Reponses Provided by Marilyn Bartlett, May 2, 2023

Questions provided by Committee on Energy and Commerce, March 28, 2023, Hearing on "Lowering Unaffordable Costs: Examining Transparency and Competition in Health Care."

The Honorable Cathy McMorris Rodgers

1. The Federal Government sponsors the largest employer sponsored group health plan in the country through the Federal Employee Health Benefits Program (FEHBP). With over 4 million employees and over 8 million lives, the FEHBP spends over $55B annually on medical and prescription drug coverage for Federal Employees and their dependents. Given the purchasing power of the FEHBP, and the responsibility of those overseeing this program to be good stewards of taxpayer and member dollars, how has the FEHBP leveraged the available transparency data to assess and analyze their spend? Specifically, has the OPM, as the administrator of the FEHBP, leveraged any of the data sources noted above to evaluate any of the following:

a. Opportunities to lower hospital spend;

b. Opportunities to engage in reference-based pricing;

c. Evaluation or Rebates and impact on FEHBP; and/or

d. Evaluation of Cash Rate versus Negotiated Rates through Carriers Currently contracted with FEHBP;

FEHBP has significant opportunities to lower their plan spend, by following actions taken by several state employee health plans and implementing recommendations presented in recent OIG Final Reports of OPM Top Management Challenges.[1]

a. Lower Hospital Spend:

1) A 2018 OIG audit recommended OPM conduct an **eligibility audit** to ensure financial integrity of the plan, with only eligible members receiving benefits and the potential of $1 billion in savings to the FEHBP. The 2021 through 2023 OIG Final Reports of OPM Top Management Challenges (OIG Final Reports) continue to recommend OPM proceed with an audit. The Centralized Enrollment Clearing House receives enrollment information from the carriers and agencies, but ongoing review of dependent eligibility is left to the carriers.

   As with the Medicaid Redetermination rules, OPM could be required to confirm plan eligibility, removing participants that are ineligible. Industry consultants estimate 10% of dependents covered by an employer plan are ineligible. Such an audit would improve FEHBP financial integrity, reduce plan expenses related to ineligible member claims, and reduce federal agencies contributions moving forward.

[1] Final Report: The U.S. Office of Personnel Management's Top Management Challenges for Fiscal Year 2023 (oversight.gov) AND Final Report: The U.S. Office of Personnel Management's Top Management Challenges for Fiscal Year 2022 (oversight.gov)

2) Employer health plans are improving the financial integrity of plans by engaging a **pre-pay and post payment audit.** An independent audit firm completes a thorough analysis of Third Party Administrator (TPA) medical claims, identifying overpayments, missed recoveries, duplicate claims, etc., recovering millions for clients.

   For example, the New Jersey public employee health plan which covers approximately 800,000 members and is one of the largest public sector purchasers behind only California and the FEHBP contracted with a third-party payment integrity company to review all the medical claims generated by public workers in a "regular, frequent and ongoing" oversight process. The program was officially launched in February 2021 with an aggregate savings number, to date, of over $152 million. The state deployed pre-pay and post pay clinical concepts in the following areas: (1) DRG coding and validation (2) place of service appropriateness (3) inpatient psychiatric services (4) medical drugs (5) inpatient rehabilitation facility (5) hospice and (6) readmissions. These reviews include complex algorithms, artificial intelligence, purpose-build review platforms and medical documentation reviews by clinicians and certified coders with oversight by medical directors.

   Of note, the claims audited were processed by Horizon BCBS NJ, a carrier that currently covers a significant number of FEHBP employees and which was previously audited by OIG in 2020 with the following findings, *inter alia*:

   The [Horizon BCBS] did not properly manage and/or account for all FEHBP funds from 2015 through March 31, 2019… [t]he results of our tests indicate that, with respect to the items tested, the Plan did not comply with all provisions of the contract and Federal regulations…

   Throughout the audit process, we encountered numerous instances where [Horizon BCBS] responded untimely, and/or initially provided incomplete responses, to various requests for explanations and supporting documentation"[2]

   To put this scale of potential savings in perspective, medical claims spend for a New Jersey public employee health plan member was approximately $700 per member per month (PMPM) in 2022, and the savings generated by the payment integrity program resulted in savings of approximately $17 PMPM.[3]

   These types of medical reviews can be performed on every claim, on a prepayment and/or post payment basis, and ensure that FEHBP funds are spent appropriately. While the size and scale of the FEHBP might make such an initiative seem daunting, a majority of FEHBP members are located within highly concentrated geographic areas. The project's implementation could be rolled out in phases, with the goal of reaching the entire FEHBP population within 5 years. The majority of the savings and efficiency would be achieved within the first 1-2 years of deployment, bringing down the medical claims spend moving forward.

3) Rather than obtaining TPA services through the standard procurement process, FEHBP issues **Carrier Letters**, allowing any willing carrier with basic requirements to participate. With the current governance structure of the FEHBP relationship with carriers, there is limited or no

[2] https://www.oversight.gov/sites/default/files/oig-reports/OPM/1a-10-49-19-036.pdf
[3] https://www.nj.gov/treasury/pensions/rate-renewal.shtml

contract management, performance monitoring or accountability. Key contract terms provide employers with leverage over the performance of their TPAs, as presented in *Attachment A*. OIG audits have rarely resulted in meaningful reform, where tight contract provisions could enhance enforcement.

4) As the largest employer health plan in the county, FEHBP has **buying power**. The carriers' provider network agreements basically govern the hospital pricing for FEHBP. With the size of FEHBP, OPM could consider direct contracting with health systems and hospitals.

   Large employers, such as Walmart, Boeing, General Motors, and Intel pioneered direct contracting with hospitals, and have been successful in lowering costs and receiving quality care for their members. Employers can expect annual savings between 10% and 20% on average. [4]

b. Reference Based Pricing:

1) Contracting with hospitals to set reimbursement as a multiple of Medicare rates vs. negotiated TPA or Carrier rates would result in significant savings to FEHBP. Conservatively, FEHBP could save at least 18% of their hospital spend a year.
   i. The State of Montana Employee Group Benefit Plan contracted with all Montana hospitals to pay a multiple of Medicare rates for inpatient and outpatient services, saving at least $47.8 million in 3 years. The plan has been able to return over $50 million to the State of Montana from excess plan reserves, without raising employee contributions since 2017.
   ii. The State of Oregon passed legislation in 2017 limiting hospital payments for the Oregon Educators Benefit and the Public Employees' Benefit programs. Payments are limited to a multiple of Medicare rate, and an audit of 2021 claims showed $112.7 million in savings was achieved. [5]

2) FEHBP can participate in the RAND 5.0 study, an independent analysis of current hospital claims payments. Enroll in RAND 5.0 Study (employerptp.org) The study "reprices" the claims as a multiple of Medicare, allowing FEHBP to have data to compare to state and national medians, comparison of hospital rates, and receive actionable data to better manage the plan. Participation in the study will not cost FEHBP, but FEHBP may request an individual analysis at a cost of $15,000.

c. **Pharmacy Benefit – Rebates.** The 2023 OIG Final Report identified variances among several of the FEHBP fee-for-service carriers with respect to contractual arrangements with pharmacy benefits managers (PBMs). Since a study has not been completed in over a decade, the report recommends that OPM conduct a new, comprehensive study by seeking independent expert consultation on ways to lower prescription drug costs in the FEHBP. Such a study will most likely result in significant savings for FEHBP.

[4] https://www.benefitspro.com/2021/08/11/how-direct-contracting-can-succeed-where-high-deductible-health-plans-fail/over current provider network structures.
[5] https://nashp.org/oregon-saves-millions-using-reference-based-pricing/

It appears that the pharmacy benefit is "carved in" to the medical benefit of the carriers, rather than "carved out" as a benefit separated from the carrier. In many cases, a "carved out" benefit, with direct agreements PBM agreements, will reduce costs and improve transparency. Over the past decade, the market has seen dramatic consolidation. Caremark (CVS Health), Express Scripts (CIGNA), and Optum Rx (United Health) now control almost 80% of the market. [6] With this level of consolidation, it becomes even more critical for plans to demand transparency and complete a thorough analysis of pricing, PBM remuneration, formulary placement, 340B drug pricing, and more.

States employee health plans have utilized various methods to lower the drug spend, including moving to transparent, pass through PBMs, implementing lowest net cost formularies, and increasing audits of PBM transactions. The New Jersey public employee health plan, with 800,000 public employees, conducted a reverse auction for PBM procurement in 2017, with projected savings of $2.5 billion over 5 years. Since then, Colorado, Louisiana, and Minnesota have enacted laws enabling reverse auctions to procure PBM services for their state employee health plans.[7]

d. Cash Rate vs Negotiated Rates through carriers with FEHBP. For 2023, FEHBP lists 87 carriers and 17,877 plans providing health plans for members.

- Using Hospital Price Transparency files, FEHBP would be able to compare the prices for FEHBP plans to other plans within hospitals.
- FEHBP would be able to compare the hospital cash prices to FEHBP plans' negotiated rates, providing leverage to address carrier negotiated rates. A recent study looked at 70 shoppable services at 2,300 hospitals, finding cash prices were lower than the median commercial negotiated rates in 47% of the instances. [8]
- FEHBP could also access medical claims data from the TPA to verify prices paid align with Hospital Price Transparency file rates, auditing the TPA payments.

2. 54.3 % of Americans covered by health insurance, receive that coverage through their employer. How can employer health plans utilize the Hospital Price Transparency Data to manage their employee health plans more effectively?

The Employee Retirement Income Security Act of 1974 (ERISA) established fiduciary duties for employer health plan sponsors and administrators. ERISA requires plan sponsors to pay reasonable expenses for benefits offered through a health plan.[9] Determining the "reasonable expense" for hospital services is challenging without having full transparency into hospital prices, including cash prices, and negotiated network prices.

Hospital Price Transparency Data will allow the plan sponsors to meet their fiduciary responsibility by analyzing prices paid through the medical claims data to hospital price data. For example, Lehigh County, Pennsylvania,

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[6] Source: Bobby Clark and Marlene Sneha Puthiyath, "Are Pharmacy Benefit Managers the Next Target for Prescription Drug Reform?," *To the Point* (blog), Commonwealth Fund, Apr. 20, 2022.

[7] https://nashp.org/three-more-states-enact-reverse-auction-laws-to-reduce-prescription-drug-spending/

[8] https://publichealth.jhu.edu/2023/study-finds-hospitals-cash-prices-for-uninsured-often-lower-than-insurer-negotiated-prices

[9] Technical Release No. 1992-01, DOL Enforcement Policy for Welfare Plans with Participant Contributions. Technical Release No. 1992-01 | U.S. Department of Labor (dol.gov). The Department cautioned that plan sponsors and fiduciaries must ensure participant contributions "are applied only to the payment of benefits and reasonable administrative expenses of the plan."

provides a self-funded health plan for about 2,400 lives. The county controller compared the plan's hospital medical claims paid to available hospital transparency data, finding:

- Potential $4 million annual savings if the plan had paid the hospitals' cash prices instead of the third party administrator (TPA) negotiated prices.
- Variation of pricing between the major hospitals in the county, with one having prices averaging three times higher than the other.
- Significant variation in TPA network prices, opening opportunities for renegotiation with the TPA or changing TPAs.

3. The testimony you provided to the Committee included a comment that a recent Patient Rights Advocate analysis reported only 25% of hospitals have published complete machine-readable files, containing all data fields prescribed by law.

a) What data is currently missing or misrepresented in the 75% of hospitals determined to have partially complete files?

Excerpts from PatientRightsAdvocate.org Fourth Semi-Annual Hospital Price Transparency Compliance Report published February 2023:

> "[Our report], published just over two years after the Hospital Price Transparency Rule's implementation, analyzed the websites of 2,000 U.S. hospitals focusing on the nations' largest health systems, and found only 24.5% of them (489) to be compliant with all the requirements of the rule. Though the majority of hospitals have posted files, the widescale noncompliance of 75.5% of hospitals is due to most hospitals' files being incomplete, illegible, or not having prices clearly associated with both payer and plan."
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> Consistent with our earlier reports, many hospitals identified only payer names and not the associated plan names. We frequently found that hospitals listed a far greater number of "accepted insurance plans" elsewhere on their websites than they showed in their standard charges file, implying that their standard charges file did not include all accepted plans. We deemed files noncompliant due to incomplete or missing data fields, formulas instead of actual dollar amounts as prices, or fields with zeros, blanks, and asterisks for negotiated rates. Also of note, a significant number of hospitals posted their files in obscure locations on their websites, and many posted multiple pricing files with incomplete data in each. These tactics of noncompliance prohibit consumers and technology developers from accessing, parsing, and comparing the pricing data."

Most hospitals have pricing files that are incomplete and missing swaths of pricing data or cannot be evaluated or downloaded in a machine-readable format. Most frequent forms of noncompliance are:

1. Hospitals failing to list both insurance carrier and specific plan names by each associated and varied actual price in the machine-readable files as required, and
2. Hospitals not adhering to the requirement of posting the actual prices in the required data fields, and instead posting a majority of N/As, hyphens, dashes, blanks, and various forms of non-readable formulas, instead of actual prices, when actual prices do exist (when the data is compared to the associated Transparency in Coverage (TiC) files)).

The rule could not be clearer when it comes to reporting payer and plan. Page 318 of the federal regulations state: 'Each payer specific negotiated charge must be clearly associated with the name of the third-party payer *and plan*.'

And while it is not an expectation for hospitals to have a price for *every* item and service they provide, hospitals are taking advantage of N/As, hyphens, dashes, blanks, or other types of non-pricing information at a large scale. When the majority of the pricing file contains no prices, that raises some understandable concerns. When cross referencing the non-pricing information in the hospital files with the data in the TiC files, we find prices reported in dollars and cents in the TiC files.

By not listing an actual price in dollars and cents, hospitals are directly opposing what CMS promulgates in their rule: ''…we proposed to define standard charges by the regular rate established by the hospital for an item or service. . . The term "Rate" is defined in the Oxford dictionary as "a fixed price paid or charged for something, especially goods or services.' (Federal Register, Vol. 84, No. 229, 11/27/2019, p.65539.)

Actual prices are the expectation, not the various forms of non-pricing information we are seeing in many hospital files.

Different forms of noncompliance include:

- 75.3% of the hospitals (1,506/2,000) did not post a complete machine-readable file of standard charges.
- 48.8% of the hospitals (975/2,000) did not publish all payer-specific negotiated charges "clearly associated with the names of each third-party payer and plan" as required.
- 46.2% of the hospitals (923/2,000) did not publish a sufficient amount of negotiated rates.
- 16.4% of the hospitals (327/2,000) did not publish any discounted cash prices.
- 5.8% of the hospitals (116/2,000) did not post any usable standard charges pricing file.

Examples of specific noncompliant files are presented in ***Attachment B.***

b) What actions could CMS take to ensure a higher percentage of hospitals publish complete files?

Require attestation of compliance and standardized file submission to CMS

- Require submission of price information directly to CMS with a certification of completeness and accuracy through attestation into a CMS cloud service where all files for all hospitals can be provided for public access and are fully transparent to any technology developer and consumer.

Develop and require standard data layout, definitions, and data template:

- Require CMS suggested standard format be mandatory.
- Require prices be posted in dollars-and-cents, no algorithms, symbols, or multiple of Medicare Rate.
- Include the use of extrinsic sources, such as Transparency in Coverage data, to identify gaps and verify compliance.
- Withdraw and supersede sub regulatory guidance suggesting that hospitals can avoid disclosing prices by inserting "N/A" in data fields.
- Expand the required disclosures under the rule to include the range of cash prices accepted by the hospital, facility fee charges, and publish criteria for charity/indigent care and associated discounts.
- Expand the scope of the Hospital Price Transparency Rule to include Ambulatory Surgery Centers and thus provide consumers with information at more sites of care.

Eliminate the price estimator loophole:

- Instead of estimates or a tool, provide a machine-readable shoppable display for the 300 most common procedures, including the 70 CMS mandated codes with all five standard actual charges, clearly, in a consumer-friendly format without barriers.

Enforcement

- All enforcement actions (warnings, corrective action plans, civil monetary penalties, notifications of closure) must be made public with the corresponding dates of notice.
- Assess a fine to all noncompliant hospitals immediately.
- All 6,000 hospital files should be audited yearly.
- Double the price transparency fines.
- Require actual hospital price transparency as a condition of participation in Medicare and Medicaid programs and include prices for all care including any in-network and out-of-network contracted clinicians, ASCs, and ACOs, to providing complete and actual, upfront prices for consumers.
- Require machine-readable file submission in a standard format directly to CMS with a certification of completeness and accuracy. Require CMS publicly and transparently publish this information in a cloud based solution, allowing anyone to use the CMS site to access this data in one central location.

Establish and require uniform data standards and file prices, such as those recommended below.

- Require machine-readable pricing files be disclosed in ONE (1) Standard File Format, e.g., JSON, in addition to a human-readable price file disclosed in ONE (1) Standard File Format, e.g., CSV.
- Require disclosure of the full payer and plan name and provide hospitals with a uniform, nationally applicable set of abbreviations for the most common payers and plans.
- Mandate that plan specific rates be disclosed in the machine-readable file and updated in real time.
- Define and require a standard schema for machine-readable file disclosures, including all names and data types which at a minimum, contains all data fields and types reflected in the suggested (but not mandated) file data standards currently offered by CMS.
- Require pricing data be provided for free via application programming interfaces (APIs).
- Provide a safe harbor or require that the use of CPT or DRG codes be made available without royalty, copyright, or other fees for the purpose of price transparency including by any downstream software.
- Require that explicit billing codes, such as CPTs or DRGs, be identified for each procedure, and require separate tabs for each billing code type, including CPT, DRG, HCPCS and NDC.
- Require that the pricing file can be found with just a single click from the hospital's homepage.
- Require all hospitals to post a machine-readable file with actual prices (discounted cash prices and insurance-negotiated rates) for the 300 shoppable services, whether or not they have a price estimator tool.
- Implement a standard for representing where there is no data for a particular field or provide a legend to help users understand the meaning of a dash or "N/A," or another symbol or acronym that we have observed on these pricing files.
- Require all hospitals to post a list of insurers, payers, and specific plans accepted, so patients will know in advance whether the hospital is in-network.

Require Full Disclosure on Ownership and Interests in Other Provider Entities

- For each hospital, require disclosure of all ownership interests in the hospital and all ownership interests of the hospital in any entity that provides services or receives payment related to the healthcare products or services, including without limitation, ASC's, ACO's, physician practices, imaging or other diagnostic centers, laboratories, insurance, provider networks and data services.

4. The Hospital Price Transparency rules require hospitals to post a display of standard prices for 300 shoppable services. CMS allows hospitals to meet this requirement with an internet-based price estimator tool. Do you believe this tool meets the intent of the Hospital Price Transparency rules and if not, what can be done to improve it?

The estimator tool is a loophole, which harms patients and employers. It is problematic because of the lack of accountability and the inconsistency with only showing an estimate of out-of-pocket costs, instead of all actual, complete, and total prices across payers and plans.

Be requiring this actual pricing, the law intended the transparency to advance:

- Hospitals, insurance companies and provider networks to compete on price and quality.
- Consumer shopping for hospital services, comparing facility prices.
- Employer sponsored health plans to obtain the best option for their employees, by comparing pricing among various plans.
- All users compare their plan prices to discounted cash prices within the same hospitals and across competing hospitals.

The price estimator tool only meets a small portion of the Hospital Price Transparency rules and does not satisfy the intent of the regulation.

To display standard prices for 300 shoppable services, shoppable tools with real pricing information would support best-informed decision making for users. The machine-readable standard charges file for all items and services with all standard charges (gross charge, discounted cash price, de-identified minimum and maximum charges, and all negotiated rates by payer and plan) is the bulk of the requirement and the only source that provides actual, accountable, and guaranteed prices.

Furthermore, estimates are not real prices. They are not binding, and they provide no accountability. We all know estimates are often off by hundreds, thousands, and even tens of thousands of dollars. Or estimates are so broad as to be useless with some estimates displayed as a range of prices where the highest is 10x the amount of the lowest.

To use a hospital's price estimator tool, patients must check a box to assure that they agree the estimate will not be the final price and they are responsible for whatever the final price may be. Estimator tools do not allow for price comparisons. They only allow patients to see prices within their specific insurance payer and plan and some do not even show the cash price.

Estimator tools also require the user to enter personal health information (PHI) to access the estimated price, which violates the intent of the law. Such information includes name, DOB, insurance information, email, phone, address, date of service, and sometimes social security information related to the specific hospital service inquiry.

To improve the consumer-friendly requirements, price estimator tools should not be allowed. The hospital must post the consumer-friendly display of actual standard charges for the 300 most common shoppable procedures, including the 70 CMS mandated codes, which offers actual, accountable prices that provide remedy and recourse when a surprise bill comes in the mail.

5. Critics of price transparency, particularly among hospitals, have noted that an unintended result will be higher hospital prices, rather than lower prices. When hospitals and health plans can see that others have higher prices, they will raise theirs accordingly. Is there evidence that this is not the case?

NASHP knows of no evidence that the federal transparency requirements have resulted in higher reimbursement by health plans. Requiring the monitoring of these prices to capture the trends over time could help to understand the policy's impact. NASHP convenes a network of state employee health plans and a number of those officials have vocalized their interest in this data, but they don't have any way to digest the machine-readable files, which significantly limits the usefulness of the data.

In a recent research paper, "Estimating the Impact of New Health Price Transparency Policies", Stephen T Parente, PhD, the author estimated 6.7% annual savings to consumers, employers, and insurers by 2025 with tools to allow consumers to purchase medical services. [10]

Beyond consumer shopping, hospital price transparency provides a "hub" that enables other changes that reduce hospital prices. This includes improved contract negotiations, reference pricing models, improved competition, etc.

In a broader context, a recent article in the AMA Journal of Ethics outlined three reasons why hospital price transparency is economically important for the United States[11]:

1) Hospital price transparency is in its infancy. As hospital compliance improves and price transparency tools become more commonplace, patient behavior will similarly adapt. The study cites the example of Singapore, where price information is regularly incorporated in medical decision making.
2) Hospital price transparency can be used by purchasers other than patients, noting some innovative employers have already used pricing information to redesign health benefits and inform purchasing decisions.
3) Hospital price transparency can be used to "name and shame" higher-priced providers, and support policy options, limiting market consolidation, etc.

6. The intent of Section 201 of the Consolidated Appropriations Act was to improve transparency for employer sponsored health plans in furtherance of their fiduciary roles as administrators of ERISA sponsored health plans and non-federal government employer health plans.

> **a. In your opinion, have these provisions of the law been effective in giving the employers access to the information they need to make the type of informed and prudent decisions expected of a fiduciary in this context?**

While the clear intent of Section 201 was to improve transparency for employers in giving them access to the de-identified claims data of their employee health plan, including all encounter and financial information,

[10] https://doi.org/10.117/00469580231155988
[11] https://journalofethics.ama-assn.org/article/if-patients-dont-use-available-health-service-pricing-information-transparency-still-important/2022-11

carriers and large third party administrators are refusing to comply with the express language of the law. By blocking access to this information, these parties prevent employers from fulfilling their fiduciary role established in law.

Examples of such frustration include requiring prohibitive data access fees, insistence on non-disclosure agreements that include gag orders around use of the data, cost prohibitive cyber security insurance, disavowing data accuracy, etc. As a result, employers are moving to legal action to gain access to the information permitted under Section 201. One such case is a lawsuit filed in the US District Court for the Eastern District of Virginia. In Owens & Minor Inc. said Anthem Health Plans of Virginia Inc., the employer (Owens and Minor) claims Anthem repeatedly refused to turn over claims data requested since 2021.[12]

b. What could HHS, DOL and IRS do to improve compliance with Section 201 to fully realize the original intent of the provisions?

The Department of Labor, Department of Health and Human Services and the Internal Revenue Service (the Departments) are charged with implementation of Section 201 law. These agencies must put forth detailed, prescriptive regulations requiring access to all claim fields required in standard HIPAA transaction files, without conditions of additional fees, cybersecurity insurance, disavowing data accuracy, or restrictions on use of the data. Compliance with HIPAA rules is already a requirement on data exchange, which TPAs and other service providers follow. This guidance should be as prescriptive as possible with respect to the standards and fields that employers are entitled to, and the purposes for which they are permitted to use this data. All such lists should always be by way of illustration, and not limitation, and this point should be made clear to the TPAs and other service providers.

In February 2023, the Departments issued the FAQ clarifying specific aspects of Section 201 and instructions for submitting attestation of compliance.[13] The FAQ again stated the requirements around gag clauses, noting:

To the extent a term in a contract, either directly or indirectly, prevents a plan or issuer from providing, accessing, or sharing the information or data, as provided for under the statute, that term in the contract violates the gag clause prohibitions and is prohibited under Code section 9824, ERISA section 724, and PHS Act section 2799A-9

The FAQ added a provision for attestation, allowing a TPA, Pharmacy Benefit Manager (PBM), managed behavioral health organization of any other service provider to attest on behalf of the self-funded group health plan, provided the parties enter into an agreement to do so. In any case, the legal requirement remains with the health plan.

If service providers are unwilling to follow the law set forth in Section 201, there must be meaningful repercussions to financially incentivize the service providers to comply. The penalties need to be strong enough to force compliance, and without requiring employer group health plans to use the courts to access their data.

7. Federal law established the 340B Drug Pricing Program to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

a) What concerns or issues have you seen with the 340B Program in the marketplace?

[12] https://www.docketalarm.com/cases/Virginia_Eastern_District_Court/3--23-cv-00115/Owens_%26_Minor_Inc._et_al_v._Anthem_Health_Plans_of_Virginia_Inc/

[13] https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-57.pdf

Prior to 1990, drug manufacturers had traditionally stratified contracted rates so charity care providers serving the uninsured could receive lower priced drugs to treat their patients. When the Medicaid Drug Rebate Program was established in 1990, it lowered overall prices, but unintentionally raised prices for these charity care providers. The 340B Program was signed into law in 1992, in response to unintended consequences of the 1990 Medicaid Drug Rebate Program. Since 1992, the 340B Program has exploded in growth:

- 1992: Covered entities included disproportionate share hospitals and several non-hospital entities referred to as "federal grantees".
- 1996: Contracted pharmacies were permitted, to support the needs of smaller hospitals without an outpatient pharmacy. These smaller hospitals were able to contract with a separate pharmacy for dispensing 340B eligible drugs.
- 2005: Only 583 hospital organizations participated in the 340B Program.
- 2010: The Affordable Care Act (ACA) expanded covered entity eligibility to include critical access hospitals, sole community hospitals, rural referral centers, and stand alone cancer centers. In addition, 340B hospitals with offsite outpatient clinics ("Child sites") could become 340B covered entities.
- 2020: Covered entities totaled 50,000; 28,000 contracted unique pharmacy locations. A covered entity can contract with an unlimited number of pharmacies.

HRSA released 2021 data showing hospitals now account for 86.9% of the 340B purchases, with Disproportionate Share Hospitals comprising the bulk of these purchases at 78.1%. Federally Qualified Health Centers are included with "All Other Federal Grantees", consuming only 0.3% of the purchases. *(Attachment B)*

The report also shows covered entity discounted purchases under the 340B program reached a record $43.9 billion, a 15.6% increase over 2020 purchases. More importantly, the list prices were estimated to be $93.6 billion, generating as estimated profit of $49.7 billion to 340B covered entities, contracted pharmacies, and other players.

The 340B Program has grown to be the second largest federal government pharmaceutical program, but unlike Medicare Part D and Medicaid, the 340B Program lacks clear legislation to guide the program, well-developed administrative controls, and aggressive audit requirements *(Since 2011, HRSA has conducted fewer than 200 audits).*

Additional concerns:

- Apexis is contracted by HRSA's Office of Pharmacy Affairs to manage the 340B program. Apexis is owned by Viziant, one of the largest hospital group purchasing organizations. In other words, the federal government outsources operations of a federal program that primarily benefits hospitals to an organization owned by hospitals.
- The 340B Program is unusual among federal programs as it mandates the transfer of resources from one group of private entities (manufacturers/wholesalers) to another (providers).

b) What could Congress do to further ensure this program goal is met?

The 340B program has been examined regularly by the Government Accountability Office (GAO) and the Department of Health and Human Services Office of Inspector General (OIG), and their reports have highlighted

several issues with the program, including limited oversight, lack of transparency, concerns stemming from DSH hospitals and contract pharmacies, and duplicate discounts.

The 340B law could be stronger to meet the legislation's original intend:

- **Purpose of 340B Drug Program.** Current law states the purpose is to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. The law doesn't go further in defining specifically what is considered compliance with these provisions.
- **An eligible patient** is an individual who has an established relationship with the covered entity, who provides a range of services to the patient and maintains the patient's health care records. The definition should be changed to specify patient characteristics more in line with the needs of the patient, such as income levels, uninsured status, etc.
- **Transparency** is lacking. Currently there is no transparency into the 340B Program list of drugs, drug prices, covered entity profits, contract pharmacy profits, covered entity use of 340B profits, split fee vendor compensation, 340B volume, and more. Transparency is required to understand the impact and use of profits in the program. States are beginning to introduce state level legislation to advance transparency, as seen in the current Maine proposed legislation. [14]
- **Covered Entity definitions** need to be redefined to ensure the goals of the program are met. As reported in a recent Wall Street Journal article, the Cleveland Clinic's flagship hospital does not qualify as a Disproportionate Share Hospital but does qualify as a Rural Referral Center under the 340B Program. Despite the location in the center of Cleveland and $1.35 billion net income, the hospital can reap the profits of the 340B Program.

8. While at the State of Montana Employee Health Plan, you contracted with Montana hospitals to change the basis of payment to a multiple of Medicare instead of a discount from charge master rates, saving millions of dollars for the plan. Have you seen other employer health plans do the same? If not, why?

Since 2017, when The State of Montana Employee Health Plan contracted to pay Montana hospitals based on a multiple of Medicare, we have seen very few examples of other plans doing the same.

- The Oregon Educators Benefit and the Public Employees' Benefit programs adopted a cap on hospital payment based on a multiple of Medicare rate. An audit of 2021 claims showed $112.7 million in savings was achieved. [15]
- The 2023 Indiana Legislature passed HB 1004; the bill is awaiting governor approval. The bill will cap hospital prices at 285% of Medicare rate and is projected to save Indianans $1.275 million from 30 hospitals owned by the 5 largest health systems in the state. The Employer Forum of Indiana has worked diligently for 5 years to advance this legislation, against the strong opposition of the hospitals, hospital association and insurance companies.
- The Alliance, a Wisconsin employer coalition with 300 employer groups, negotiates hospital contracts for its employer members. Rates are a multiple of Medicare rate, rather than a discount off billed charges, with several Wisconsin hospitals accepting 150% of Medicare rates.

[14] https://legislature.maine.gov/bills/getPDF.asp?paper=SP0562&item=1&snum=131
[15] https://nashp.org/oregon-saves-millions-using-reference-based-pricing/

Employers have been reluctant to move to a multiple of Medicare reimbursement model, and are more comfortable staying with standard Preferred Provider Organization (PPO) Networks offered by carriers and TPAs, where reimbursement is a discount off billed charges, for several reasons:

- Employers rely on middlemen in making employee health plan decisions, and these parties are usually conflicted. Most brokers and consultants receive commissions from carriers and TPAs for selling products with the PPO Networks and are not bringing other solutions to employer health plans.
- The Minimum Loss Ratio (MLR) provisions of the Affordable Care Act provide misaligned incentives to health insurance carriers. The law requires a carrier to spend specified amounts on clinical care and quality care, or they must pay a rebate premium to subscribers. For individual and small group markets, at least 80% or premium revenue is required; for large group market, at least 85% of premium revenue is required. This reduces the incentives to lower medical claims expense, including hospital reimbursements which are the largest component of health insurance payments.
- Direct responsibility for an employer health plan usually rests in the human resource department, with little or no focus on the financial aspects of the plan. Until the CEOs and CFOs become involved in the decision making of their health plan, the required level of decision making based on thorough financial analysis is lacking.
- The hospital and insurance lobbies are strong in states and at the federal level. Without an incentive to lower costs, we continue to face strong opposition from these parties.
- Following the money in healthcare is very difficult and lacks transparency. It takes a lot of work to examine alternative solutions and negotiate alternative payment options. Unfortunately, this falls to the bottom of the list for many employers.

9. In 2021, around 156 million, or 49% of the country's population, received health insurance through their employer. Given their significant role in healthcare, how can employers (both public and private), benefit from more transparency in healthcare purchasing. Specifically, how can employers' benefit from:

a. Hospital Price Transparency Data

- Using Hospital Price Transparency files, the employer health plan can compare the prices paid by their plan to those paid by other plans for identical services within hospitals. This allows the employer plan leverage when negotiating with their TPA, information for direct contracts with hospitals, or changing their TPA.
- Employer health plans can compare the hospital cash prices to their plans' negotiated rates, Where cash prices are lower, the plan can consider direct contracting with the hospital for specified services.
- Employer health plan can compare payments between hospitals, directing members to less expensive hospitals through plan design.
- Employer health plan could also access medical claims data from the TPA to verify prices paid align with Hospital Price Transparency file rates, auditing the TPA payments.
- The Hospital Price Transparency data can support a consumer shopping tool for plan members. As administrator of the State of Montana Employee Health plan, we implemented Health Care Blue Book, providing members with pricing for inpatient and outpatient services. Many plans that utilize such tools also include quality information and member incentives for selecting lower cost, higher quality services.

b. TiC Compliance

Transparency in Coverage (TiC) regulations require insurance carriers and group health plans to report negotiated rates for all in-network providers, including hospitals, independent physicians, imaging centers, physical therapists, labs, and others.

The TiC data files are voluminous and cannot be accessed using typical computers and business software. Private firms are developing data sets for business use or defined projects, for a fee. A fully available self-serve database of TiC files does not exist with easy consumer-friendly access. This limits employer access.

If the TiC information were easily accessible, employers could benefit in several ways:

- Employers could access and analyze pricing data for many providers, including hospitals, out-patient clinics, imaging centers, independent physicians, specialists, and other services occurring in non-hospital settings.
- For employer sponsored health plans that offer more than one carrier network option, the plan could provide price information allowing the employee to determine which network option would best meet their needs.
- Technology developers could build mobile/online tools for employers and employees that enable direct comparisons of service and price options.
- The employer sponsored health plan could choose to directly contract with hospitals, knowing the pricing provided to other plans.

c. CAA Section 201 De-Identified Claims Data including Financial Information

- By removing contracted gag clauses, employers can gain access to data needed for sound decision making in line with their fiduciary responsibilities over service providers. The employer can audit the TPAs performance and contract compliance.
- Employers can audit 100% of claims data, where TPA contracts usually limit the scope of audits to 200 to 300 claims.
- Employers can examine TPA payment practices, finding where TPA may
    - Pay a hospital more than billed charges,
    - Make “value based payments” exceeding contracted provisions
    - Pay third party service fees the employer believed were included in TPA administrative fees.

d. CAA Section 204 RxDC Reporting Data

CAA Section 204 requires health plans to submit information on prescription drug spending, prescription drugs accounting for most of the spending, prescription drugs most frequently prescribed, drug rebates from drug manufacturers, patient premiums and cost sharing, and spending on other health care services.

The data submission is called the RxDC report and is submitted online to CMS, with CMS providing the data dictionary, data file templates, and instructions. [16] The first submission was due on December 27, 2022, with a non-compliance penalty of $100 per affected person per day.

[16] https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection

CMS states the data will identify major drivers of prescription and healthcare spending, an understanding of prescription drug impacts on premiums and out-of-pocket costs and promote **transparency in drug pricing**. The findings are to be published in a report, downloadable from the Department of Labor or the Department of Treasury websites.

To date, the process and results are problematic:

- For most employers, the service providers (TPA and/or PBM) completed the data transmission to CMS and they have NOT provided the data to the employer health plan.
- No reports or data are publicly available

10. We hear that enforcing compliance with the Hospital Price Transparency Rule can be daunting for CMS, and that they do not have the resources to monitor full compliance given the size and scope of the market. Do you believe that we should consider a form of self-reporting whereby a senior officer and/or director within a hospital, as well as senior leadership from a hospital system (if applicable), must attest on an annual or semi-regular basis to being fully compliant with the Hospital Price Transparency Rule – assuming that we have adopted standardized formats and requirements to ensure uniformity in file layouts and reporting?

I agree that senior officer and/or director of a hospital must attest the hospital file is compliant with the Hospital Price Transparency Rule, and in compliant with adopted standardized formats and requirements.

For example, hospitals who receive funding or payments from Medicare are required to complete a Medicare Cost report annually. Shown below is a copy of the required attestation of the accuracy, completeness, and truth of the report that is required by a chief financial officer or administrator of the hospital. Note the provision that misrepresentation or falsification of information may be punishable by criminal, civil and administrative action, fine and/or imprisonment.

PART II - CERTIFICATION BY A CHIEF FINANCIAL OFFICER OR ADMINISTRATOR OF PROVIDER(S)

MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

CERTIFICATION BY CHIEF FINANCIAL OFFICER OR ADMINISTRATOR OF PROVIDER(S)

I HEREBY CERTIFY that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by _____ (Provider Name(s) and Number(s)) for the cost reporting period beginning _____ and ending _____ and that, to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

	SIGNATURE OF CHIEF FINANCIAL OFFICER OR ADMINISTRATOR	CHECKBOX	ELECTRONIC SIGNATURE STATEMENT
	1	2	
1			I have read and agree with the above certification statement. I certify that I intend my electronic signature on this certification be the legally binding equivalent of my original signature.
2	Signatory Printed Name		
3	Signatory Title		
4	Signature date		

11. The intent of Section 201 and Section 202 of the Consolidated Appropriations Act was to improve transparency for employers in furtherance of their fiduciary roles as administrators of ERISA sponsored health plans. In your opinion, have these provisions of the law been effective in giving the employers access to the information they need to make the type of informed and prudent decisions expected of a fiduciary in

this context? If challenges persist, what are some ways in which these laws can be improved upon in order to fully realize the original intent of these Transparency provisions of the CAA?

While the intentions of Sections 201 and 202 are meant to provide support for employers to meet their fiduciary responsibilities, the implementation associated with the two provisions is lacking compliance and necessary enforcement.

Section 201 addresses the elimination of gag clauses in service provider contracts, allowing a health plan to have access to its claims data. The Department of Labor, Department of Health and Human Services and the Internal Revenue Service (the Departments) are charged with implementation of Section 201 law. These agencies must put forth detailed, prescriptive regulations requiring access to all claim fields required in standard HIPAA transaction files, without conditions of additional fees, cybersecurity insurance, disavowing data accuracy, or restrictions on use of the data.

In February 2023, the Departments issued the FAQ clarifying specific aspects of Section 201 and instructions for submitting attestation of compliance.[17] The FAQ again stated the requirements around gag clauses, noting:

To the extent a term in a contract, either directly or indirectly, prevents a plan or issuer from providing, accessing, or sharing the information or data, as provided for under the statute, that term in the contract violates the gag clause prohibitions and is prohibited under Code section 9824, ERISA section 724, and PHS Act section 2799A-9

If service providers are unwilling to follow the law set forth in Section 201, there must be meaningful repercussions to financially incentivize the service providers to comply. The penalties need to be strong enough to force compliance, and without requiring employer group health plans to use the courts to access their data.

Section 202 addresses the disclosure of direct and indirect compensation for brokers and consultants, including monetary and non-monetary compensation. The main provisions of the law require the service to disclose to the plan fiduciary:

- Description of services to be provided;
- Statement that covered service provider, an affiliate or a subcontractor will perform specified services;
- Description of all direct compensation received by service provider, affiliate, or subcontractor;
- Description of all indirect compensation received by service provider, affiliate, or subcontractor;
- Description of arrangement between payer and service provider, affiliate, or subcontractor;
- Description of compensation that is paid among the service provider, an affiliate or subcontractor.

Responsibility for compliance rests solely with the health plan, not the service provider. The health plan must submit a written request to the service provider for the information. If the service provider fails to respond to the written notice, within 90 days of the request, the health plan must notify the Secretary of the failure within 30 days. If the service provider still fails to comply, the health plan must determine if the existing arrangement should be terminated. If the request relates to future services, the health plan shall terminate the arrangement.

This information is invaluable to a health plan in fulfilling their fiduciary role. Knowing how the plan assets are spent is a key responsibility. The Department of Labor issued a Field Assistance Bulleting 2021-03[18] in

[17] https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-57.pdf
[18] https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03

December 2021, stating the CAA does not require the Department to issue regulations, and did not believe comprehensive implementation regulations were needed.

Some carriers and TPAs have offered guidance literature to consultants to assist in their disclosures, as shown by a United Health Care example. [19] Employers have noted that they are not aware of this requirement or have reached out to their service providers with no response.

Recommendations for Section 202 compliance include:

- Provide education to health plans and service providers regarding Section 202 requirements.
- The CAA defines brokerage and consulting services broadly and employers are usually not aware of this broad spectrum.
    - Selection of insurance products (including dental and vision);
    - Development or implementation of plan design;
    - Recordkeeping services;
    - Medical management vendors;
    - Benefits administration (including dental and vision);
    - Stop-loss insurance;
    - Pharmacy benefit management services;
    - Wellness design and management services;
    - Transparency tools and vendors;
    - Group purchasing organization preferred vendor panels;
    - Disease management vendors and products;
    - Compliance services;
    - Employee assistance programs; and/or
    - Third-party administration services.
- Clarify enforcement of the law, including penalties for service provider non-compliance.

12. We have heard of the importance of the 340B program to financially challenged hospitals in helping them give greater access and services to those most in need in challenged communities. We have also heard that the 340B program is being taken advantage of by large non-profit health systems that utilize rural hospitals, clinics, and contract pharmacies to profit from 340B pricing without delivering the benefit for which the program was originally intended. Given these two very important issues that must be addressed in tandem, how would you suggest the 340B program be reformed in order to allow the program to fulfil its intended purpose while not allowing enterprising and profiteering institutions to take advantage of the program to the detriment of the Federal Budget, taxpayers, and those most in need of the promised benefit of the 340B program?

The 340B program has been examined regularly by the Government Accountability Office (GAO) and the Department of Health and Human Services Office of Inspector General (OIG), and their reports have highlighted several issues with the program, including limited oversight, lack of transparency, concerns stemming from DSH hospitals and contract pharmacies, and duplicate discounts.

The 340B law could be stronger to meet the legislation's original intend:

[19] https://www.uhc.com/content/dam/uhcdotcom/en/Legal/PDF/UHC_Broker_Compensation_Guide.pdf

- **Purpose of 340B Drug Program.** Current law states the purpose is to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. The law doesn't go further in defining specifically what is considered compliance with these provisions.
- **An eligible patient** is an individual who has an established relationship with the covered entity, who provides a range of services to the patient and maintains the patient's health care records. The definition should be changed to specify patient characteristics more in line with the needs of the patient, such as income levels, uninsured status, etc.
- **Transparency** is lacking. Currently there is no transparency into the 340B Program list of drugs, drug prices, covered entity profits, contract pharmacy profits, covered entity use of 340B profits, split fee vendor compensation, 340B volume, and more. Transparency is required to understand the impact and use of profits in the program. States are beginning to introduce state level legislation to advance transparency, as seen in the current Maine proposed legislation. [20]
- **Covered Entity definitions** need to be redefined to ensure the goals of the program are met. As reported in a recent Wall Street Journal article, the Cleveland Clinic's flagship hospital does not qualify as a Disproportionate Share Hospital but does qualify as a Rural Referral Center under the 340B Program. Despite the location in the center of Cleveland and $1.35 billion net income, the hospital can reap the profits of the 340B Program.
- **Contracted pharmacy** requirements were greatly expanded with the Affordable Care Act, with large national pharmacy chains receiving most of the financial benefit. The Berkeley Research group found that over half of the 340B profits retained by contracted pharmacies are concentrated in 4 for-profit corporations (Walgreens, Walmart, CVS Health, and Cigna's Accredo specialty pharmacy[21] The role of contracted pharmacies should be analyzed, with consideration of limiting contracted pharmacies to covered entities that do not have an in-house outpatient pharmacy.

13. I was encouraged to read in the 2023 Medicare Trustees Report that CMS actions, most notably removing hip and knee procedures off the "inpatient only list" and allowing patients to receive and doctors to perform additional services in the more efficient and less expensive outpatient setting have reduced total Medicare expenditures and contributed to extending the program's solvency a little longer through 2031. How should Congress think about additional actions to enhance patient and provider choices by encouraging more services to be safely administered in the outpatient setting?

Procedures secured in outpatient settings, such as ambulatory surgery centers (ASC) can be significantly lower in cost and higher in quality than securing those procedures in a hospital setting. To enhance choice, Congress could consider:

- The Hospital **Price Transparency** rule currently applies to only hospitals. Including Ambulatory Surgery Centers and other such outpatient facilities in price transparency would greatly enhance visibility into the market and consumer choice. Recent studies show ASC prices are increasing, but without transparency, the market is unable to determine appropriate pricing and choice.

- A hospital can charge **Facility Fees** for outpatient services at affiliated clinics or doctor offices, even if they are not near the hospital. This fee is added on top of the service fee and on top of a doctor's fee. Facility fees have been allowed in hospitals as additional funding to maintain 24/7 services, but

[20] https://legislature.maine.gov/bills/getPDF.asp?paper=SP0562&item=1&snum=131
[21] https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf

do not seem appropriate for off-site locations. Patients report paying higher amounts for services obtained from their doctor AFTER the doctor's office was acquired by a hospital, with the billing noting "facility fees".

Texas, Colorado, Indiana, Connecticut, and Massachusetts have 2023 legislation related to limiting or eliminating facility fees. [22]

a. In your experience in Montana, how did you think about the site of service cost differentials and incentives to encourage patients to receive quality care in lower cost settings?

In 2013, the Montana State Employee Health Plan implemented 5 on-site and near-site primary care health clinics. The clinics were in 5 different cities, offering primary care services to plan members, providing access to 73% of plan members.

In 2015, we enhanced the clinics to include more outpatient services at lower costs and improved quality:

- Contracted with independent imaging centers, radiology centers, and a medical laboratory to significantly lower costs by taking these procedures and services out of the hospital setting.
- Aligned medical referrals to lower cost, higher quality providers for services that could not be performed in the health clinic setting.
- Expanded services in behavioral health, diabetes management, asthma care, exercise physiology, and nutrition coaching, which were less costly.

In 2017, we implemented Reference Based Pricing contracts with hospitals, reimbursing acute care hospitals for outpatient services as a multiple of Medicare OPPS rates, excluding facility fees.

The Honorable Dan Crenshaw

One of the most under-discussed supply-side barriers to competition are state certificate-of-need laws. My state of Texas recognizes the burden and does not have them, but in the more than 30 states that maintain these laws (Certificate of Need State Laws (ncsl.org)), new health care providers are typically prohibited from entering the market without a government-ordained "certificate-of-need." Nearly 20 years ago, the FTC said these laws were not successful in containing costs, and that they can actually increase prices by fostering anticompetitive barriers to entry (Improving Health Care: A Dose of Competition (ftc.gov)).

1. **Ms. Bartlett, having been at the state level, do you believe these reforms to remove CON laws were a step in the right direction towards fostering competition**

Certificate of need (CON) is a regulatory tool primarily designed to control the number of health care resources in a given area. At its core, it requires a hospital or health system to obtain approval from the state before establishing or expanding a health care facility or service by demonstrating a need for it. Historically, the theory behind CON was based on the premise that managing the volume of health care resources available in a region would allow policymakers to mitigate overuse of services and thereby contain health care costs for patients, payers, and providers. Critics of CON argue that it creates more barriers to entry for new facilities leading to greater consolidation and higher health care costs. Some also argue that "regulatory

[22] https://nashp.org/state-legislative-action-to-lower-health-system-costs/

capture" has led the industry to steer CON review processes – meaning that large health systems may use the process to keep out potentially more affordable competitors.

Evidence suggests that the effectiveness of CON programs to limit consolidation and contain rising health care costs largely depends on how a state program is designed and implemented. Anecdotally, NASHP has heard from state officials that the purpose and use of CON has shifted over time. States are mixed in whether they view CON as a form of state health planning (i.e., focused on allocating resources, ensuring access) or a form of cost control. CON is viewed by some as a tool to increase transparency in the health care market, but CON reform alone is not likely to reduce hospitals costs.

NASHP conducted a 50-state-scan of Certificate of Need (CON) programs in 2020. State CON laws differ across states but are generally organized around the following common domains, as detailed in NASHP's 50-state scan:

- The types of health care facilities governed by CON requirements;
- Activities that trigger CON review;
- The agency or board that reviews and approves applications; and
- The information considered during state CON review.

On a personal note, I was working at the Montana Insurance Commissioner office in 2019 and in that capacity, I completed analyses related to Montana's existing CON law and the results of repealing Montana's Certificate of Public Advantage (COPA) law in 2006. The work supported HB 537 to repeal the CON law, as there was no evidence that the CON law reduced prices nor limited consolidation. The bill passed the Montana Legislature but was vetoed by the Governor. In 2021, the bill was again introduced into the Legislative process, and was amended to limit CON provisions to long-term care facilities and swing beds only.

Definitions	Critical concepts that must be opened up in the contract to be discussed and allowed later in the agreement. Difficult to deny the black-and-white existence and justify deletion of a concept.
Carrier Responsibilities:	Outline critical items that the carrier should be obligated to perform and held accountable for on behalf of the employer, for example: • Standardized FWA Programs • Data Specification and Delivery Obligations • Recovery Services, Subrogation and COB standards
Financials	This governs the payments, transparency, fee changes, and other items under the services outlined in the agreement. Examples include: • Preclusion on cross-plan offsetting • Fee transparency (reprocessing fee for errors caused by carrier)
Data Rights and Ownership	Clearly establish FEHBP/OPM right, obligation, control, and primacy over all FEHBP data, layouts, etc.
Audit Rights and Review	Appropriate language to ensure that OPM/OIG, e, as the plan fiduciary, has the freedom needed to review its own data and recover against any fraud, error, waste, or abuse. Examples: • Clinical review filters, • Coding review filters, • Rebate audit flexibility, • Audit determination responsibility (should set forth that in case of disagreement, plan sponsor has final determination rights). • Reserve right of extrapolation.
Overpayment Recoveries	Ensure proper measures, timeframes and means of extrapolation are established, with the goal of limiting potential abuse in this area which can be highly problematic. Examples: • Third party claim recovery utilization approvals; • Overpayment recovery reconciliation reporting requirement; • Preservation of direct recovery authority; • Right to carve out recovery services; • Explicit recovery/remittance timelines and guarantees.
Medical Plan Rebates	Establish how medical plan rebates are tracked, reported, and accounted for in transparent manner including remittance timelines and requirements, specific categorization of medical plan rebates as plan assets, and reporting requirements clearly set forth.
Removal of suboptimal contract provisions	Removal of contract provisions which are unacceptable to the employer as plan fiduciary (i.e., gag clause or limitation on right to carve out PBM services, hidden provider arrangements, hidden fees, etc.)
Performance Guarantees	Move beyond SLA's like "answer time" and "ID card delivery" and include unit price guarantees, trend guarantees, aggregate discount guarantees, etc.
Eligibility Criteria and Monitoring	Ensure all eligibility requirements and ongoing monitoring requirements are uniform across all carriers to ensure program integrity and risk mitigation.

ATTACHMENT B. Examples of noncompliance with Hospital Price Transparency Law.

Example 1:

- Noncompliant: Maimonides Midwood Community Hospital – Brooklyn, NY
- Owner: New York-Presbyterian Healthcare System
- Download Date: 2/22/2023
- Reason: Standard Charges File fails to provide an adequate amount of de-identified minimum (96% N/A), maximum (96% N/A), and negotiated
- Reason: Standard Charges File fails to provide an adequate amount of de-identified minimum (96% N/A), maximum (96% N/A), and negotiated rates (98% N/A).

Code	Description	Type	Package/ Line_Level	Gross Charge	Discounted Cash Price	De-identified min contracted rate	De-identified max contracted rate	1199SEIU-Commercial HMO/ POS_Avg	AETNA-Commercial PPO/Open Access_Avg	AETNA-Commercial HMO/ POS_Avg	AETNA-Medicare Advantage HMO_Avg	AFFINITY-Commercial PPO/ Open Access_Avg	ALLIED BENEFIT-Commercial other_Avg	AMERIGROUP-Commercial other_Avg	BRMS-Commercial other_Avg	CIGNA-Commercial PPO/Open Access_Avg	C
423980	IBUPROFEN INJ 100MG/ML 8ML *R*	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
423990	CLARITHROMYCIN-AMOX-LANSOPRAZ	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
423990	CLARITHROMYCIN-AMOX-LANSOPRAZ	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424020	DICLOFENAC 100MG TAB	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424020	DICLOFENAC 100MG TAB	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424050	DILTIAZEM 360MG UD CAP	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424050	DILTIAZEM 360MG UD CAP	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424070	DOXYLAMINE 25MG TAB	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424070	DOXYLAMINE 25MG TAB	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424170	GLUTAMIC 340MG CAP	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424170	GLUTAMIC 340MG CAP	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424190	IMIGLUCERASE 200U INJ	N/A	N/A	1260	1260	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424190	IMIGLUCERASE 200U INJ	N/A	N/A	1260	1260	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424200	OMEGA 3 OIL INJ 50 ML *IND*	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424200	OMEGA 3 OIL INJ 50 ML *IND*	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424210	FISH OIL FAT EMUL 10G/100ML	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424210	FISH OIL FAT EMUL 10G/100ML	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424230	FISH OIL CONCENTRATE 1000 MG C	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424230	FISH OIL CONCENTRATE 1000 MG C	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424260	CALCITRIOL 1MCG/ML 15ML ORAL L	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424260	CALCITRIOL 1MCG/ML 15ML ORAL L	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424290	UBIDECARENONE Q10 10MG CAP	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424290	UBIDECARENONE Q10 10MG CAP	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424310	POVIDONE IODINE 10% OINT FOILP	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424310	POVIDONE IODINE 10% OINT FOILP	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424320	EPIRUBICIN *NF* 2MG/ML 25ML VI	N/A	N/A	1222	1222	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424320	EPIRUBICIN *NF* 2MG/ML 25ML VI	N/A	N/A	1222	1222	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424340	FINASTERIDE 1MG TAB BULK	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424340	FINASTERIDE 1MG TAB BULK	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424380	KETOTIFEN *NF* 0.025% OPH SOLN	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424380	KETOTIFEN *NF* 0.025% OPH SOLN	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424400	RABEPRAZOLE *NF* 20MG UD TAB	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424400	RABEPRAZOLE *NF* 20MG UD TAB	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424450	FINASTERIDE TAB 1MG	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424450	FINASTERIDE TAB 1MG	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424470	BERACTANT SUSP 4ML VIAL	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424470	BERACTANT SUSP 4ML VIAL	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424490	RED YEAST RICE 600MG CAP	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424490	RED YEAST RICE 600MG CAP	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424520	ESTRADIOL-NORETHINDRONE *NF* 5	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424520	ESTRADIOL-NORETHINDRONE *NF* 5	N/A	N/A	1257	1257	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424550	AMPHOTERICIN LIPID COMPLEX *NF	N/A	N/A	1260	1260	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424550	AMPHOTERICIN LIPID COMPLEX *NF	N/A	N/A	1260	1260	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/
424560	TIROFIBAN 12.5MG 250ML.2MG	N/A	N/A	1260	1260	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/

When cross referencing the N/As under the Cigna PPO plan in the hospital data, prices were found for certain CPT codes listed as N/A for the same Cigna PPO plan in the Transparency in Coverage data. Shown on following page.

Code Type	Code	Code Description	Payer	Price in Maimonides (New York Community Hospital) File	Price in Transparency in Coverage File
CPT	70553	MRI scan of brain before and after contrast	Cigna PPO	N/A	$536.25
CPT	72110	X-ray of lower and sacral spine, minimum of 4 views	Cigna PPO	N/A	$82.93
CPT	72148	MRI scan of lower spinal canal	Cigna PPO	N/A	$307.86
CPT	72193	CT scan pelvis with contrast	Cigna PPO	N/A	$422.58
CPT	73721	MRI scan of leg joint	Cigna PPO	N/A	$346.56
CPT	74177	CT scan of abdomen and pelvis with contrast	Cigna PPO	N/A	$535.50
CPT	76805	Abdominal ultrasound of pregnant uterus (greater or equal to 14 weeks 0 days) single or first fetus	Cigna PPO	N/A	$202.15
CPT	77065	Mammography of one breast	Cigna PPO	N/A	$196.15
CPT	77066	Mammography of both breasts	Cigna PPO	N/A	$250.88
CPT	77067	Mammography of both breasts	Cigna PPO	N/A	$207.39
CPT	80055	Obstetric blood test panel	Cigna PPO	N/A	$102.72
CPT	80069	Kidney function blood test panel	Cigna PPO	N/A	$18.74
CPT	81000	Manual urinalysis test with examination using microscope	Cigna PPO	N/A	$9.00
CPT	81002	Urinalysis, manual test	Cigna PPO	N/A	$7.50
CPT	81003	Automated urinalysis test	Cigna PPO	N/A	$4.50
CPT	85027	Complete blood cell count (red cells, white blood cell, platelets), automated test	Cigna PPO	N/A	$14.25
CPT	85610	Blood test, clotting time	Cigna PPO	N/A	$9
CPT	85730	Coagulation assessment blood test	Cigna PPO	N/A	$12.75

Example 2:

- Noncompliant: Eastern Idaho Regional Medical Center – Idaho Falls, ID
- Owner: Hospital Corporation of America
- Download Date: 2/22/2023
- Reason: Standard charges file fails to provide adequate pricing information for major payer negotiated rates as well as de-identified min/max charges; has non-searchable incomplete, overbroad, or inapplicable descriptions; contains calculation instructions in place of numerical prices in negotiated rates, minimum and maximum fields, and non-searchable code ranges.

Aetna		
Service Description	Coding	Rate
Burn		62.5% of BC
Cardiac Cath		57.4% of BC
Critical Care		62.5% of BC
ER		62.5% of BC
ICU/ Other		62.5% of BC
ICU/ Trauma		62.5% of BC
Intensive Care		62.5% of BC
Neonate		62.5% of BC
Other Inpatient		47.5% of BC
Other Outpatient		47.5% of BC
Other Surgical Services		57.4% of BC
Post ICU		62.5% of BC
Trauma Team - Level 1		62.5% of BC
Trauma Team - Level 2		62.5% of BC
Trauma Team - Level 3		62.5% of BC
Trauma Team - Level 4		62.5% of BC
Trauma Team Other		62.5% of BC
Urgent Care		62.5% of BC
BC ID		
Service Description	Coding	Rate
Behavioral Health	MS-DRG 880-897	$1,643.00
Behavioral Health	CPT/HCPC 90853, 90857	$100.00
Behavioral Health	CPT/HCPC H0015	$274.00
Behavioral Health	CPT/HCPC S9480	$274.00
ECT		$345.00
Inpatient DRG		$22,457.00
Neurosurgery	MS-DRG 028	$44,068.00
Neurosurgery	MS-DRG 030	$23,733.00
Neurosurgery	MS-DRG 471	$43,367.00
Neurosurgery	MS-DRG 472	$27,269.00
Neurosurgery	MS-DRG 473	$19,617.00

Blue arrows indicate no plan names (this hospital just lists Aetna and BlueCross Idaho), vague service categories (Other Inpatient/Other Outpatient), no specific codes (blanks), and no prices just algorithms (% of BC, but what is BC?).

ATTACHMENT C – 340B Prime Vendor Apexus Report. *Note: There are 2 errors in the report: The date should have been entered as August 12, **2022**; 2015 column sums to $8,892,304,847, but the total is shown as $12,129,305,547 (previous HRSA reporting indicates the $12,192,305,547 is the correct figure.)*

340B Program Annual Sales By Covered Entity Type - Calendar Year 2015-2021

Entity Type	2015	2016	2017	2018	2019	2020	2021
Black Lung Clinics	$ -	$ -	$ -	$ -	$ 16,778	$ 18,663	$ 189,963
Critical Access Hospitals	$ 257,123,362	$ 267,773,283	$ 314,757,526	$ 365,069,301	$ 401,718,853	$ 523,607,285	$ 620,923,559
Free-standing Cancer Centers	$ 77,983,883	$ 109,562,532	$ 128,913,179	$ 248,934,285	$ 167,479,811	$ 224,260,557	$ 304,098,033
Consolidated Health Center Programs	$ 656,965,520	$ 882,238,476	$ 1,070,480,602	$ 1,341,425,022	$ 1,600,976,635	$ 1,973,000,093	$ 2,215,221,250
Disproportionate Share Hospitals	$ 6,323,756,520	$ 13,097,758,367	$ 15,513,410,649	$ 19,330,988,761	$ 23,750,617,275	$ 29,800,239,635	$ 34,288,472,705
Family Planning Clinics	$ 101,370,490	$ 107,126,469	$ 81,149,895	$ 121,564,544	$ 93,789,017	$ 83,817,433	$ 74,912,338
Tribal Contract/Compact with IHS (P.L. 93-638)	$ 28,005,517	$ 27,274,783	$ 26,030,341	$ 27,958,680	$ 25,078,575	$ 29,330,475	$ 30,973,328
Federally Qualified Health Center Look-Alike	$ 27,667,252	$ 23,346,274	$ 16,278,291	$ 41,094,733	$ 115,779,226	$ 117,309,366	$ 173,025,319
Comprehensive Hemophilia Treatment Center	$ 66,462,384	$ 97,500,034	$ 87,840,523	$ 89,376,046	$ 132,378,826	$ 213,701,367	$ 192,106,843
Ryan White Part C	$ 200,886,863	$ 257,673,661	$ 276,770,653	$ 314,011,208	$ 357,086,962	$ 412,826,646	$ 519,299,391
Native Hawaiian Health Care Programs	$ 1,674	$ 1,616	$ 992	$ 311	$ 3,727	$ 17,600	$ 23,305
Children's Hospitals	$ 232,735,778	$ 345,931,885	$ 402,179,065	$ 541,214,979	$ 784,312,496	$ 1,166,186,227	$ 1,330,248,212
Rural Referral Centers	$ 150,485,850	$ 145,044,196	$ 262,730,171	$ 403,259,214	$ 430,924,967	$ 870,752,351	$ 1,174,151,155
Ryan White Part D	$ 14,873,952	$ 15,376,732	$ 16,424,189	$ 24,902,844	$ 33,854,867	$ 37,751,212	$ 43,419,350
Ryan White Part A	$ 318,375,942	$ 368,952,764	$ 487,655,040	$ 619,967,731	$ 871,962,191	$ 1,064,750,068	$ 1,151,719,110
Ryan White Part B	$ 75,371,845	$ 123,025,622	$ 132,148,555	$ 190,775,092	$ 235,600,108	$ 235,353,430	$ 234,735,497
Ryan White Part B ADAP Direct Purchase Option	$ 126,175,607	$ 127,118,281	$ 132,469,021	$ 132,924,412	$ 227,355,275	$ 264,264,575	$ 230,807,198
Ryan White Part B ADAP Rebate Option	$ 125,873	$ 101,637	$ 724	$ 1,884	$ 16,192	$ 31,728	$ 23,336
Sole Community Hospitals	$ 157,193,849	$ 173,048,114	$ 206,172,786	$ 283,320,713	$ 337,622,313	$ 406,279,878	$ 451,594,319
Sexually Transmitted Disease Clinics	$ 35,377,731	$ 60,834,866	$ 126,679,237	$ 224,033,737	$ 375,361,823	$ 564,787,289	$ 871,036,833
Tuberculosis Clinics	$ 9,744,111	$ 9,117,705	$ 6,891,828	$ 8,642,773	$ 5,950,017	$ 4,673,856	$ 4,278,525
Urban Indian Hospitals	$ 357,014	$ 425,094	$ 1,266,290	$ 1,225,226	$ 929,863	$ 758,122	$ 1,154,612
Unidentified*	$ 31,263,830	$ 6,072,411	$ 210,178	$ 921,260	$ 157,921	$ 87,647	$ -
TOTAL	$ 12,192,304,547	$ 16,245,304,800	$ 19,290,459,716	$ 24,311,612,555	$ 29,948,773,738	$ 37,993,805,503	$ 43,912,414,181

*Unidentified - Sales that have been reported, but inadequate information in the transaction leads to the sale not being attributable to a specific covered entity.

Source: 340B Prime Vendor, August 12, 2021

Note: These sales data are provided by the 340B Prime Vendor Program and do not capture the entire universe of 340B Program sales (e.g. the Prime Vendor Program does not collect all direct sales). The Prime Vendor Program was established pursuant to section 340B(a)(8) of the Public Health Service Act for price negotiation, distribution facilitation, and other activities in support of the 340B Drug Pricing Program. It is managed by Apexus through a contract with the Health Resources and Services Administration.

These figures are accurate as of August 12, 2021. The sales data provided is a culmination of transactional data captured by the Prime Vendor Program at a given point in time. The totals reflected in this chart may change, as the 340B Prime Vendor is constantly reviewing and updating the data as transactions occur. There are times when adjustments to invoices are made impacting the total sales reported (i.e., a return of product which resulted in a decrease in the sales volume). In addition, the reporting of data has improved over time, which may reflect the various increases over time.

Entity organizations are defined at section 340B(a)(4) of the Public Health Service Act.