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Drug Pricing Reforms are Here: Gauging the Impact on Industry

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Yesterday afternoon, the Senate cleared the Inflation Reduction Act on a party-line vote of 51 – 50 with Vice President Harris breaking the tie. The legislation will be taken up and very likely passed by the House of Representatives on Friday. Thus, after decades of trying, Democrats will enact into law for the first-time material changes to how the Medicare program prices and pays for prescription drugs.

While we have discussed these issues frequently in prior reports, we review once more the legislative changes since they are nearly final. Below we detail the four drug pricing reforms included in the IRA, outline our expectation for the impact of these policy changes on the pharma, biotech, and managed care / pharmacy benefit manager (PBM) subsectors, and explain why we believe this represents a generational policy change that establishes a durable "new normal" for drug pricing policy rather than the proverbial camel's nose under the tent.

In aggregate, we continue to believe that these reforms represent the second-best outcome for industry. While it is undeniably worse than the status quo and will disproportionately impact specific drugs and manufacturers, in aggregate we believe the reforms are relatively modest, adaptable, and manageable, allowing for substantial growth in coming years for national prescription drug spending, and profitability.

The Four Reforms

The drug pricing reforms finalized by Democrats include four components:

(1) Limited direct government price negotiation in Medicare (Part D + Part B).

(2) Inflation caps in the Medicare market (Part D + Part B).

(3) A redesign of the Medicare Part D benefit to relatively shift liability for expensive drugs away from beneficiaries and the government and towards plans and manufacturers.

(4) Out-of-pocket (OOP) caps on insulin in the Medicare market (Part D + Part B) of no more than $35 per month.

We discuss each component in detail below.

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Limited Direct Government Price Negotiation in Medicare

Moderate and progressive Democrats reached a compromise last year to implement a limited drug price negotiation construct in Medicare. The federal government is required to directly negotiate the Medicare price of a subset of mature, branded drugs without generic or biosimilar competition that have the highest spend in Medicare. The program includes the following parameters:

- **Timing & Number of Drugs Negotiated**: The legislation establishes a construct in which the negotiations between the government and applicable manufacturers will take place two years prior to the application of the negotiated price. Negotiation for the first 10 drugs will commence in late-2023 to affect pricing in 2026 since the legislation allows extra time for the first round of negotiations. The government will then negotiate the prices of 15 additional eligible drugs in 2025 (affecting pricing in 2027) and 2026 (affecting pricing in 2028), respectively, and 20 additional drugs annually thereafter to affect pricing two years hence. For the first two rounds of negotiation, only eligible Part D drugs can be negotiated; negotiations on Part B drugs cannot begin until 2026 to affect 2028 pricing.

- **Announcement of Selection**: Other than the first round of negotiations that will begin on September 1, 2023, with the announcement of the first 10 drugs selected for negotiation, the negotiation timeline begins each year on February 1 when the government announces which drugs have been selected for that year's negotiation. The process concludes on September 1, 2024, or November 30 of each year thereafter, when the negotiated rate for selected drugs is publicly announced. That price then applies starting January 1 of the pricing year.

- **Drugs Eligible for Negotiation**: Under this framework, branded drugs without generic or biosimilar competition that have been on the market for at least 9 years (small molecules) or 13 years (biologics), and that are among the drugs with the highest spend in Medicare over a prior 12-month period ending the previous October 31, are potentially subject to being selected for Medicare price negotiation. To be clear, a drug is eligible for negotiation in 7 years (small molecule) or 11 years (biologics) after its FDA approval, but the negotiated prices cannot go into effect until 9 years (small molecule) or 13 years (biologics) after the FDA approval date. Each year, the federal government must array all drugs from the highest to the lowest Medicare expenditures and, starting from the top of the list, select for negotiation the appropriate number of drugs that meet the eligibility criteria, excluding those drugs that are exempt or currently within the negotiation construct.

- **Exemptions**: Certain drugs and drug categories are exempt from selection for negotiation: (a) drugs less than 7 years (small molecule) or 11 years (biologics) from FDA approval, (b) drugs with at least one generic or biosimilar competitor on the market, (c) orphan drugs that are designated as having orphan status for only one rare disease and for which the

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only approved indication is for that disease; (d) blood products; and (e) drugs with total Medicare expenditures of less than $200 million over the applicable 12-month window. The $200 million floor will increase annually by the consumer price index (CPI-U). Additionally, "small biotech drugs" are temporarily exempt from negotiation until 2027 to effect 2029 pricing. A "small biotech" drug is a product that accounts for at least 80 percent of a company's Part D or Part B revenues, respectively, but less than 1 percent of total Medicare Part D or Part B drug spending, respectively, in 2021.

- **Negotiated Price**: The ceiling price established for drugs selected for negotiation depends on how long the drug has been on the market, starting with the date of approval by the Food and Drug Administration (FDA) of the product's New Drug Application (NDA) or Biologics License Application (BLA). For drugs that are 9 – 12 years old, the ceiling price is 75 percent of the non-federal average manufacturer price (non-FAMP); for drugs 12 – 16 years post-launch, the ceiling price is to 65 percent of non-FAMP; and for drugs 16+ years since launch, the ceiling price is 40 percent of non-FAMP. The term "non-FAMP" is defined in federal law as the price paid by wholesalers for drugs delivered to the commercial market, meaning it is a gross price that does not include rebates paid to pharmacy benefit managers (PBMs). Thus, the ceiling price for a drug essentially requires manufacturers to provide Medicare a discount of 25 percent, 35 percent, or 60 percent from the inflation-adjusted 2021 non-FAMP price (or launch price if after 2021), depending on the age of the drug. We note that the ceiling price of a drug also cannot exceed the negotiated net Medicare price of the drug in the year prior to the first negotiation with the government, meaning that the initial ceiling price of a drug selected for negotiation is the lower the applicable percent of non-FAMP or the net Medicare price in the prior year. Finally, "small biotech drugs" have a temporary pricing floor equal to 66 percent of non-FAMP in 2029 and 2030.

- **Post-Negotiation Pricing**: Drugs selected for negotiation remain part of the negotiation construct until such time as a generic or biosimilar competitor product that references the negotiated drug is launched. While a drug is part of the negotiation construct, the ceiling price can drop as the drug ages into a new category (i.e., from 11 to 12 years post-launch or 15 to 16 years post-launch). Otherwise, the price of the drug can increase annually from the first negotiated rate commensurate with inflation as measured by CPI-U.

Figure 1. Summary of Drug Pricing Construct.

(See next page)

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Negotiation Year	Pricing Year	Drug Types Eligible for Negotiation	Number of Drugs Selected for Negotiation	Total Drugs Selected for Negotiation	Dates of Medicare Drug Expenditures Evaluated	Announcement Date of Drugs Selected for Negotiation	Announcement Date of Ceiling Price	Start of Negotiated Pricing	Temporary "Small Biotech" Floor Price
2023 - 2024	2026	Part D	10	10	June 1, 2022 - May 31, 2023	September 1, 2023	September 1, 2024	January 1, 2026	N/A
2025	2027	Part D	15	25	November 1, 2023 - October 31, 2024	February 1, 2025	November 30, 2025	January 1, 2027	N/A
2026	2028	Part D + Part B	15	40	November 1, 2024 - October 31, 2025	February 1, 2026	November 30, 2026	January 1, 2028	N/A
2027	2029	Part D + Part B + Small Biotech	20	60	November 1, 2025 - October 31, 2026	February 1, 2027	November 30, 2027	January 1, 2029	66% of non-FAMP
2028	2030	Part D + Part B + Small Biotech	20	80	November 1, 2026 - October 31, 2027	February 1, 2028	November 30, 2028	January 1, 2030	66% of non-FAMP
2029	2031	Part D + Part B + Small Biotech	20	100	November 1, 2027 - October 31, 2028	February 1, 2029	November 30, 2029	January 1, 2031	N/A
2030	2032	Part D + Part B + Small Biotech	20	120	November 1, 2028 - October 31, 2029	February 1, 2030	November 30, 2030	January 1, 2032	N/A

Source: Inflation Reduction Act, Veda Partners

Realistically, we believe that no more than 100 – 120 drugs would ever be subject to negotiation at one time due to the various exemptions. Most significantly, only so many drugs are likely to exceed the spending floor, which is initially $200 million in Medicare expenditures per year and increases annually by CPI-U.

Identifying "The List" is Not Straightforward

Identifying which drugs will be selected for negotiation in any given year is difficult to ascertain. We note that the Medicare Drug Pricing Dashboard maintained by the Centers for Medicare and Medicaid Services (CMS) offers insight since it lists every drug and its total Medicare expenditures in Part D and Part B for calendar years 2016 – 2020. However, because the dates of Medicare drug spending evaluated are not over a calendar year and are dynamic, because spending patterns will change as new drugs enter the market and generic and biosimilar competitors launch, because the age of a drug determines when it becomes eligible for negotiation, and because of the exemptions for certain orphan drugs and "small biotech" drugs, it is not possible to identify with certainty a specific "list" of drugs that will be negotiated.

Below is a list of the top 20 Part D drugs by spending in CY20 per the drug dashboard. Presumably, some subset of this list will likely be among the first 10 drugs announced on September 1, 2023, as the first to be selected for negotiation, affecting Medicare pricing beginning January 1, 2026. We note that many of the drugs on this list now or will soon have generic or biosimilar competitors, and thus will not be eligible for negotiation.

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Figure 2. List of Top 20 Drugs by Part D Gross Spend in CY2020.

Drug	2020 Part D Spend	Manufacturer
Eliquis	$ 9,936,069,814	BMY
Revlimid	$ 5,356,050,275	BMY
Xarelto	$ 4,701,314,805	JNJ
Januvia	$ 3,865,087,773	MRK
Trulicity	$ 3,284,873,062	LLY
Imbruvica	$ 2,962,909,304	ABBV
Lantus Solostar	$ 2,663,360,232	SNY
Jardiance	$ 2,376,166,292	Boehringer
Humira(Cf) Pen	$ 2,169,430,424	ABBV
Ibrance	$ 2,108,937,188	PFE
Symbicort	$ 1,979,983,682	AZN
Xtandi	$ 1,968,567,948	ALPMY
Novolog Flexpen	$ 1,844,084,368	NVO
Biktarvy	$ 1,775,846,507	GILD
Myrbetriq	$ 1,749,232,347	ALPMY
Levemir Flextouch	$ 1,554,791,325	NVO
Victoza 3-Pak	$ 1,545,815,415	NVO
Breo Ellipta	$ 1,504,155,910	GSK
Trelegy Ellipta	$ 1,487,802,308	GSK
Ozempic	$ 1,455,812,267	NVO

Sources: CMS, Veda Partners

The Excise Tax "Hammer"

Finally, we note that manufacturers of drugs that are selected to participate in the negotiation program are subject to a punitive excise tax if they fail to engage in the construct or to offer Medicare the negotiated rate. While the tax is nominally equal to 65 – 95 percent of an applicable drug's daily sales during the noncompliance period (the rate increases 10 percentage points every 90 days), in actuality the tax is equal to up to 1,900 percent of sales. No manufacturers are expected to pay the tax. If a manufacturer wishes not to participate in the negotiation construct, and also wishes to avoid the excise tax, the legislation offers the option for the manufacturer to exit the Medicare and Medicaid markets entirely for all of its products.

Inflation Caps in Medicare

The second component of the Democrats' drug pricing reforms would establish inflation caps in Medicare, Part D + Part B. The original version of the bill also included an inflation cap in

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the commercial market, but this was jettisoned because – as we projected – the Senate Parliamentarian found it does not comply with the Byrd Rule.

Under this construct, starting in 2023 (or 2025 if the Secretary of Health & Human Services decides a two-year delay in implementation is functionally easier to implement), the Medicare price of a drug cannot increase annually faster than CPI-U. If the drug's price increases faster than CPI-U, the manufacturer would owe a rebate to the federal government equal to the difference between the inflation-adjusted price and the actual price. We note that the 2021 price of a drug is the baseline price to prevent manufacturers from rapidly increasing price prior to implementation of this policy.

There are three important items to consider about this policy:

(1) The inflation caps apply only to branded products that cost more than $100 per year. Most generic and biosimilar products and very inexpensive branded products are exempt from the inflation price caps. A generic drug is subject to the inflation cap only if it is the only generic product on the market and the reference branded product has been discontinued.

(2) For Medicare Part B drugs, the inflation cap applies to the Average Sales Price (ASP) of the drug, which is a *net* price inclusive of price concessions. For Medicare Part D drugs, the inflation cap applies to the Average Manufacturer Price (AMP) of the drug, which is essentially a *list* price of the drug that does not include price concessions provided by manufacturers to health insurers or PBMs. Thus, the impact of the inflation cap on Part D drugs is more restrictive than that on Part B drugs.

(3) We also think the application of the policy in Medicare is unlikely to begin until 2025, though since prices are tethered to those in 2021, such a delay has only a small practical impact on actual pricing.

These new inflation caps will likely spur higher launch prices. We also note that manufacturers can still increase prices faster than inflation in the commercial market with relative impunity; to the degree that a drug has disproportionately lower Medicare volumes, it is possible that the revenue growth from price increases in the commercial market could more than offset any inflation cap rebates owed to the federal government.

Medicare Part D Redesign

The Medicare Part D benefit is very complex, and the IRA redesigns it beginning in 2025 to relatively shift liability for expensive drugs away from beneficiaries and the government and towards Part D plans and manufacturers. The legislation caps the out of pocket (OOP) expenditures of seniors at $2,000 per year, lowers the government's reinsurance payments for catastrophic drug spending from 80 percent of to 20 percent for branded and biosimilar drugs

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and to 40 percent for generic drugs, place a greater onus on plans to control high drug spending, and require branded and biosimilar manufacturers to discount the price of drugs by 10 percent in the new initial phase of the benefit and 20 percent in the catastrophic phase.

Below we show the current benefit design and the proposed benefit design that would go into effect in 2025. In each case, the phase of the benefit is based on how much drug spending a Part D beneficiary accrues in a calendar year, and in each case the beneficiary, government, plan, and manufacturer have different levels of exposure depending on the phase. (All dollar amounts are approximate).

Figure 3. Current Medicare Part D Benefit Design for Branded Drugs.

Benefit Phase	Appx. Beneficiary Drug Spending in CY	Beneficiary Liability	Government Liability	Plan Liability	Manufacturer Liability
Phase #1: Deductible	$0 - $500	100%	0%	0%	0%
Phase #2: Initial Coverage Limit	$500 - $4,500	25%	0%	75%	0%
Phase #3: Coverage Gap	$4,500 - $10,500	25%	0%	5%	70%
Phase #4: Catastrophic	$10,500+	5%	80%	15%	0%

Sources: Inflation Reduction Act, Veda Partners

Figure 4. Medicare Part D Benefit Redesign in Inflation Reduction Act for Branded Drugs.

Benefit Phase	Appx. Beneficiary Drug Spending in CY	Beneficiary Liability	Government Liability	Plan Liability	Manufacturer Liability
Phase #1: Deductible	$0 - $500	100%	0%	0%	0%
Phase #2: OOP Cap	$500 - $6,500	25%	0%	65%	10%
Phase #3: Catastrophic	$6,500+	0%	20%	60%	20%

Sources: Inflation Reduction Act, Veda Partners

From a branded manufacturer's perspective, the biggest change is that Phase #3 of the current benefit, the "Coverage Gap," during which the manufacturer must provide a 70 percent

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discount, is eliminated. Instead, manufacturers owe a 10 percent discount in a newly expanded Phase #2 (OOP Cap) and a 20 percent discount in the newly defined catastrophic phase.

Whether this redesign is a negative, a positive, or neutral for a manufacturer depends largely on the price of the drug and how it impacts total Medicare spending on behalf of the beneficiary.

- ✓ For inexpensive drugs (i.e., less than ~$4,500), the manufacturer may newly owe a 10 percent discount and therefore the benefit redesign may have a modestly negative impact.

- ✓ For moderately expensive drugs (i.e., drugs that cost $4,500 - $23,000) the impact of the redesign is potentially *positive*. Branded and biosimilar manufacturers currently owe a 70 percent discount in Phase #3 of the existing benefit design, which is in effect when a beneficiary's annual drug spending is approximately $4,500 - $10,500. Thus, for drugs that cost more than $10,500, the manufacturer owes a rebate of about $4,200, i.e., 70 percent of the $6,000 in spending accrued in Phase #3. However, Phase #3 is eliminated in the redesign. Instead, a manufacturer owes a 10 percent discount in the new Phase #2 (or about $600, maximum) and a 20 percent discount in the new Phase #3. The total discount owed under the redesign does not exceed the $4,200 required under current law until total spending exceeds about $23,000. Therefore, drugs in this range may net benefit from the redesign.

- ✓ For expensive drugs (i.e., drugs that cost more than $23,000), the manufacturer will very likely owe more than $4,200 in discounts under the redesign, meaning the policy change has a negative impact.

Actual Drug-Specific Impact is Speculative

It is very difficult to ascertain the true impact of the redesign on any one drug or manufacturer because a manufacturer's liabilities are dependent on the phase of the benefit, which is predicated on the total drug spending on behalf of the *beneficiary* for all drugs prescribed in a calendar year. Thus, the manufacturer has no control over the phase of the benefit or the requisite liabilities. For example, if a beneficiary is taking 5 drugs for which total spending for the calendar year has exceeded $10,000, at which point a sixth drug is prescribed, the manufacturer of the sixth drug will be required to provide a discount of 20 percent regardless of the price of the drug because the beneficiary is in the catastrophic phase of the benefit.

Additionally, under the redesign, manufacturers will for the first time owe discounts on drugs furnished to the 27 percent of Part D program enrollees that qualify for the Low-Income Subsidy (LIS). Thus, the number of drug claims on which a discount is owed is meaningfully expanded.

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The only thing that can be said with certainty is that drugs that cost more than about $23,000 will owe more in discounts under the redesign than under current law, meaning the net Medicare revenues that accrue to the manufacturer will decline. Therefore, the redesign is a headwind of some magnitude to manufacturers of very expensive prescription drugs that run through the Part D benefit.

Finally, we note that drugs that are selected for negotiation in Medicare are not subject to the 10 percent and 20 percent discounts. Thus, once a drug's Medicare price is set by the government, no additional statutory discounts are required of that drug.

Impact of Redesign on Part D Plans

From a Part D plan perspective, it seems likely that these reforms will cause premiums to increase as plans face greater liabilities for expensive drugs. However, we note that the IRA will cap how much Part D *beneficiaries* are affected by annual premium increases. Beginning in 2024, beneficiary premiums cannot increase YoY by more than 6 percent. Any overages will be subsidized by the federal government. This means that total government subsidization of the Part D program is likely to increase from the statutory 74.5 percent required by law. We will discuss the broader impact of the drug pricing reforms on managed care organizations and PBMs later in this report.

Insulin OOP Caps

The IRA includes three insulin-specific policies. These policies were added back into the legislation just prior to its passage in the Senate.

(a) **Medicare Part D**: Starting in 2023, all insulin products are exempt from the Medicare Part D deductible and monthly cost-sharing cannot exceed $35, or, starting in 2026, the lower of $35 or 25 percent of the negotiated price.

(b) **Medicare Part B**: Starting in 2023, any insulin product furnished through durable medical equipment (DME) in Medicare Part B is exempt from the Part B deductible and monthly cost-sharing cannot exceed $35. Medicare will ensure that DME suppliers are compensated in full by subsidizing any cost-sharing obligations above the cap.

(c) **High-Deductible Health Plans**: Starting in 2023, a high-deductible health plan (HDHP) in the commercial market can retain its status as such even if the plan chooses to exempt insulin from the deductible. Typically, an HDHP must subject nearly all items and services to the deductible.

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We note that the Senate Parliamentarian ruled against allowing insulin OOP caps in the commercial health insurance market because it violated the Byrd Rule. Democrats attempted to waive the point of order, which requires 60 votes, but the effort fell three votes shy.

Impact on Pharma & Biotech: Manageable for Industry

We recognize that our contention that the drug pricing reforms in the IRA are manageable for the pharma and biotech subsectors is contrarian, but we believe that our thesis is backed by qualitative and quantitative data. These reforms are undeniably worse than the status quo and the impact will certainly affect specific drugs and manufacturers disproportionately, but in aggregate we think there is still significant growth potential for pharma and biotech.

From a qualitative perspective, we note that these policies –

- ✓ Leave alone the commercial market entirely.
- ✓ Continue to permit unfettered pricing at launch.
- ✓ Prevent government negotiation for nearly a decade or more after a drug's launch and limit negotiations to a subset of mature drugs with high Medicare spending and without generic or biosimilar competition.
- ✓ Temporarily exclude "small biotech" drugs from the Medicare price negotiation construct.
- ✓ Permanently carve out certain orphan drugs for rare diseases from price negotiation.
- ✓ Essentially guarantee annual inflationary increases for Medicare prices if not directly negotiated by the government, which is notable in the current high-inflation environment.
- ✓ Cap the monthly and annual OOP expenditures of Medicare beneficiaries, thus likely leading to improved drug adherence, which will likely result in increased sales volumes and manufacturer revenues. Additionally, we think the OOP cap will lead to a qualitative lessening of the political pressure placed on politicians to address drug pricing because the new construct shields seniors from drug price increases.

Quantitative Impact is Relatively Limited

From a quantitative perspective, we note that the Congressional Budget Office (CBO) projects that in 2031 the drug pricing reforms will cause total Medicare drug spending to be about $34.6 billion less than under current law due to the combined effects of government price negotiation and inflation caps. This represents a 9.5 percent decline from the projected baseline of $365 billion in total Medicare drug spending in 2031. However, Medicare drug

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spending is projected to nearly double (95 percent growth) from 2023 – 2031 under current law. Consequently, under the IRA, total Medicare drug spending would still be projected by CBO to grow over that time by more than 76 percent. Put differently, the compound annual growth rate (CAGR) of total Medicare drug spending is projected decline from 8.7 percent under current law to a still robust 7.4 percent under the Senate's policies.

We note, too, that these reforms will have no direct impact on commercial drug spending, which is projected to grow by about 51 percent from 2023 – 2031, to $335 billion in 2031. Thus, in aggregate, Medicare and commercial drug spending is projected to grow from about $410 billion in 2023 to over $700 billion in 2031 under current law, or nearly 72 percent. Even with the drug pricing reforms in the IRA, total drug spending in the Medicare and commercial markets is still projected to grow to about $665 billion in 2031, which equates to growth of over 63 percent over 8 years.

A Clearing Event

To be clear, we do not discount the effect of the pricing reforms, but we believe there is still ample opportunity for adaptation and growth. We also believe that these reforms represent a clearing event that lifts a perennial policy and sentiment overhang that has plagued the pharma and biotech subsectors. While we have heard arguments from Democratic lawmakers and other stakeholders that these reforms are merely the start to additional future actions, we disagree with that sentiment for a host of reasons.

1) This is largely predictable messaging and spin from Democratic lawmakers to placate their left flank and the progressive grassroots, which is decidedly unimpressed with the drug pricing reforms that were largely written by Sen. Kyrsten Sinema (D-AZ). We think the statements from lawmakers are more performative than substantive, i.e., they have less to do with explicit promises of future legislative action and more to do with whipping votes in the present. While there is no doubt that progressives, in particular, and many mainstream Democrats, too, will never stop trying to expand the negotiation construct, we think the pathway forward for such efforts is quite fraught.

2) Expanding the negotiation construct is not a clear-cut endeavor, practically or politically. Recall that the decision to limit the number of new drugs negotiated per year to no more than 20 is that CMS indicated that was the maximum number it felt it could handle. Thus, expanding the number of drugs subject to negotiation would require placing an additional burden on CMS. Perhaps that does not concern lawmakers, but the limits were not picked out of thin air and that must be taken into consideration. Politically speaking, if Democrats eventually push to expose drugs to negotiation earlier in their life cycle, it will require political support from historically pro-pharma Democrats that only acquiesced to the dynamic in the IRA because of its limitations.

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3) Politically, the relatively limited negotiation construct Democrats are discussing now is inarguably the furthest that Democrats can push on this issue at this time because it is the furthest that moderate Democrats at the outer margins of the Caucus are willing to go. Expanding the program in future years would almost certainly require a political earthquake that places progressive supermajorities in Congress and in the White House. It is not at all clear that such a dynamic is likely to occur any time soon.

4) As discussed above, the Medicare Part D redesign will cap seniors' OOP spending at $2,000 per year. If seniors are not directly subject to the actual prices of their drugs, they probably will be less likely to advocate on the issue, which means politicians will face less immediate pressure to respond with legislation.

5) It has taken nearly 20 years of trying since the Part D program was created in 2003 for Democrats to get even limited direct negotiation in Medicare. We think this is a generational policy change and that it is entirely speculative that Democrats could just continuously build on this construct. These types of policy changes happen infrequently when the political winds are just right. It is not clear that such a dynamic can or will be replicated in the immediate future.

6) Now that this bill has passed, Democrats will largely have "checked the box" on drug pricing. We realize there will still be pressure from the left to go further, but we doubt that Democratic leaders will continue to elevate this issue to #1 as they have in the past decade because there are innumerable other issues that have waited for legislative action that Democrats will likely prioritize more now that drug pricing has been "addressed."

7) We agree that this is the not the end of the road for pharma and biotech and political pressure: there is no doubt that, at some point, these subsectors will again be in the crosshairs. However, we think this buys the subsector maybe up to a decade of relative "peace," but perhaps less. We believe this legislation largely clears the decks and sets a pathway forward that is manageable. As with the managed care industry in the aftermath of passage of the Affordable Care Act (ACA), we think pharma and biotech are well positioned to grow under the new normal.

8) Regarding potential administrative actions by CMS, while we believe the agency and the White House will continue to jawbone the drug pricing issue and perhaps work with Congress on issues like patent reforms, we note that these are highly complex issues that have gained almost no real traction in decades of trying. Furthermore, the Administration will have its hands full for several years implementing the reforms included in the IRA. The amount of work that is being foisted on CMS is substantial. We do not see how (or why) the Administration would muddy the waters by attempting quixotic administrative reforms when they will need all hands-on deck for implementing the generational reforms recently enacted. Additionally, the Supreme Court's recent ruling in *EPA v West Virginia* on the

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"major questions" doctrine could rein in the CMS Innovation Center should it attempt broader drug pricing reforms that exceed the bounds of the IRA.

We recognize that pharma and biotech will not get a "free pass" now that the drug pricing reforms in the IRA are imminent. But we do believe that the political calculus has changed just enough that the sectors will get *relative* policy relief. Thus, we believe that passage of the IRA represents a clearing event that serves as a relative countervailing tailwind.

Impact to Part D Plans & PBMs: Relatively Modest Headwind, Likely Spurs Continued MA Growth

Managed care will benefit from a separate portion of the reconciliation bill that extends through 2025 the enhanced subsidies for purchasing coverage on the ACA Exchanges. Recall that in 2021 the subsidies were temporarily for 2021 and 2022 expanded to individuals and families earning greater than 400 percent of the poverty level and enhanced for all recipients, which caused enrollment in the Exchanges to grow from about 11 million to about 14 million. The reconciliation bill keeps these expansions and enhancements in effect through 2025. While the impact is fairly small in aggregate, it is beneficial to managed care plans with disproportionate exposure to the Exchange market.

As for the drug pricing reforms' impact on Part D plans and PBMs, there are some knock-on effects that – in aggregate –likely represent a modest headwind.

- ✓ First, any drug that is negotiated by Medicare *must* be covered by a Part D plan, meaning plans / PBMs will surrender any rebates on those drugs once the negotiated price goes into effect.

- ✓ Second, because the AMP of a Part D drug can no longer increase YoY faster than inflation, or else the manufacturer owes a rebate to the federal government, in relative terms this likely will cause a decline in the list-to-net ratio and therefore relatively cause a decline in rebate growth. Recall that AMP is the price that wholesalers pay for drugs, meaning it is essentially a list price rather than a net price. In other words, list price for Part D drugs cannot grow faster than the consumer price index (CPI – U), which perhaps places a bit of a natural limit on rebate growth.

- ✓ And third, the Part D redesign in the bill caps seniors' out of pocket (OOP) spending at $2,000, caps OOP spending on insulin at no more than $35 per month, lowers government reinsurance payments for catastrophic spending from 80 percent to 20 percent (branded and biosimilar) or 40 percent (small molecule generic), and increases plan liabilities for catastrophic spending from 5 – 15% to 60 – 80%. While total federal subsidization remains constant at 74.5% of total Part D spending, plans will face increased liability and pressure

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to control catastrophic spending, though the government will naturally have to increase its direct premium subsidies as it lowers reinsurance payments.

In aggregate, the redesign likely will cause premiums to increase as plans must adjust to the new limitations on beneficiary and government reinsurance spending and the plans' new liabilities in the catastrophic phase. However, we note that the bill also caps beneficiary spending on premiums to a 6 percent increase YoY, with the government subsidizing any overages. This is obviously relatively good news for plans since their customer base will be protected from large premium spikes. But Part D premiums will almost certainly increase for the first time after a decade or so of declining rates.

Relative Benefit for MA Plans

We think the aggregate impact of these reforms relatively benefits Medicare Advantage (MA) plans offering Part D benefits (MA-PDs) because it will be easier for such plans to "hide" the drug-related premium hikes. Standalone Part D plans (PDPs) that sell drug coverage to seniors in fee-for-service (FFS) Medicare likely are relatively disadvantaged because their premium increases of up to 6 percent annually will be readily apparent.

Thus, in aggregate, we believe the drug pricing reforms are a bit of a headwind for Part D plans and their PBMs. Rebates will likely decline in relative terms as plans' exposure in the catastrophic phase increases. The likely only way to address these changes is for plans to increase premiums. The 6 percent cap on premiums growth for seniors is obviously a relative plus for the plans, and therefore somewhat limits the headwind for the industry, but these policies will likely end years of stable or declining Part D premiums. Again, we believe MA-PD plans have an advantage over standalone PDPs. Indeed, these policies likely will further incentivize seniors to move towards MA.

Concluding Thoughts: A Lot of Work and Controversy Still to Come

The IRA represents a generational reform of drug pricing policies in Medicare. These policy changes are undeniably worse for industry than the status quo and will reduce the life cycle for many drugs. However, in aggregate we believe the reforms are manageable and that there is still meaningful growth potential for pharma and biotech, particularly since the negotiation construct is relatively limited and the reforms are quarantined to the Medicare program with no direct effect on the commercial market.

We have stated since the limited construct was developed a year ago through a compromise between moderates and progressives that we felt this outcome represented the second-best outcome for pharma and biotech, and we continue to hold that opinion now that the legislation is on its way to passage and enactment. We are cleareyed about the impact it will have,

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including a disproportionate effect on certain drugs and manufacturers, but in aggregate we view this as an important clearing event.

Going forward, there remains much to be determined through the regulatory process and, inevitably, litigation. We will continue to closely track these important issues and attempt to ascertain the impact to industry and investors.

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