

I N T E G R I S

H E A L T H

Regulatory Changes to Prescription Drug Pricing

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Disclosure Information

I have no financial relationship to disclose.

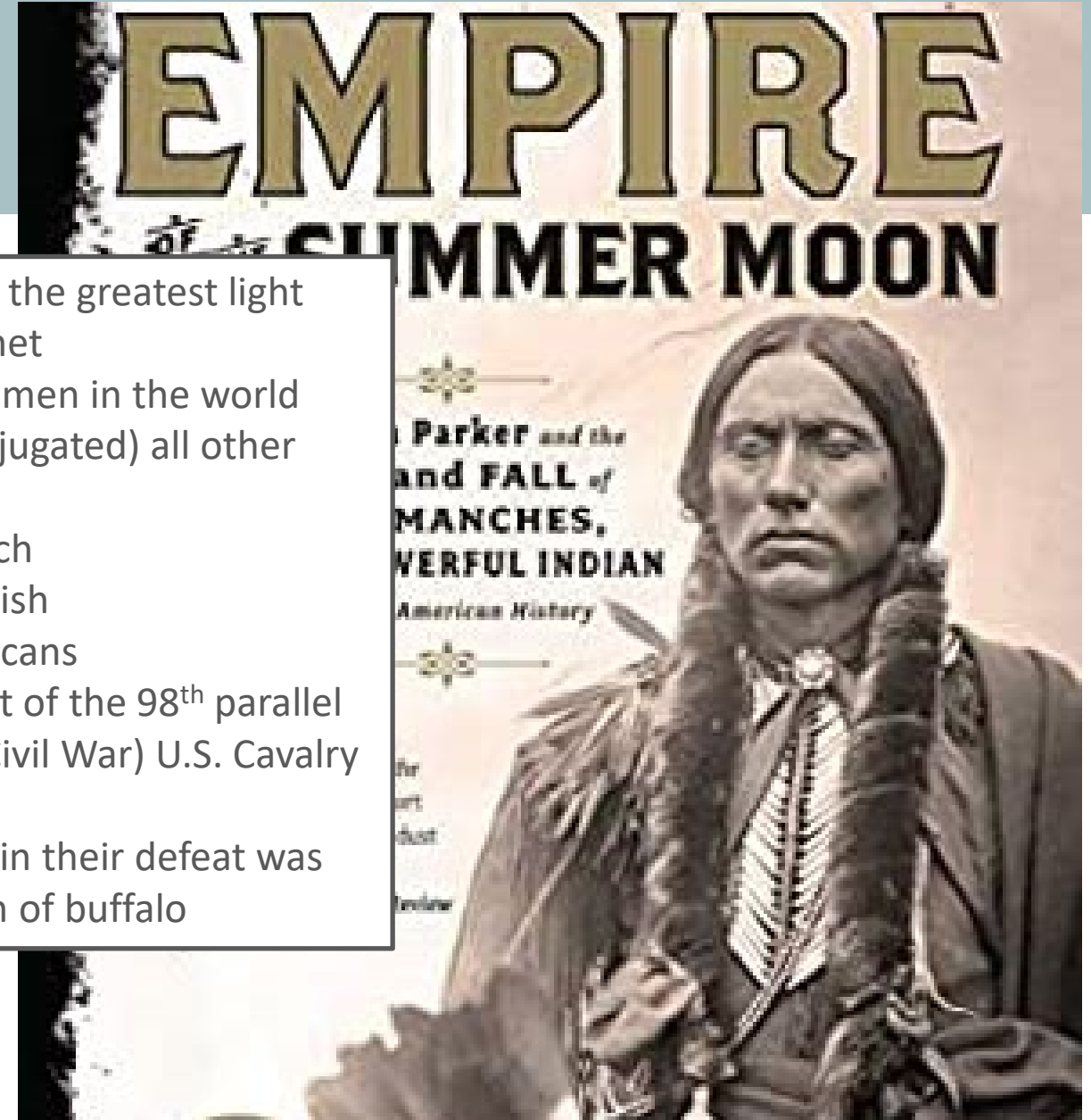
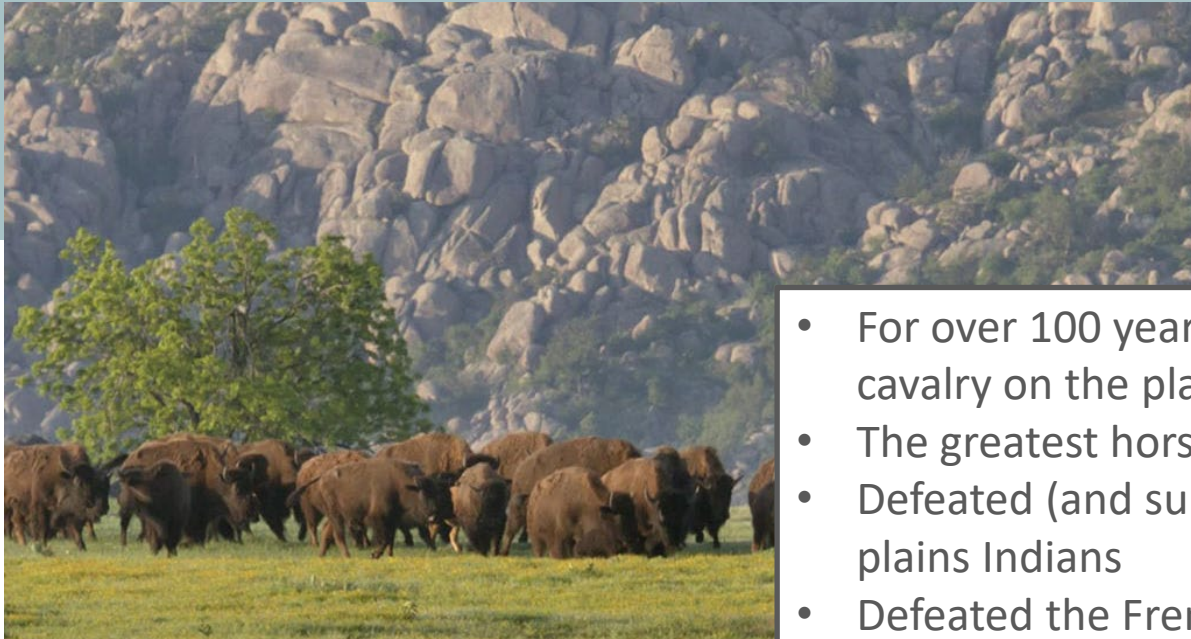
AND

I will not discuss off label use and/or investigational use in my presentation.

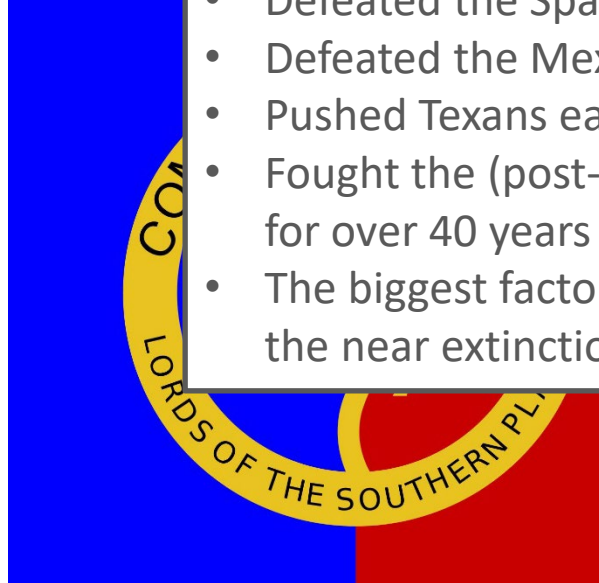
I have been a member of the Ohio Pharmacists Association Legal and Regulatory Affairs Committee

Learning Objectives

1. Explain the impact of PBM spread-pricing on the cost of prescription medications.
2. Identify recent statutes, rules and regulations, and executive orders that and their impact on the cost of prescription medications.
3. Recognize the impact of federal rules and regulations regarding COVID-19 vaccine administration and the impact on pharmacy practice.
4. Formulate Christian responses to regulatory changes in pricing of prescription medications to have a beneficent impact on patients.



- For over 100 years the greatest light cavalry on the planet
- The greatest horsemen in the world
- Defeated (and subjugated) all other plains Indians
- Defeated the French
- Defeated the Spanish
- Defeated the Mexicans
- Pushed Texans east of the 98th parallel
- Fought the (post-Civil War) U.S. Cavalry for over 40 years
- The biggest factor in their defeat was the near extinction of buffalo



Pharmacy Benefit Manager (PBM) Spread Pricing

Which of the following is the correct definition of the practice of Pharmacy Benefit Manager (PBM) “spread pricing”?

- The PBM charges the health plan more than they pay the pharmacy and keeps the difference
- The PBM charges the health plan the pharmacy acquisition cost and pays the pharmacy a standard dispensing fee
- The PBM charges the health plan the average wholesale price and pays the pharmacy the acquisition cost and a dispensing fee

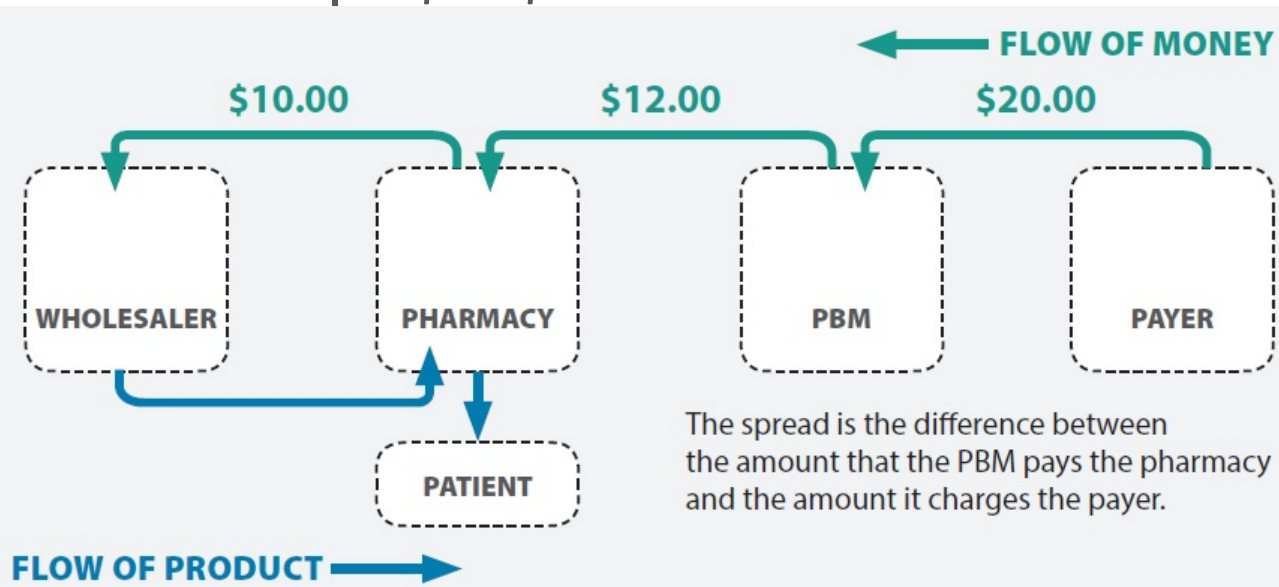
The Ohio Pharmacy Benefit Manager Story

- The Ohio Pharmacists Association and Ohio pharmacies began investigating CMS data
 - Columbus Dispatch began highlighting the controversy
- State lawmakers began questioning Medicaid on discrepancies
- Summer 2018, a state audit revealed **\$244 million excess by Medicaid managed care PBMs**



How PBM Spread Pricing Works

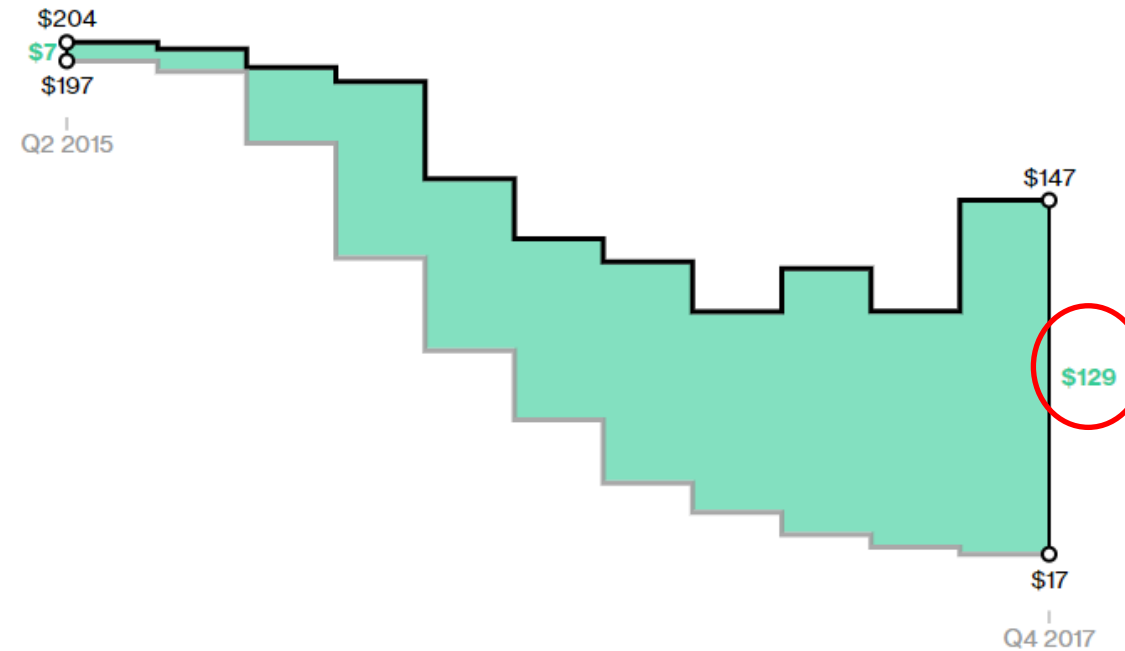
- PBM charges health plan \$A
- PBM pays pharmacy \$B
- PBM keeps \$A-\$B



Esomeprazole 40 mg (generic Nexium) in Indiana

Disease: Heartburn

Cost to pharmacy Cost to state Medicaid program Combined pharmacy and PBM spread and fees



Note: Drug prices reflect a 30-day supply; numbers may not add precisely due to rounding

Langreth R, Ingold D, Gu J. The Secret Drug Pricing System Middlemen Use to Rake in Millions. Bloomberg. 2018.

“Transparent” Contract

The profit is in opacity

- Payer who is signing the contract with PBM
 - PBM charges health plan \$A
 - PBM pays pharmacy \$B
 - PBM keeps \$A-\$B
- The difference is both \$A and \$B are known to the Payer when the contract is signed.

How it “transparency” works

- HCTZ 12.5 mg
 - 30 day supply from wholesaler: \$1.80
 - PBM charges health plan: \$1.80
 - PBM pays pharmacy: \$1.80
 - Health plan has the right to audit
- Patient pays
 - Tier 1 copay: \$1
 - Tier 2 copay: \$5
 - T

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HEALTHCARE

Ohio's proposed state-run pharmacy benefit manager plan draws skepticism

Darrel Rowland and Catherine Candisky The Columbus Dispatch

Published 6:08 a.m. ET Dec. 7, 2020 | Updated 10:27 a.m. ET Dec. 7, 2020



US Supreme Court rejects PBMs' challenge of state's ability to regulate the drug middlemen

Darrel Rowland The Columbus Dispatch
Published 2:25 p.m. ET Dec. 10, 2020 | Updated 2:34 p.m. ET Dec. 10, 2020



Pharmacy benefit managers lost their US Supreme Court challenge

The PBMs contended Arkansas' regulations violated the Employee Retirement Income Security Act of 1974 (ERISA). They won in lower federal courts, so Thursday's 8-0 ruling by the high court reversed those lower-court decisions.

In a ruling that could pave the way for increased regulations by states such as Ohio, the U.S. Supreme Court on Thursday rejected a challenge of a 2015 Arkansas law putting restrictions on pharmacy benefit managers.

"We have overwhelming evidence that the PBM marketplace is highly dysfunctional and exceedingly costly," said Antonio Ciaccia, former lobbyist for the Ohio Pharmacists Association. . .



Ohio Pharmacy Newsline

A bi-weekly member news brief brought to you by the Ohio Pharmacists Association



DECEMBER 25, 2020

Top News

New Ohio coalition seeks to turn PBM drug-middleman profits into savings for patients

The Columbus Dispatch

For the past couple of years, America has witnessed a [growing movement](#) led by Ohio and a few other states to crack down on once-obscure pharmacy benefit managers, who are accused of huge overcharges in their role as middlemen in the prescription drug supply chain.



HB 396: Impose requirements on pharmacy benefit managers

- **Current Status: Referred to House Health Committee**
- **Provisions:**
 - Prohibits a pharmacy benefit manager (PBM) from engaging in spread pricing, retroactively denying a claim, reducing payment to a pharmacy, or paying a pharmacy less than a certain specified cost.
 - Requires a PBM to file reports with the Superintendent of Insurance regarding rebates and payments.
 - Explicitly includes certain items in the definition of “maximum allowable cost.”
 - Requires a PBM that has a contract with a Medicaid managed care organization regarding pharmacy benefit services or administration to comply with the bill’s provisions as well as all laws governing PBMs.

Insulin Prices

Which of these insulin products is the least expensive?

- a) Apidra[®] (Insulin glulisine)
- b) NovoLOG[®] (Insulin aspart)
- c) HumaLOG[®] (Insulin lispro)
- d) Novolin R[®] (Human insulin, regular)

TO SUPPLY INSULIN FREE.

Treatment to Be Provided for Britishers Who Cannot Pay.

Copyright, 1924, by The New York Times Company.
Special Cable to THE NEW YORK TIMES.

LONDON, March 12.—Scotch people who need insulin are to have it whether they can pay for it or not, and Englishmen will probably be put on the same footing. The Government will introduce in the Lords a bill to enable the Scottish local authorities to provide the cure for all diabetic patients who cannot afford it.

Some local authorities in England are already doing this and the Government is considering a bill to establish their right to do so. The present cost of insulin to a patient is estimated at 8 to 10 shillings a week.

The New York Times

Published: March 13, 1924

The Chicago Tribune

April 1, 1941

INSULIN PRICE FIXING CHARGED TO 3 COMPANIES

Washington, D. C., March 31 (P).—
A federal grand jury indicted three drug manufacturing companies and

Everything You Need
to Know About
Walmart Insulin

Vieira G. Everything You Need to Know About Walmart Insulin. Diabetes Strong. Published 2020. Accessed December 24, 2020.

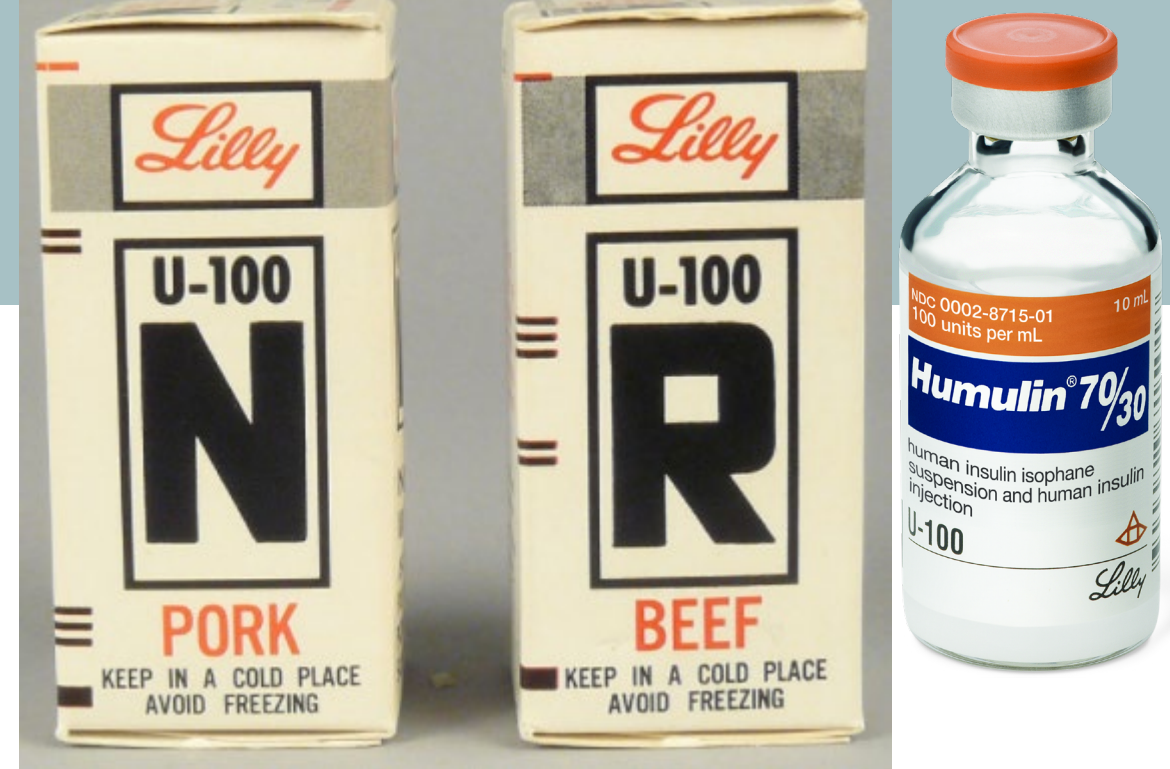
Is Walmart insulin a good option for you?

Considering that today's most modern insulin options cost at least \$300 per vial, the affordability of Walmart's insulin is appealing. Unfortunately, the rigid schedule and limitations of these insulins truly make them a "last resort" option.



Beef/Pork vs Human vs Insulin Analogs

- Late 80s: beef, pork (and fish)
 - Humulin much more expensive
 - Significant therapeutic advantages to human insulin
- Early 2000s: Insulin analogs
 - Human NPH and Regular insulin is cheaper
 - Significant therapeutic advantages to insulin analogs, but they are more expensive
- Many comparisons of historic insulin prices use pre-human insulins (i.e. beef and pork) that are no longer on the market
- Comparing prices of beef/pork, human, analogs is apples to oranges to bananas



Medicare Prescription Drug Benefit (aka Part D)

- Originally proposed by President Bill Clinton in 1999
- Then by both political parties and Houses of Congress and President Bush during 2002 and 2003
- Final bill was enacted as part of the Medicare Modernization Act of 2003
 - Which also made changes to the public Part C Medicare health plan program
 - Went into effect on January 1, 2006.

2021 Medicare Part D and Medication Coverage

Phase 1

- Annual Deductible
- Member pays 100% of medication costs until deductible met up to \$445

Phase 2

- Initial Coverage
- Member pays set copays or coinsurance based on formulary tiers of coverage
- Plan pays remainder of cost
- Phase 2 coverage lasts until \$4,130 is paid on medications by member and plan combined

2021 Medicare Part D and Medication Coverage

Phase 3

- Coverage Gap (aka The Donut Hole)
- Member pays **25% of medication cost** (e.g. if a medication costs \$400 then a member will have to pay \$100)
- Plan pays 5% of medication costs
- Pharmaceutical manufacturer pays 70% of medication costs in this phase
- Phase 3 lasts until the member has paid **\$6,550 of out-of-pocket costs** (deductibles, copays, and coinsurance)
- Members may be eligible for pharmaceutical manufacturer-sponsored patient assistance programs during this phase if he/she meets income and out-of-pocket spending criteria. Your PCP's pharmacist can assist with these.

2021 Medicare Part D and Medication Coverage

Phase 4

- Catastrophic coverage
- Member pays the greater of **5% of medication cost OR \$9.20/month for brand name medications and \$3.70 for generic medications**
- Plan pays most of medication cost
- If the member has Medicare Extra Help or dual coverage with Medicare & Medicaid, they might be in phase 4 coverage throughout the full year



Presidential Documents

Executive Order 13948 of September 13, 2020

Lowering Drug Prices by Putting America First

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Lowering Drug Prices by Putting America First

- **Secretary of Health and Human Services**
 - “Immediately take appropriate steps to implement his rulemaking plan to test a payment model” by putting in place “most favored nations” policy.
 - Translated: As with most executive actions, this only just begins what will be a lengthy bureaucratic process that may or may not ultimately result in the promised policy.

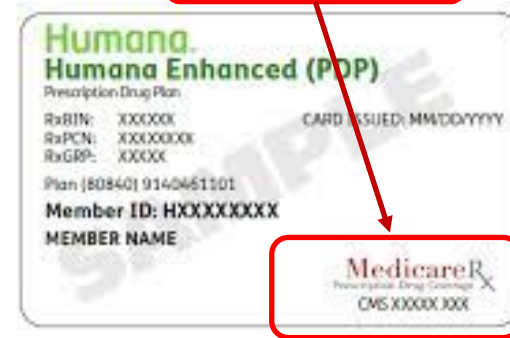
Lowering Drug Prices by Putting America First

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- **Update: Jan 2021 Biden administration announces administrative hold, but then allows the plan to continue**

Case #1 – 74 yo Female, “Deloris A.”


- Hx of:
 - DM Type 2
 - Hyperlipidemia
 - Hypertension
 - Osteoporosis
 - Hypothyroidism
- Meds
 - Glipizide XL 20 mg daily
 - Metformin 1000 mg twice daily
 - Dulaglutide (Trulicity®) 0.75 mg SC weekly
 - Previously on Empagliflozin (Jardiance®) but d/c 2° to cost
- Most recent A1c: **6.4**
 - Goal < 7

- Humana Medicare Advantage
 - **H6622 071 0**



Deloris A.'s Prescription Coverage

— Medicare Plan Features —

| | | |
|---|--|--|
| Monthly Premium: | \$0.00 (see Plan Premium Details below) | |
| Annual Deductible: | \$0 | |
| Annual Initial Coverage Limit (ICL): | \$4,130 | |
| Health Plan Type: | Local HMO | |
| Special Needs Plan (SNP) Eligibility Requirement: | Cardiovascular Disorders, Chronic Heart Failure and Diabetes | |
| Additional Gap Coverage? | No additional gap coverage, only the Donut Hole Discount | |
| Total Number of Formulary Drugs: | 3,427 drugs | Browse the Humana Gold Plus - Diabetes and Heart (HMO C-SNP) Formulary |
| This plan has 6 drug tiers. See cost-sharing for all pharmacies and tiers.  | | |

D.A.'s Prescription Coverage

Metformin 1000 mg tablets

- 30 day preferred pharmacy copay:
 - \$0
- Plan's average negotiated retail drug price:
 - **\$2.40** for 30 day supply
- Negligible impact on total drug expenditure

Glipizide XL 10 mg tablets

- 30 day preferred pharmacy copay:
 - \$0
- Plan's average negotiated retail drug price:
 - **\$10.20** for 30 day supply
- Negligible impact on total drug expenditure

Adds **\$12.60** per month to accumulated total

Deloris A.'s Prescription Coverage

Dulaglutide (Trulicity®) (GLP-1 RA)

- 30 day preferred pharmacy copay:
 - \$47
- Plan's average negotiated retail drug price:
 - **\$890.20** for 30 day supply

What Happens to Her Finances

| Month | Copay | Negotiated Price | Accumulated Total |
|----------|--------------|-------------------|-------------------|
| January | \$47 | \$890.20 | \$890.20 |
| February | \$47 | \$890.20 | \$1,780.40 |
| March | \$47 | \$890.20 | \$2,670.60 |
| April | \$47 | \$890.20 | \$3,560.80 |
| May | \$47 | \$890.20 | \$4,451.00 |
| June | \$223 | Donut Hole | |

Putting America First

Insulin Prices

- 30 day preferred pharmacy copay:
 - \$35
- Plan's average negotiated retail drug price:
 - \$0 for 30 day supply
- Negligible impact on total drug expenditure
- Includes insulin analogs

Other Products

- Insulin glargine (basal) and lixisenatide (GLP1 RA) (SOLIQUA®)
 - \$35 for 30 day supply
 - Impact on accumulated total costs:
 - \$0 for 30 day supply
 - Negligible impact on total drug expenditure
- Insulin degludec (basal) and liraglutide (GLP1 RA) (Xultophy®)
 - \$35 for 30 day supply
 - Impact on accumulated total costs:
 - \$0 for 30 day supply
 - Negligible impact on total drug expenditure

Cost of Insulin

| Product | Copay | Cost |
|----------|-------|-----------|
| Lantus | \$35 | \$447.60 |
| Levemir | \$35 | \$972.90 |
| Lispro | \$35 | \$281.50 |
| Soliqua | \$35 | \$815.40 |
| Xultophy | \$35 | \$1206.00 |

Commercial plans pay this. What is going to happen to these costs under this plan?

Law of unintended consequences

What Happens



Country 1

- Pays this high price

Country 2

- Pays this medium price

Country 3

- Pays this low price

What Happens



Country 1

- Pays this high price

Country 2

- Pays this medium price

Country 3

- Pays this low price

Options for Deloris A.

- **Continue Trulicity until she climbs out of the donut hole**
 - Not gonna happen
- **Start on insulin**
 - Basal + meal = \$70 per month
- **Start on an insulin+GLP-1 RA**
 - \$35 per month

Which of the following are required for pharmacy technicians to be able to administer COVID-19 vaccines?

- a) A physician-approved protocol
- b) ACPE approved training in immunization
- c) Advanced Cardiac Life Saver (ACLS) training
- d) A license from Ohio Board of Pharmacy

Pharmacy Technician Administration of Vaccines during the COVID-19 Pandemic

- U.S. Dept. HHS Public Readiness and Emergency Preparedness (PREP) Act
 - Under supervision of qualified pharmacist
 - Ages 3 or older according to ACIP standard immunization schedule
 - Well-child visit reminder
 - No physician-approved protocol is required
 - Must report vaccination to primary care, except flu vaccine for pts > 18 yo
 - Authorizes “qualified” pharm techs to administer childhood immunizations and COVID-19 vaccines
 - Licensed or registered, or
 - CPhT in states without licensing or registration
 - Training requirements:
 - Minimum 2 hours ACPE approved training program that includes hands-on injection technique
 - Current BLS certification
- Immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of such vaccines.
- States and Tech vaccination: Oklahoma

Operation Warp Speed

- Coronavirus Aid, Relief, and Economic Security (CARES) Act
 - Passed March 27, 2020
 - \$10 B to OWS
- OWS included:
 - Government: DHS, CDC, FDA, NIH, Biomedical Advanced Research Authority (BARDA), DoD, Dept. of Agriculture, Dept. of Energy, Dept. of Veterans Affairs
 - Private:
 - Directly funded: Johnson & Johnson (Janssen Pharmaceutical), AstraZeneca–University of Oxford and Vaccitech, Moderna, Novavax, Merck and IAVI, Sanofi and GlaxoSmithKline
 - Indirectly funded: Vaxart (in collaboration with Emergent BioSolutions), Inovio
 - **Not received any funding: Pfizer-BioNTech**
- Monoclonal antibodies: Regeneron

Taking 'Extraordinary Measures,' Biden Backs Suspending Patents on Vaccines

The Biden administration, siding with some world leaders over the U.S. pharmaceutical industry, came out in favor of waiving intellectual property protections for coronavirus vaccines.

By [Thomas Kaplan](#), [Sheryl Gay Stolberg](#) and [Rebecca Robbins](#)

May 5, 2021

Waiving Patent Protection

Arguments for

- The rest of the world still needs the vaccines and this could get it to the world faster

Arguments against

- Moderna and Pfizer have both already offered to license their vaccines and have had no takers
 - Under licensing agreement M & P retain control and oversight of manufacture
- It requires expertise and technology to:
 - Manufacture
 - Deliver } Capability
- What about next time?

Medical Principlism

- **Beneficence**: always act for the benefit of our patients
- **Nonmaleficence**: first do no harm
- **Distributive Justice**: treat all patients equally regardless of irrelevant factors
- **Patient autonomy**: to the degree they are capable, patients should be fully informed and make decisions about their own health

The Christian Response

The Commandments of Jesus

1. Love God with all your heart, mind, strength, and soul. Luke 10:27, Matt 22:37
2. Love your neighbor as yourself. Luke 10:27, Matt 22:38
3. Treat others as you would want to be treated. Luke 6:31, Matt 7:12
4. Spread the Gospel to the entire world. Mark 16:15, Luke 14:23, Matt 28:19-20

“If this were your Grandmother, what would you want done?”

Questions?



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- c) HumaLOG[®] (Insulin lispro)
- d) Novolin R[®] (Human insulin, regular)

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