

Regulatory & Market Trends in Health Insurance

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AGENDA

- Transparency in Coverage
- No Surprises Act (Consolidated Appropriations Act, 2021)
- COVID-19 Testing
- Market Trends in Pharmacy
- What's Next in Healthcare and Health Insurance?

Transparency in Coverage



WILL DATA TRANSPARENCY “UN-BREAK” THE HEALTHCARE DELIVERY SYSTEM?

- People say the U.S. healthcare system is “broken.” We spend 18% of the GDP on healthcare, when similar nations spend around 11%.
- Healthcare’s core dysfunction is misalignment of incentives.
 - Medical providers succeed by maximizing the price per service and delivering as many services as possible.
 - Insurers profit by spending fewer premium dollars on healthcare, which they achieve by negotiating lower rates with providers, denying coverage, and passing costs along to members and employers.
 - Patients win when they receive high-quality care, avoid unnecessary services, and spend less money out-of-pocket.
- For any stakeholder to achieve its goals under existing incentives, the others must fail.



Final Regulations

- On Oct. 29, the Tri-agencies issued the final rule for the plan- and issuer-focused transparency requirements.
- Final Rule requires most group health plans and issuers in individual and small group markets to provide:
 - Personalized Disclosure of Out-of-Pocket (OOP) Costs
 - Public Disclosure of In-Network (IN) Negotiated Rates and Out-of-Network (OON) allowed amounts

➤ Goal:

Enable beneficiaries to obtain an estimate of OOP expenses in advance and shop for covered items and services

Transparency Tool

- Initial tools required by Jan. 1, 2023
- These estimates must be available for all types of items and services and:
 - By 2023, a subset of 500 specific items and services defined by HHS
 - By 2024, all items and services
- Tool must provide ability to search by billing code, service description, name of provider, etc.
- Must be available via website and paper upon request

➤ Goal:

Allow IT developers, researchers, industry experts, plans and issuers to further innovate using this price information

Machine-Readable Files

- Effective July 1, 2022
- The Final Rule requires health plans to make available to the public three machine-readable files of pricing information:
 - All applicable rates
 - Billed charges and allowed amounts
 - Negotiated rates and historical net prices for prescription drugs

PRICE TRANSPARENCY IS (PROBABLY) GOING TO CHANGE HEALTHCARE

- Penalties for noncompliance:
 - Insurers and employers can be fined up to \$100/day/person for noncompliance.
 - Hospital penalties are more modest and compliance has been inconsistent so far, but that will likely change over time.
- Providers and insurers take on greater accountability to reduce costs or justify higher-priced services with additional value (quality, clinical outcomes, convenience, patient experience).
 - This brings healthcare a little closer to obeying traditional market dynamics where cost and value are correlated.
- Tech companies have a huge opportunity here to provide insurers and employers with more negotiating power with providers and prevent low-value spending.
 - Just my opinion, companies like Optum and CVS will be first to figure out what this future landscape can look like.
- Incentive misalignments still exist, though.

No Surprises Act



Nebraska Out-of-Network Emergency Medical Care Act

- Nebraska Law:
 - Out-of-Network Emergency Medical Care Act, §§ 44-6836 to 44-6846.
 - Services covered: “health care services medically necessary to screen and stabilize a covered person in connection with an emergency medical condition” . . . received “at an in-network or out-of-network health care facility”
 - “Emergency” defined as treatment to diagnose and stabilize the patient.
 - Limited to a general acute hospital, satellite emergency department, or ambulatory surgical center

➤ Consideration:

Interaction between Nebraska's Out-of-Network Emergency Medical Care Act, including ERISA preemption

Surprise Billing “No Surprises Act”

- Effective for plan years starting Jan. 1, 2022
- Patients responsible for only INN cost-sharing amounts, including deductibles, in emergency situations and certain non-emergency situations
- Prohibits OON providers from balance billing patients*
- Payments to OON providers would be determined either through negotiation or arbitration
- Covers more than the Nebraska statute, including air ambulance and a little more of the hospital stay after an emergency condition is stabilized.

RESOLVING DISPUTES OVER PAYMENT AMOUNTS

- State regulators are not the facilitator for either the Nebraska or federal bill negotiation processes. The provider and insurer are required to work directly with one another.
 - For NSA, Informal Dispute Resolution (IDR) is facilitated through a portal at <https://www.cms.gov/nosurprises> using a list of approved arbitrators.
 - Federal law uses “baseball” arbitration: each party comes to the table with their best offer to settle the bill, then the arbitrator must choose one offer or the other.
 - The IDR process uses a “loser pays” rule – the party that made the losing offer is required to pay the full cost of arbitration.
 - Nebraska’s surprise balance billing law allows mediation but does not prescribe how the parties would agree on a mediator or which mediators would qualify.
 - Nebraska law uses a two-step process: 175% of Medicare is presumed reasonable, then if the provider wants to contest that amount, provider must return the payment and engage in mediation.

➤ **Consideration:**

Should an arbiter consider the median contracted rate for a service as reasonable during a payment dispute?

Texas Medical Association v. HHS

- Under Interim Final Rule, arbitrator should select the rate most closely aligned with the Qualifying Payment Amount (QPA) (“median contracted rate”)
- TMA challenged regulation:
 - Violation of APA by using an IFR
 - QPA presumption conflicts with the statute
- Court: no deference to the agencies and cannot bypass notice and comment

➤ Consideration:

Who has the enforcement authority to prevent providers from balance billing their patients?

A Regulator's Perspective

- Regulating competing state and federal laws
- Federal/state enforcement coordinated through “collaborative enforcement agreements”
- Contrasting enforcement experience with state balance billing laws in TX compared to NM and WA
- Nebraska DOI more likely to obtain voluntary compliance compared to feds (we think)

SURPRISE BALANCE BILLING ENFORCEMENT

“SEC. 2799D. ENFORCEMENT.

“(a) STATE ENFORCEMENT.—

“(1) STATE AUTHORITY.—Each State may require a provider or health care facility subject to the requirements of sections 2799, 2799A, 2799B, or 2799C to satisfy such requirements applicable to the provider or facility.

“(2) FAILURE TO IMPLEMENT REQUIREMENTS.—In the case of a State that fails to substantially enforce the requirements set forth in this part with respect to applicable providers and facilities in the State, the Secretary shall enforce the requirements of this part under subsection (b) insofar as they relate to actions prohibited under this part occurring in such State.

“(c) CONTINUED APPLICABILITY OF STATE LAW.—This part shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any requirement or prohibition except to the extent that such requirement or prohibition prevents the application of a requirement or prohibition of this part.”.

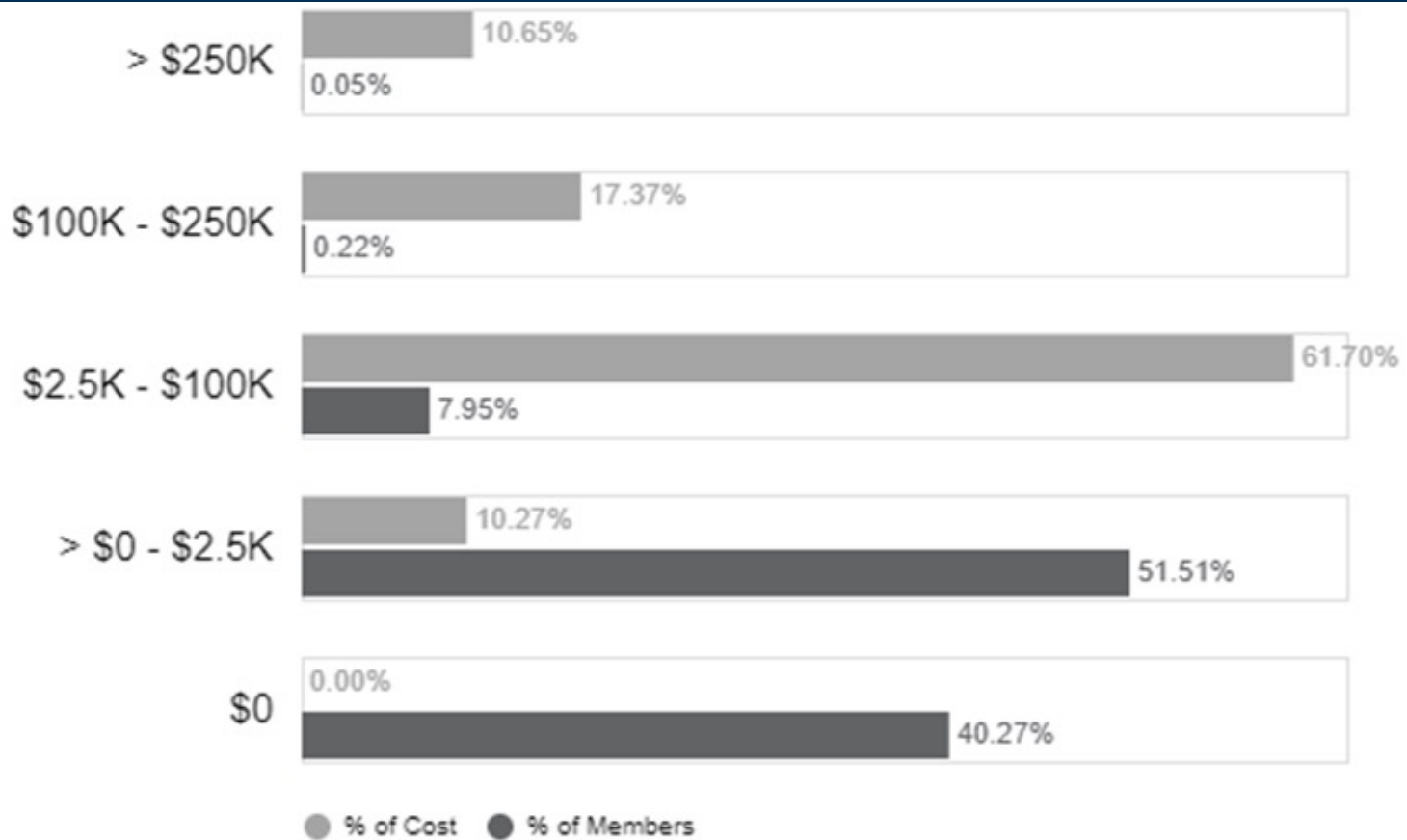
Market Trends in Pharmacy



DRUG PRICE INCREASES DURING THE PANDEMIC

- Pharmaceutical companies raised the price of 245 drugs between January 20 and June 20, 2020 according to [analysis](#) by Patients for Affordable Drugs.
- **Between the lines:** Some of these drugs are directly related to the pandemic. And the hikes occurred against the backdrop of economic calamity hitting many American families.
 - The average price increase was 23.8%.
- **By the numbers:** 61 of the drugs with price hikes were being used to treat the coronavirus, while another 30 were undergoing clinical trials for use against it.
 - Some of the drugs — like those used to sedate ventilated patients — saw both a surge in demand and an increase in price.
 - "Although some price hikes may be attributable to interruptions in global manufacturing supply chains, others can be attributed to opportunistic hikes in the face of steep increases in demand," the authors write.
- **Another 118 drugs** that saw price increases are used to manage chronic conditions.
 - These patients are generally more vulnerable to severe coronavirus infections.

Distribution of commercial drug spend and utilization



Drugs are
34%
of total health spend

2018 Medical and Pharmacy drug spend	% of cost	% of members
\$0	0%	34.4%
>\$0 to \$2,500	14.7%	58.5%
\$2,500 to \$100,000	63.8%	7.0%
>\$100,000 to \$250,000	12.9%	0.12%
>\$250,000	8.6%	0.03%



Gene therapies in the pipeline

Gene Therapy	Estimated Launch	Disease	Estimated Cost
Etranacogene Dezaparvovec (AMT-061) or fidanacogene elaparvovec (SPK-0991)	2021 2H	Hemophilia B	\$2,500,000
Libmedly (OTL-200)	2021 2H	Late Juvenile Metachromatic Leukodystrophy (MLD)	\$3,250,000
SRP-9001	2021 H2	Duchenne Muscular Dystrophy	\$2,000,000
Eli-Cel, Lenti-DTM (elivaldogene tavalentivec)	2021 Q4	childhood cerebral form of adrenoleukodystrophy (CALD).	\$2,000,000
LentiGlobin-TDT (betibeglogene darolentivec)	2021 Q4	Transfusion dependent Beta Thalassemia	\$2,000,000
PTC-AADC (eladocogene exuparvovec)	2021 Q4	Aromatic L-amino Acid Decarboxylase (AADC) Deficiency	\$4,000,000
Lumevoq® (GS010; lenadogene nolparvovec)	2022	Leber Hereditary Optic Neuropathy (LHON)	\$750,000
OTL-103	2022	Wiskott-Aldrich Syndrome	\$2,000,000
Roctavian (valoctocogene roxaparvovec)	2022	Hemophilia A	\$3,000,000
timrepigine emparvovec (BIIB111)	2022	Choroideremia	\$1,000,000
LentiGlobin-SCD	2022-2023	Sickle Cell Disease	\$1,000,000
AGTC-501	2022+	X-Linked Retinitis Pigmentosa	\$700,000
AT132 (resamirigene bilparvovec)	2022+	X-linked Myotubular Myopathy (XLMTM)	\$3,000,000
Olenasuflogene relduparvovec (LYS-SAF302) or ABO-102 (rebisuligene etiparvovec)	2022+	Muchopolysaccharoidosis III	\$2,000,000
simoladagene autotemcel (OTL-101)	2022+	Severe Combined Immunodeficiency Due to Adenosine Deaminase Deficiency (ADA- SCID)	\$2,000,000
Luxturna® (voretigene neparvovec-rzyl)	Launched	Biallelic RPE65 mutation-associated retinal dystrophy	\$850,000
Zolgensma® (onasemnogene abeparvovec-xioi)	Launched	Spinal muscular atrophy	\$2,125,000

DRUG COUPONS

- Drug coupons are usually reserved for the newest and most expensive medications.
- Coupons are usually short-lived and have annual maximums that would leave patients and Medicare accountable to pay the remaining fee for the rest of the year.
- The federal government does not allow using drug coupons together with Medicare Part D.
 - The Anti-Kickback Statute prohibits anyone – drug manufacturers included – from giving a customer anything of value that could result in referrals for items or services that are paid for by a federal healthcare program.
 - If a drug manufacturer entices a patient to choose more expensive options, Medicare would likely spend more money than it would without the kickback.
- Contrast this with the ACA, which is not a “federal healthcare program” despite federal payment of a large percentage of most enrollees’ premiums.
 - Federal regulations required that private insurers not only allow patients to use drug coupons, the insurers would have to count drug coupons as money the patient spent toward deductible and maximum out-of-pocket.
 - This rule only applied if there was no generic alternative available.
 - CMS non-enforcement because of problems with HSAs.

COVID-19 Testing



TRANSPARENCY DID NOT PREVENT HIGH PRICES FOR COVID TESTS

- Section 3202(a) of the CARES Act generally requires plans and insurers to reimburse any provider of COVID-19 diagnostic testing an amount that equals the negotiated rate or, if the plan or issuer does not have a negotiated rate with the provider, the cash price for such service that is listed by the provider on its public website.
- One COVID test provider posted a charge of \$999 for one test on its website.
 - The Medicare allowable price is \$142.63 for that test.
- The same COVID test provider posted \$799 for another test on its website.
 - The Medicare allowable price for that test is \$42.13.
- This lab does not test individuals without private insurance.
- Insurers objected to price gouging.
- Multiple states received complaints.

➤ Consideration:

What is a “cash price”?

Testing Regulatory Landscape

- HHS/DOL/Treasury: “the charge that applies to an individual who pays cash (or a cash equivalent) for a COVID-19 diagnostic test.”
- Expectation was that cash price would be lower than a negotiated rate with a contracting provider.
- What if the “cash price” is only charged to insurance, not consumers?
- Price gouging.... litigation... confusion

Crystal Ball – What's Next?



➤ **Crystal Ball:**

What's next after
Transparency in
Coverage and the
CAA?

Life After TiC/CAA

- Biden Budget: free coverage for three behavioral health visits and three primary care visits
- Focus on child and adolescent mental health
- Telehealth
- Pharmacy Benefit Managers (PBMs)
- American Rescue Plan Act (ARPA) subsidies end 12/31/22 unless Congress acts. If no action, (out-of-pocket) premiums go back up on 1/1/23.

Questions?

