

The background features a dark purple field with intricate, flowing, wavy lines in a lighter shade of purple. These lines create a sense of movement and depth. A large, semi-transparent rectangle is centered over the image, serving as a backdrop for the text.

AmerisourceBergen



Joel White

President & CEO, Horizon Government Affairs

Joel is the Founder and President of Horizon Government Affairs, a health care consultancy in Washington, DC. Previously, Joel spent twelve years on Capitol Hill and was the Staff Director of the Ways and Means Health Subcommittee where he helped enact significant health policy changes that have improved the lives of tens of millions of people. These include enactment of Medicare Part D and the creation of Health Savings Accounts.

Inflation Reduction Act and Prescription Drug Reforms

What does it mean and what will happen next?

Your Presenter



Joel White
CEO, Horizon
Government Affairs

Founded HGA, a bipartisan company health consultancy, in 2007

- 50 laws enacted for clients
- Dozens of regulatory wins
- Hundreds of millions in federal, state funding

Former Staff Director, Ways and Means Health Subcommittee

- Wrote nine laws
- Created Part D, HSAs and reformed payments for Part A and B
- Produced more than 100 hearings

Speaker is being compensated for his presentation today by International Oncology Network (“ION”), however neither ION nor any pharmaceutical company has influenced the content of this presentation nor has ION independently verified the presentation for accuracy.

End-Of-Year Outlook

September 30

CR Expires

Government Funding Deadline

FDA User Fees Expire

November 8

Election Day!

2022 Midterm Election

December 16

End of short-term CR

Omnibus Legislation to fund government

October

November 9

January 1

Campaigning

- House out
- Senate has 9 legislative days
- Regulations likely

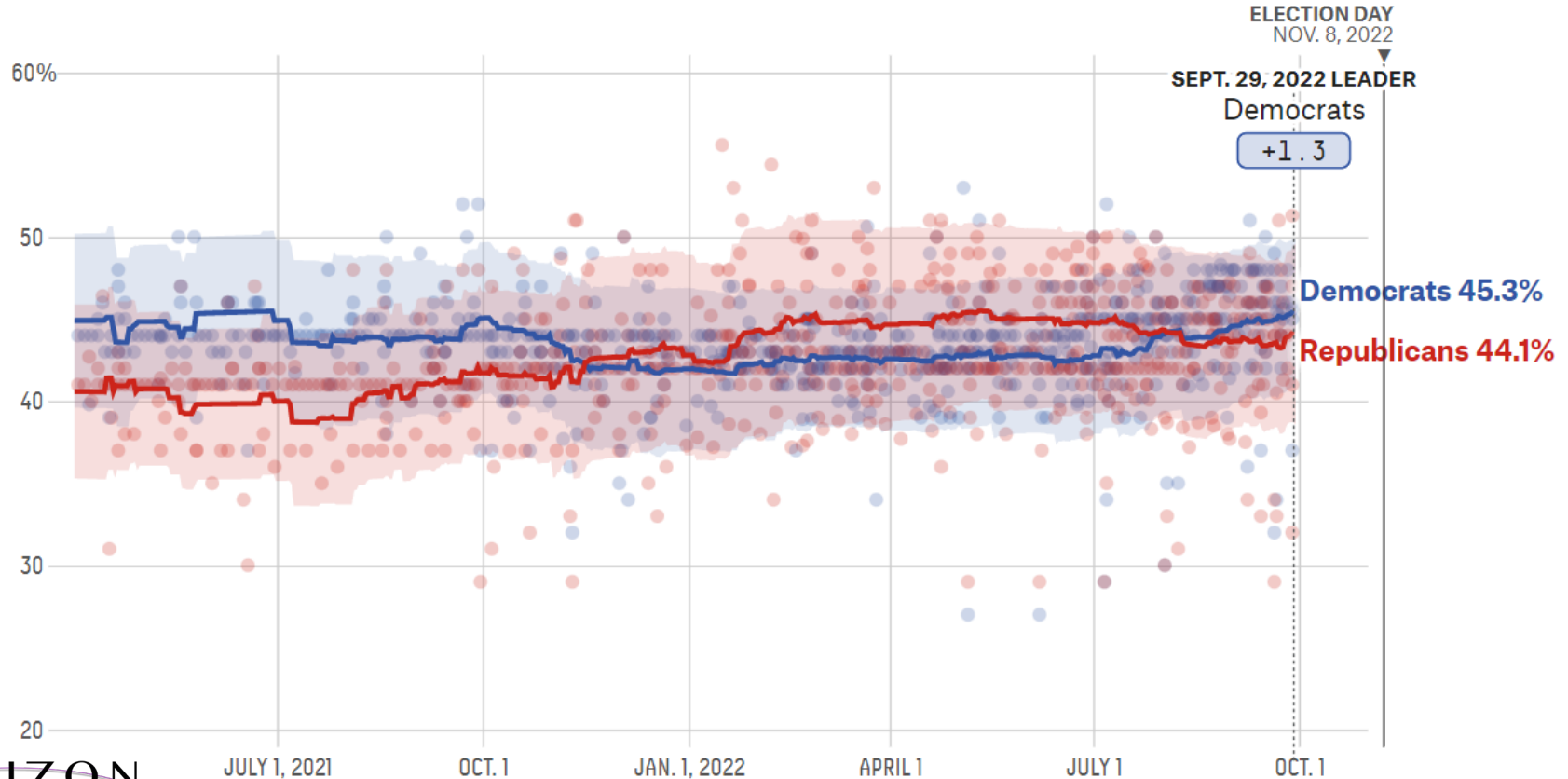
Lame Duck Begins

Potential Legislation

Medicare Payment Cuts

Do voters want Republicans or Democrats in Congress?

An updating estimate of the generic congressional ballot, based on polls that ask people which party they would support in an election.





Physician Payment Issues

A Grim Future

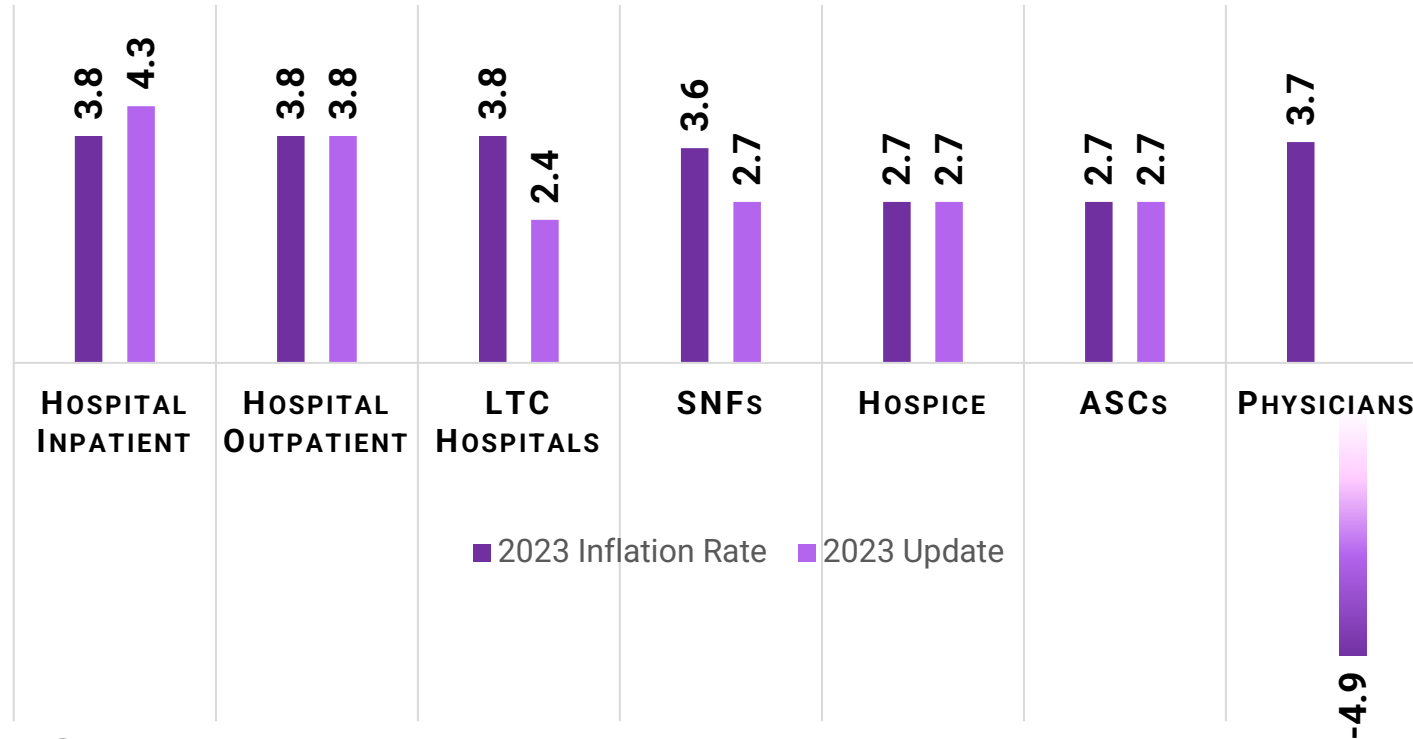
2022

- 2% Medicare sequester
- 8.3% inflation

2023

- 4% PAYGO sequester
- 2% annual sequester
- 4.4% reduction in conversion factor
- 1.5% reduction due to budget neutrality
- Expiration of the one-time 3% increase Congress passed last December
- End of 5 percent Advanced Alternative Payment Model (AAPM) participation incentive and \$500 million in exceptional performance bonuses under MIPS

2023 MEDICARE PROVIDER UPDATES



Congress to the Rescue?

- Provides a 4.42 percent physician fee schedule (PFS) adjustment from January 1, 2023, through January 1, 2024.
- HHS and Congress should execute administrative and legislative actions to:
 - (1) promote Medicare physician payment system financial stability and predictability;
 - (2) encourage and reward innovation in value-based care; and
 - (3) advance health equity by ensuring timely access to quality care.



117TH CONGRESS
2^D SESSION

H. R. 8800

To amend title XVIII of the Social Security Act to extend certain increases in payments for physicians services under the Medicare program through 2023.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 13, 2022

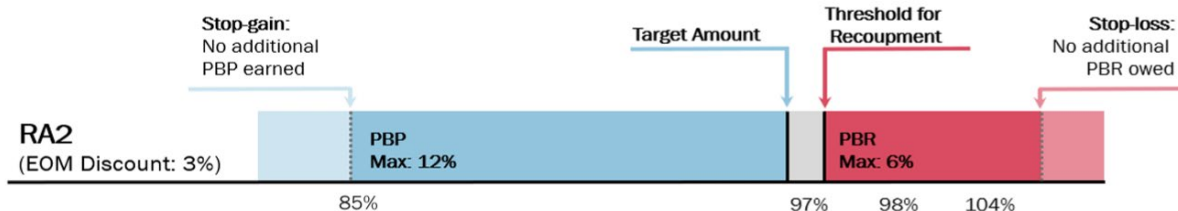
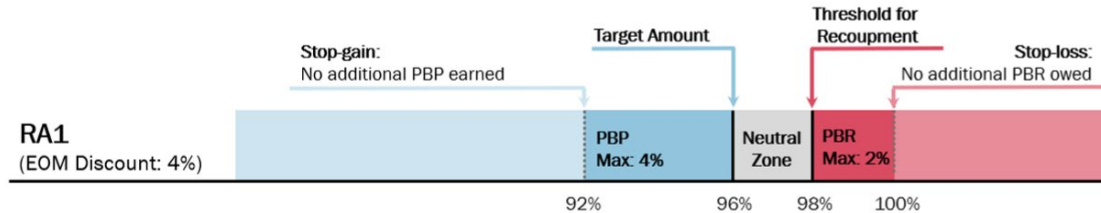
Mr. BERA (for himself and Mr. BUCSHON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition



EOM Model

OCM to EOM

	OCM	EOM
Population	21 cancer types	7 cancer types
Quality/Reporting	6 practice redesign activities	OCM + 2 new PRAs – electronically submitted patient outcomes and health-related social needs
MEOS Payment	\$160 included in TCOC	\$100 but \$30 excluded from TCOC
Downside Risk	No	Yes
Timing	Discontinued	Sign up by October 10. Program starts July 2023 and ends in 2028





Inflation Reduction Act

What Does it all Mean and What's Next?

Overview – Inflation Reduction Act Health Provisions



Medicare

- Imposes price caps on Part B and D drugs
- Reforms Part D benefit and caps out of pocket costs
- Imposes rebates on price increases greater than inflation
- Limits beneficiary out-of-pocket costs for insulin
- New add-on payment for biosimilars in Part B
- Eliminates cost sharing on some vaccines in Medicare

Rebates

- Nullifies Trump-era rule requiring plans to pass rebates on to patients at the pharmacy counter until 2032



ACA

- Extends ACA subsidies for higher income, while making more generous subsidies for lower income

Timeline for Prescription Drugs Provisions in Inflation Reduction Act

2022

2023

2024

2025

2026

2027

2028

2029

Limits Part D Premium Growth to 6 Percent Annually (2024-29)

Prohibits Implementation of Rebate Rule Prior to January 1, 2032

Medicare will pay ASP+8 percent for certain biosimilars

Requires drug companies to pay rebates if Medicare drug prices rise faster than inflation

Eliminates beneficiary cost-sharing for Part D catastrophic coverage

Adds \$2,000 out-of-pocket cap in Part D

Shifts risks between plans and taxpayers

Drug Pricing Negotiation/Caps Imposed

•10 Medicare Part D drugs

•15 Medicare Part D drugs

•15 Medicare Part B and Part D drugs

•20 Medicare Part B and Part D drugs

Eliminates cost sharing for vaccines covered under Part D and caps insulin costs to \$35/month

Expands income eligibility to 150% FPL for full Low-Income Subsidies

Allows beneficiaries to “smooth” cost-sharing throughout the year

Drugs included in price caps are cumulative - by 2029 there will be 60 drugs subject to controls.

Maximum Price Cap Guides Price Setting

- The law imposes specific price controls that must be applied for drugs
- While there is a price ceiling, there is no minimum price required. As a result, HHS can presumably set prices to \$0.01 per unit
- Only way to come off the price control list is if there is a generic competitor
- But drugs on the list are not “monopoly” products as there is brand competition and therapeutic alternatives

Category	Definition	Maximum Price
“Short monopoly drug”	approved for less than 12 years	75 percent
“Extended monopoly drug”	approved between 12 and 16 years, excluding vaccines and a selected drug with a negotiation agreement entered into before 2030	65 percent
“Long monopoly drug”	approved for more than 16 years, excluding vaccines	40 percent

Part B and D Highest Spend Drugs

- In 2020, the top 10 drugs accounted for 40% (\$15.6 billion) of Part B drug spending and 21% (\$42.5 billion) of Part D spending before rebates
- Drugs with competition are excluded from MFP
- The average length of time before entry of generic or biosimilar competition has historically exceeded 14 years



Drug (Brand Name)	2020 Medicare Gross Spending (\$, millions)	Years Since Approval	Estimated Year Eligible for MFP
Part D			
	\$9,93		
Apixaban (Eliquis)	6	10	2026
Lenalidomide (Revlimid)	5,356	17	N/A ¹
Rivaroxaban (Xarelto)	4,701	11	2026
Adalimumab (Humira) ²	4,167	20	2026
Sitagliptin (Januvia)	3,565	16	2026
Insulin Glargine (Lantus)	3,719	22	N/A ¹
Dulaglutide (Trulicity)	3,285	8	2026
Ibrutinib (Imbruvica)	2,963	9	2026
Empagliflozin (Jardiance)	2,376	8	2026
Palbociclib (Ibrance)	2,109	8	2026
Part B			
	\$3,55		
Pembrolizumab (Keytruda)	8	8	2028
Afilbercept (Eylea)	3,039	11	2028
Denosumab (Prolia)	1,996	12	2028
Nivolumab (Opdivo)	1,624	8	2028
Abatacept (Orencia)	1,435	17	2028
Rituximab (Rituxan)	1,351	25	N/A ¹
Ranibizumab (Lucentis)	1,116	16	N/A ¹
Pegfilgrastim (Neulasta)	941	20	N/A ¹
Daratumumab (Darzalex)	858	7	2029
Bevacizumab (Avastin)	700	18	N/A ¹
¹ Drug already has a marketed generic or biosimilar competitor			
² Expected biosimilar competition before 2026			

Inflation Rebates

- Requires manufacturers to pay a rebate on all non-Medicaid sales for drugs covered by Medicare Parts B and D whose ASP or AMP (respectively) in a given year is greater than its ASP or AMP in 2021, adjusted for inflation as measured by the CPI-U
- Starts in October 2022 for Part B drugs and April 2023 for Part D Drugs. Rebate is 125% of amount owed
- CBO estimates this provision would generate ~\$100 billion over 10 years

Category	Part B	Part D
Drugs	Single source drugs and biologics excluding vaccines and those less than \$100 per year	All part D drugs, including line extensions
Cost Basis	106% of ASP for the quarter six months before the current quarter	Weighted average AMP by units for each quarter
Benchmark Year	Q3 2021 or 3 rd full quarter post launch	2021 AMP or first calendar year post launch
Inflation Adjustment	September 2021 CPI-U, or first quarter post-launch	September 2021 CPI-U or January post launch to January current year
When does the this apply?	Q3 2023 or six full quarters post-launch	2023 or first full calendar year post launch

Inflation Rebates Continued



CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

Phillip L. Swagel, Director

August 4, 2022

Honorable Jason Smith
Ranking Member
Committee on the Budget
U.S. House of Representatives
Washington, DC 20515

Re: Additional Information About Prescription Drug Legislation

Dear Congressman:

This letter provides additional information that you and your colleagues

"The Congressional Budget Office projects that the inflation-rebate and negotiation provisions would increase the launch prices for drugs that are not yet on the market relative to what such prices would be otherwise ...manufacturers would have an incentive to launch new drugs at a higher price to offset slower growth in prices over time."

Biosimilars

- Updates the add-on payment for biosimilars from 6% to 8% of the reference product average sales price for 2022 to 2027

Vaccines

- Requires zero coinsurance for vaccines recommended by the Advisory Committee on Immunization Practices under Medicare Part D
- Requires coverage of certain adult vaccinations under Medicaid while also eliminating some cost-sharing
- Increases by 1% the Federal Medical Assistance Percentage (FMAP) for adult vaccines and administration
- Requires the coverage and eliminates cost-sharing of recommended adult vaccines or individuals ages 19 and older under CHIP

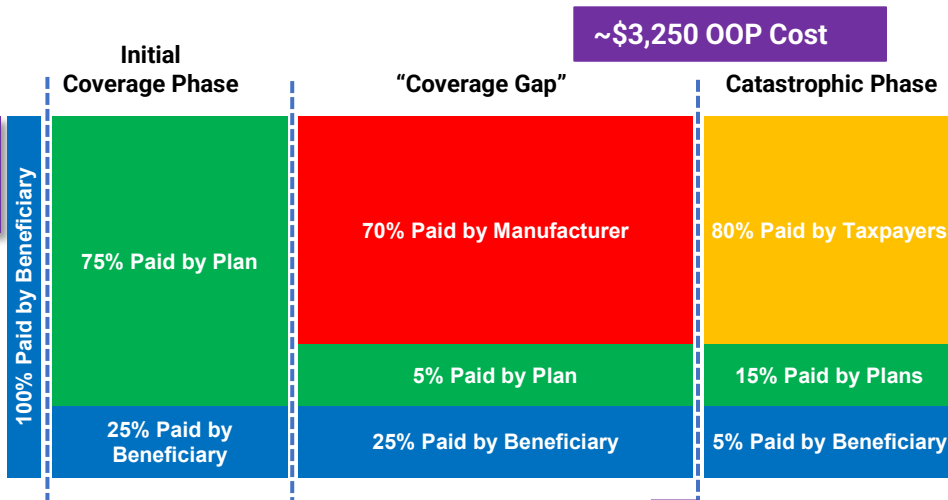
Insulin

- In Medicare Part B and D Insulin OOP costs are capped:
 - \$35 per month from 2023 through 2025
 - Beginning in 2026, insulin is capped at the lowest of:
 - \$35 per month;
 - 25% of the established maximum fair price; or
 - 25% of the negotiated price.
- Deductible does not apply
- Effective Jan. 1, 2023, creates a safe harbor that allows employers with an HSA qualified health plan to cover any insulin dosage of any type before the individual meets the plan's deductible.

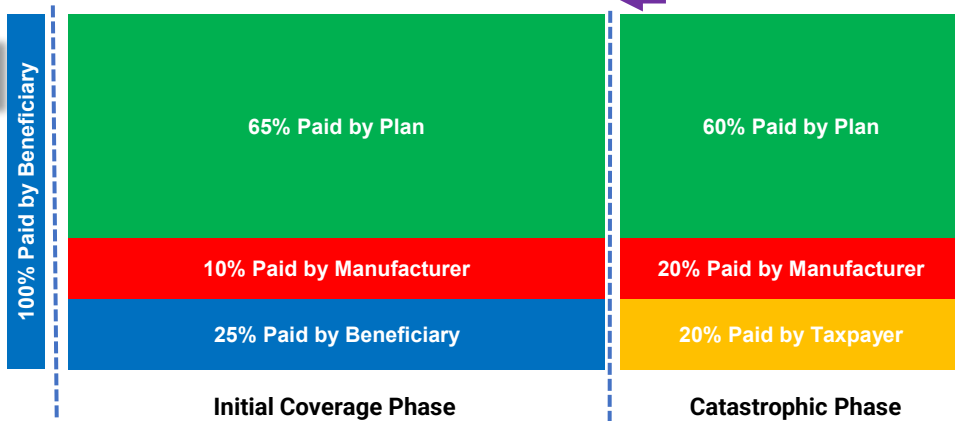
Part D Redesign

- Reduce OOP Cost to \$2,000 hard cap
- Creates new manufacturer discount program for innovator drugs (10% initial phase and 20% in catastrophic phase)
- Increases eligibility threshold for low-income subsidies to individuals below 150% FPL
- Shifts liability to plans
- Caps OOP costs for Insulin
- Allows beneficiaries to “smooth” cost-sharing throughout the year
- Caps premiums at 6%/year through new subsidy

Current
law - 2024



IRA – 2025



\$2,000 OOP Cost

Implications

**Fewer products,
higher launch prices**

**Downstream impact
of manufacturer
price controls**

**Better coverage, but
more aggressive
plan utilization
management**

**Further scrutiny of
PBM and
manufacturer
practices**

Next steps

Legal

- Expected legal challenges focus on constitutional and process issues

Regulatory

- Implementation timeline is aggressive
- Not a normal rule making process – years until formal comments on “negotiations”

Legislative

- Repeal and replace?
- Chip away at the law through minor reforms
- Expand the law to generate more savings
- Oversight

Political – how will this impact races? Control of Congress?

“This is just the beginning”

- Expand price controls to commercial markets
- Enact public option
- Government determines “value” of drugs for all programs
- Grab Patents or weaken patent process
- Drug pricing boards
- Reduce exclusivity to 5 years

Bloomberg GOVERNMENT

This document is being prepared for the exclusive use of JOEL WHITE at
HORIZON GOVERNMENT AFFAIRS

Skyrocketing Prices Fuel Drive for Fresh Crackdown on Drug Costs

By Alex Ruoff | September 19, 2022 5:01AM ET

Drug pricing advocates fresh off a major win say they're turning their attention to changes for pharmaceutical industry middlemen and to curbing high launch prices for new medicines.

These changes take aim at areas left out of the sweeping drug pricing legislation ([Public Law 117-169](#)) that Democrats passed this summer. Now, advocates say it's time to address the role of

OTHER VIEWS COMMENTARY

Congress can do more to reduce prescription drug costs

The Inflation Reduction Act is a huge step in the right direction. Two proposed laws would do more to help millions of Americans afford the prescriptions they need.

Dear Abby: My husband turns me off with kinky r

Medicare Price 'Negotiation' Process Could Enable National Value Framework – CMS' Blum

27 Sep 2022 | ANALYSIS



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HEALTH COVERAGE

Thanks!

HORIZON
GOVERNMENT AFFAIRS

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The image features a decorative header and footer with a blue and purple gradient background. Numerous thin, dark lines representing fiber optic cables extend from the top and bottom edges, each ending in a small, glowing sphere of light in shades of blue, purple, and white. The central area of the image is a solid white background.

Q&A

Thank
you