pharmaceuticals more affordable for Americans.
- At the same time, changes to drug pricing policies will have some unintended, negative impacts on safety net providers – such as CHCs – who participate in 340B.



Direct impact – Potential loss of 340B savings on Medicaid managed care drugs

- A proposal that's been circulating for a couple years would prohibit pharmacies from retaining any 340B savings on drugs dispensed to Medicaid managed care patients.
- If enacted, this section would be devastating for CHCs in many states.
 - CBO scored the Section 206 as saving less than \$1 billion over 10 years; the 340B aspect is only a fraction of this.
- Thankfully, this provision wasn't included in the House drug pricing proposal – but we're not out of the woods.

Indirect impacts – e.g., much less penny pricing

- Because of how 340B is structured, changes to standard drug prices will impact 340B prices and reimbursement – and therefore the 340B savings on which CHCs depend.
- Example: Policies that limit price increases on existing drugs to inflation will cause the 340B price of many drugs to skyrocket.
 - *Ex: the 340B price for a standard insulin (e.g., Humalog) would jump from 10 cents to over \$200 per month.*
- Example: Lower prices negotiated by Medicare will lead to:
 - Smaller losses on drugs dispensed to uninsured patients
 - Less savings on drugs dispensed to insured patients.





VERY CAREFUL
MESSAGING needed
here, to avoid being
misperceived as
opposing efforts to
lower drug prices.

Federal Vaccine Mandate on Health Care Providers



... and other COVID
updates

Federal Vaccine Mandate: What We DO Know

- Announced by White House on Thursday 9/9/2021.
- There are a LOT of unanswered questions.
 - We won't have a lot of details until CMS publishes an Interim Final Rule, expected in late October.
- Will apply to all health care providers who get paid by Medicare or Medicaid.
 - Will apply to all staff and volunteers.
- The Administration implied that a testing-only option will not be available for employees who don't want to get vaccinated.
 - While this might change, I wouldn't bet on it.

See the Federal Vaccine Mandate Toolkit – an evolving document with FAQs, info on medical exemptions, templates for H.R. use, etc. - available at ***shorturl.at/zJ0X8***

While the vaccine mandate originally applied only to nursing homes, almost all health care providers will be “in this together” now.

Federal Vaccine Mandate: What We DO NOT Know

- When it will become effective.
- Whether the mandate will apply to:
 - Board Members.
 - Contract employees (e.g., housekeeping staff, construction workers)
 - Staff who work 100% remotely.
- Whether it will apply to provider offices who don't take Medicare or Medicaid (e.g., private dentists.)
- What will be considered an acceptable religious exemption. (This will ultimately be up to each employer to decide)
 - There's a lot more clarity around medical exemptions – both when CHC providers should write them, and when CHC leaders should accept them from their employees.

We have been sharing these and other unanswered questions with CMS and the White House.

A similar approach was successful in rapidly desegregating hospitals in the 1960s.

Other COVID Updates

- After conflicting votes, HHS has now officially endorsed Pfizer booster shots for frontline healthcare workers.
- No word yet on when CHCs will receive the free testing supplies recently promised by the White House.
- CHCs now have until late November to submit report on how they used Provider Relief Funds provided automatically in spring and early summer 2020.
- CHCs can now apply for additional PRF funds – deadline to apply is Tuesday 10/26.



Speaking of Federal COVID funding



- Expect **significant** Federal oversight of how COVID/ ARPA funds are used.
 - The oversight applies to BPHC, as well as CHCs.
- If in doubt, document and save your paper trail!



“whether claims for COVID-19 diagnostic testing and treatment services reimbursed by HHS through HRSA’s COVID-19 Uninsured Program complied with Federal requirements.”

“whether health centers used their HRSA COVID-19 supplemental grant funding in accordance with Federal requirements and grant terms.”

“whether HRSA had an effective process for identifying and monitoring high-risk health centers that received COVID-19 grant funds.”



“whether [Provider Relief Fund] payments were... supported by appropriate and reasonable documentation.”

340B....



Advocacy Works!



The insulin/ epipen regulation has been stopped – thanks to CHC advocates.

No Relief in Sight....

- Unfortunately, there is no sign that the drug makers who are refusing to ship 340B-priced drugs to contract pharmacies will change their policies any time soon.
- PhRMA has tons of lawyers fighting on every point, and in every venue, possible.
- If anything, drug makers are becoming bolder about restricting shipments to contract pharmacies....



HHS is fighting back hard...

HHS clearly supports 340B providers, but is fighting an uphill battle. Its efforts include:

- Sending letters to drug makers demanding that they lift contract pharmacy restrictions by June 1.
 - *After all the drug makers refused to comply, they referred them to OIG, to issue fines.*
- Launching the Administrative Dispute Resolution (ADR) process.
 - *At least one drug maker has been exempted from this process, and its unclear what impact the process will ultimately have.*
- Fighting all the lawsuits that drug makers have launched.



Status of NACHC Lawsuit

- NACHC's lawsuit about the contract pharmacy restrictions is still on the books, but is effectively "on hold" until a decision is reached through the ADR process.
 - *HRSA tried to move the process forward this week – and got hit with another lawsuit....*
 - *Once that decision is reached, it will likely just lead to more lawsuits....*
- All the other 340B provider groups have hit the same roadblock.



So what now?

This stand-off will end in one of two ways:

- Through a definitive court decision
 - *This could take years, and we'd be without contract pharmacies in the meantime), or*
- Congressional action.



In the meantime:

- things could get worse before they get better....
- drug makers are telling everyone in Congress that contract pharmacy restrictions have no negative impact on patients.

Kalderos goes to
court to try to
advance its “rebate”
model



The 340B focus is shifting to Congress

- On contract pharmacy restrictions, HHS is hamstrung by never-ending lawsuits, while drug makers will likely get bolder.
- On pick-pocketing, states can't solve the issue on their own – but Congress can.
- Drug pricing reform may have significant/unintended negative effects on CHCs' 340B savings and overall budgets – even if the reforms never mention 340B!
- And Congress can block the rebate model once and for all.



The **PROTECT 340B** bill of 2021

PROTECT
340B

Many more details tomorrow – but the bottom line is **WE NEED HOUSE CO-SPONSORS** – both to address pick-pocketing & contract pharmacy.

Advocacy Request



Please ask your House Member to cosponsor
the PROTECT 340B Act!

We're working on getting a companion bill introduced in the Senate but
we're not there yet.

We need co-sponsors from Tennessee!

- We do not yet have a single cosponsor from Tennessee on the PROTECT 340B Act.
- Steve Cohen, John Rose, and Tim Burchett should be relatively “low-hanging fruit”, given their past support for 340B providers.
- This is not be a “hard ask”; it’s a complicated issue, but not a complex one.

The fact that Tennessee enacted an extensive state law on this issue – and by wide margins -- should make this a relatively easy “ask” for your Members of Congress.

The PROTECT 340B Advocacy Toolkit

Starts with two one-page summaries of the bill:

- an overview of how 340B savings accrue to CHCs and how pick-pocketing occurs
 - for *education about the underlying issue*. (Has colored boxes.)
- a summary of the provisions of the bill.

The toolkit
is available
at
***shorturl.at
/kml89***

Templates for requesting co-sponsors

- Talking points for verbal requests.
- Two templates for email requests:
 - A brief, generic email template (220 words) that is suitable for advocacy platforms
 - A long email template that can be personalized to the member and provides more details around pickpocketing. Content

Whenever possible, please try to personalize your requests with info that is specific to your CHC, member, and state. There are tools on the CHC Resource Spreadsheet to help.

Tools for personalizing your requests

The talking points and templates both refer to the following tabs on the CHC Resource Spreadsheet:

- Tab 1: For each member of Congress, this spreadsheet indicates if they:
 - Have signed any joint letters supporting 340B providers
 - Sit on the Energy and Commerce Committee (and its Health Subcommittee), to which this bill has been referred, and
 - Have a similar bill passed or under consideration in their state.
- Tab 2: This outlines state-level anti-pickpocketing bill that have been passed, or are under consideration.

The “target points” on the Member spreadsheet are a rough, non-scientific way to help identify “low-hanging fruit” for co-sponsor request. Each member got one point:

- for each letter they signed
- If they are on the E&C Committee

Tab 1 – House Member Data

CHC Reference Spreadsheet (aka "Mega-Spreadsheet")

File Edit View Insert Format Data Tools Add-ons Help

Last edit was 11 hours ago

100% \$ % .0 .00 123 Calibri 12 B I U A

Q361

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	
1	PROTECT 340B Act -- House Member Data								Last updated 10/6/2021		Total Co-Sponsors to date: 46						
2	Representative (highlighted names are cosponsors)		Party	State	Target Points <small>(one for each column checked)</small>	State 340B Law?	Member of Energy & Commerce?		Total letters signed	Signed supportive Congressional letters? <small>(details & links at bottom of spreadsheet)</small>							
Full Committee							Health Sub-committee	#1		#2	#3	#4	#5	#6	#7		
	9/14/2020	2/26/2021						11/13/2020		9/15/2020	9/10/2020	9/3/2020	9/3/2020				
	To HHS	To HHS						To HHS		To HHS	To PhRMA	To HHS	To drug cos.				
	Re: contract pharm, data demands	RE: contract pharm, Kalderos						Re: Kalderos		Re: CHC insulin/epipen reg	Re: contract pharm, data demands	Re: contract pharm	Re: contract pharm, rebates, data				
355	Johnson	Dusty	R	SD	4	Enacted			3	X	X	X					
356	Cohen	Steve	D	TN	5	Enacted			4	X	X	X	X				
357	Rose	John	R	TN	4	Enacted			3	X	X	X					
358	Burchett	Tim	R	TN	3	Enacted			2	X	X						
359	Cooper	Jim	D	TN	2	Enacted			1		X						
360	Fleischmann	Chuck	R	TN	2	Enacted			1		X						
361	Harshbarger	Diana	R	TN	2	Enacted			1		X						
362	Kustoff	David	R	TN	2	Enacted			1		X						
363	DeJarlais	Scott	R	TN	1	Enacted			0								
364	Green	Mark	R	TN	1	Enacted			0								
365	Fletcher	Lizzie	D	TX	5		Yes	Yes	3	X	X	X					

340B - What Can You Do Now?

1. Get your Member of Congress to co-sponsor to PROTECT 340B Act.
2. Be ready to explain how the loss of contract pharmacies would impact your CHC and your patients.
3. Educate your Member of Congress about how the changing environment is harming patients – not only in terms of Rx access, but also other services.
4. ***Be on alert for future advocacy requests.***



Other Administration Updates



Some historic firsts at HHS



Xavier Becerra
HHS Secretary
First Latino and first child
of immigrants to hold this
post.



Dr. Rachel Levine
HHS Assistant Secretary
for Health
First Senate-confirmed
transgender Federal
official in US history._



Chiquita Brooks-LaSure
CMS Administrator
First Black woman to
hold this post.



HRSA Administrator

“Whiplash” on the Regulatory Front

- **Immigration:**

- Most (all?) Trump-era immigration policies have been rescinded, including the public charge rule.



- **LGBTQ+ rights:**

- Trump lifted a ban on discriminating against LGBTQ+ persons in health care.
- Biden reinstated it.

- **Title X:**

- Trump-era rule that prohibited referrals to abortion providers, or any physical or logistical overlap of Title X and abortion services was officially rescinded this week.

- **Diversity, Equity and Inclusion:**

- Pres. Trump banned Federal agencies or contractors from discussing DEI topics/
- Pres. Biden is making health equity a top priority.

Telehealth

- Congress has expressed great interest in making current telehealth flexibilities permanent – but likely won't act until those flexibilities have almost expired.
- Current Medicare flexibilities will last as long as the Federal (not state) Public Health Emergency (PHE) lasts.
 - The Biden Administration has promised that:
 - The PHE will last at least through 12/31/2021
 - they will give the public at least 60 days notice that the PHE is ending.
- There's a lot of hesitancy around audio only.
 - “Experts” have voiced concerns about cost, potential for abuse.



FCC COVID Telehealth Program

To date, the FCC has only awarded one-third of the funding available for “Round Two.”

New Requirement to Provide Good Faith Estimates to Uninsured Patients

- On September 30, HHS released an Interim Final Rule (IFR) implementing parts of the “No Surprises Act” enacted in December 2020.
- This IFR requires health care providers (including CHCs) to provide “self-pay” patients with a Good Faith Estimate (GFE) of their total out-of-pocket cost for specific services within 1 to 3 days of the patient scheduling the care or requesting the GFE.
- The new rules go into effect on Jan. 1, 2022.
- Earlier today, the TN PCA received has a two-page preliminary summary of how the rules impact CHCs and their patients.



Free Resources

for tracking Federal policy information

CHC Resource Spreadsheet (aka mega-spreadsheet)

<https://bit.ly/2Us9yKI>

This is a 'living' document that is regularly updated, with the following tabs:

Tab 1 – PROTECT 340B – Info on House Members

Tab 2 – State-level 340B protection bills.

Tab 3 – Upcoming Deadlines re: Federal resources.

Tab 4-- Federal bills we're tracking

Tab 5- Federal funding opportunities for PCAs, HCCNs, CHCs, and patients

Tab 6 – Federal Telehealth Bills

Tab 7 – Federal COVID funding sources, and the related requirements

Tab 8 – 340B Threats

Tab 9 – Responding to 340B data requests

Current Tab 3 – Deadlines related to Federal Resources

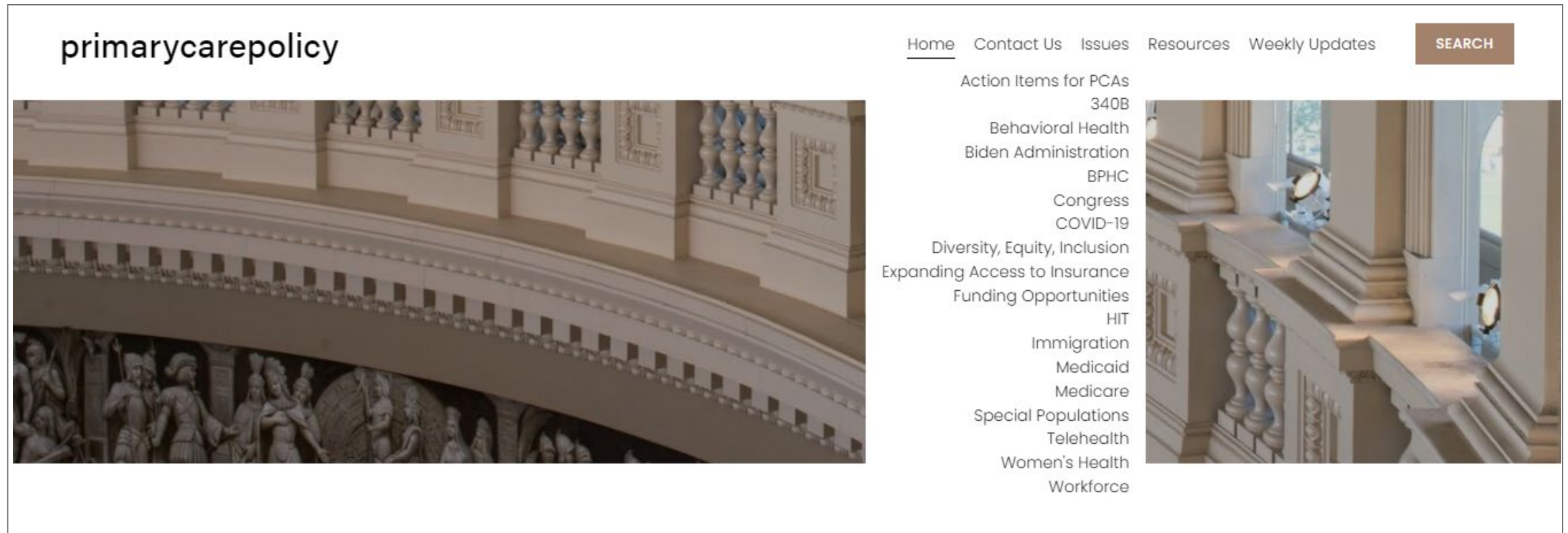
CHC Reference Spreadsheet (aka "Mega-Spreadsheet")						
File Edit View Insert Format Data Tools Add-ons Help Last edit was 11 hours ago						
100% \$ % .0 .00 123 Default (Ca... 11 B I S A						
H30	fx					
	A	B	C	D	E	F
1	DEADLINES RELATED TO FEDERAL FUNDING AND RESOURCES FOR CHCS					
2	Last updated 10/8/2021 - Recent changes in bright green.					
3	Date	Which program?	Task	Due to	Where/ How to submit	Notes
30	Summer/ Fall 2021 (exact date varies based on when loan received)	Paycheck Protection Program	Submit application for loan forgiveness	The bank who processed the loan	Submit standard application to your lender	First payments are due 10 months after the end of the 24-week "covered period", so forgiveness application should be submitted well in advance in order to avoid the need to make a payment. While CHCs whose PPP loans exceeded \$2 million were initially advised to hold off on applying for forgiveness, as of 6/18 they are encouraged to apply whenever they are ready.
32	Thurs. 10/14	BPHC/ ARP Funds	Submit Quarterly Progress Report	BPHC	EHB	To cover period July1 - Sept. 30, 2021
33	Fri. 10/22/21	Immigration/ Public Charge	Sign onto comment letters in response to Biden Administration's Advanced NPRM	ICE	regulations.gov	
34	Tues. 10/26	Provider Relief Fund - Phase Four & APR Rural Funds	Last day to apply for Phase 4 & new rural funds	HRSA	https://cares.lnkhealth.com/#/	Funds available to cover COVID-related lost revenues & expenditures incurred between 7/1/2020 and 3/31/2021 that have not been covered by other sources. Rural and safety-net providers are to receive relatively higher reimbursement
35	Mon. 11/29/21 (previously 7/31 & 9/30/21)	Provider Relief Fund	Report on use of PRF funds.	HHS	HHS portal	Reporting requirements were issued on 6/11 and are available here
36	Tues. 12/14	BPHC HIV Prevention	Preliminary application due	Grants.gov	grants.gov	grants.gov application due for Ending the HIV Epidemic -- Primary
+ 1. PROTECT - House mbrs 2. State 340B Laws 3. Deadlines 4. Bills we're tracking 5. Funding Opps 6. Fed Telehealth						

Current Tab 4 – Bills We're Tracking

BILLS WE ARE TRACKING - As of 9/2/2021											
Topic		Title	Summary	Bill Number & Link to Text		Original Sponsors		Status	History/Comments	Recommended position	For more info
Main	Sub-topic			House	Senate	House	Senate				
330 FUNDING	Capital/ NAPS	MOBILE Health Act (Maximizing Outcomes through Better Investments in Lifesaving Equipment)	Allows BPHC to make award New Access Point funding for: acquiring/ leasing/ renovating mobile medical equipment or vehicles; leasing/expanding/renovating/ constructing CHC buildings		S. 958 Text	Susie Lee (D-NV), Herrera Beutler (R-WA)	Sens. Jacky Rosen (D-NV) & Susan Collins (R-ME)	Introduced March 25, 2021		Support (NACHC has endorsed)	Press Release
340B	Pick-pocketing	PROTECT 340B Act of 2021	Prohibits a broad range of pick-pocketing practices by PBMS & insurers in the private insurance and Medicare Parts C & D markets. Established a national clearinghouse to avoid Medicaid duplicate discounts.	H.R.4390		Abigail Spanberger (D-VA); David McKinley (R-WV)		Introduced July 9, 2021		STRONGLY SUPPORT, and seek co-sponsors	
BEHAVIORAL HEALTH	Buprenorphine / X Waivers	Mainstreaming Addiction Treatment Act	Ends the X-waiver requirements	H.R.1384	S.445	Paul Tonko (D-NY), Antonio Delgado (D-NY), Anthony Gonzalez	Maggie Hassan (D-NH), Lisa Murkowski (R-AK)	Introduced Feb. 2021	Previously introduced in 2019.	STRONG SUPPORT	
	Expansion of mental health services	Excellence in Mental Health and Addiction Treatment Act of 2021.	Expanding community mental health and addiction services by allowing services to be funded through the health care system, instead of just grants. Works to expand treatment for mental health in response to the increase in anxiety, depression. The goal is to allow every state to join the CCBHC Medicaid demonstration and authorize investments for current and prospective clinics.				Debbie Stabenow (D-MI) and Roy Blunt (R-MO)	Introduced 6/15/21 and referred to the Committee on Finance			
BROADBAND ACCESS		Broadband Reform and Investment to Drive Growth in the Economy (BRIDGE) Act	Provide \$40 billion to increase affordability and accessibility of broadband. Targets rural and tribal areas, and low-income urban residents.		S-4113	(R-OH), Mike Turner (R-OH)	Bennet (D-Colo.), King (I-ME), Rob Portman (R-OH)	Re-introduced by 3 Senators on June 17, 2021	Introduced by Bennet in 2020, as \$30 billion.		
						Weich (D-VT),					

Primary Care Policy website

- www.primarycarepolicy.com (password “pca”, 3 letters, all lower case)
- You can find archived copies of weekly policy updates
- You can search for updates by topic area (e.g., immigration) or term (e.g., Merck).





Q&A

The image features the text "Q&A" in a bold, blue, 3D sans-serif font. The letters are thick and have a slight shadow beneath them, giving them a three-dimensional appearance. The ampersand is stylized with a central loop. The text is centered horizontally against a plain white background. A thin, light green horizontal line is positioned at the top of the image, and a dark blue horizontal bar is at the bottom.