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INFLATION REDUCTION ACT

Part 1: Overview of Major Provisions Affecting Medicare Part D

On August 16th, President Biden signed H.R. 5376—commonly referred to as the Inflation Reduction Act—into law. The legislation includes major changes to Medicare prescription drug pricing that impact both Part D and Part B. The prescription drug changes are divided into three distinct sections: price negotiations for the highest cost drugs, inflation protections for rebatable drugs, and a significant benefit redesign for Part D. The timing of the provisions is staggered; price negotiation will not impact Medicare until 2026 (although the process to determine negotiated drugs begins soon), inflation protections will be in place in 2023, and the major provisions of the Part D benefit re-design occur in 2025. Each provision is covered in the order it appears in the legislation.

Price Negotiation on the Highest Cost Drugs in Medicare Part D and Part B

The first part of the legislation establishes the authority and creates the framework for the Secretary of Health and Human Services (HHS) to negotiate ceiling prices for a qualifying set of high-cost drugs for drugs utilized under the Part D and Part B populations. The qualifying conditions that a drug needs to meet to be eligible to be considered for negotiation include:

A. The drug must be in the Top 50 in total drug spend for Part D or Part B

B. The drug must be approved via a 505c (for drugs) or 351a (for biologics) application

C. The drug is not the listed drug or reference product for another drug that is approved/licensed and marketed

D. The drug is approximately 9 years or 13 years from initial approval

The first year for which drug prices will be negotiated is the 2026 plan year. CMS[1] will select 10 Part D drugs for price negotiation to go into effect in 2026. In 2027, CMS will select up to 15 additional Part D drugs for price negotiation. In 2028, the drugs will be expanded to include Part B, with up to 15 more Selected Drugs from both Part D and Part B. In 2029 and all subsequent years, there will be up to 20 Selected Drugs from Part D and Part B.

To select the drugs that will be the drugs for price negotiation, CMS will identify the top 50 high spend drugs for Part D and Part B, and then rank the drugs based on total spend (calculated as allowed cost,

[1] Please note that the HHS Secretary has the legal authority for implementing the provisions but the Centers of Medicare and Medicaid Services (CMS) will operationalize the implementation. For purposes of this paper, we will use CMS to denote both entities.

not ingredient cost). The highest ranked qualifying drugs that meet all required criteria (including a provision in the initial years of the program that exclude many biosimilar drugs from selection) will be selected for negotiation and are deemed Selected Drugs. Once a drug is selected, that drug remains a Selected Drug until "the first year that begins at least 9 months after the date on which the CMS determines at least one drug or biological product" is approved or licensed under a 505(j) or 351(k) application and is subsequently marketed (i.e., the Selected Drug has generic/biosimilar competition in the market). Therefore, once the Top 10 drugs are selected for the initial negotiation, those drugs will remain Selected Drugs until a generic competitor enters the marketplace. For newly qualifying Part D drugs less than 10 years out from initial approval, this provision could result in a Selected Drug remaining a Selected Drug for a decade or more.

The timeline for measuring the drug-level spend that will be used to select and rank the top 50 Part D/Part B Qualifying Single Source drugs, and then the timeline to select and publish the Selected Drugs, is far in advance to the plan year in which the negotiated prices will be realized by the Medicare-eligible members. For all but the first year (2026), the Selected Drugs must be published by February 1st two years before the affected plan year. In other words, for plan year 2027, the Selected Drugs must be selected and published by February 1st, 2025. The 12-month window for measuring the spend must close no later than October 31st three years before the plan year for most years, with the exception of 2026, for which the latest window available to CMS for measuring drug spend is June 1, 2022 to May 31, 2023. The law appears to allow for a gap between the measurement/ranking of drug spend and publication of Selected Drugs, and the deadline for removal of a Selected Drug due to the emergence of a generic competitor. This may create a situation in which a Selected Drug is on the published drug list that comes out 23 months before the beginning of the plan year but is eventually removed from the list due to generic competition emerging earlier than 9 months before the start of the plan year. While it is unclear to us exactly how this situation would be handled, we believe that this scenario would result in less than the maximum number of drugs with a reduced/negotiated price for that particular plan year.

Inflation Protections for Part B/Part D

In addition to the hard cap price negotiations for the small set of Part B and Part D drugs, the legislation also controls price increases for the larger set of non-negotiated drugs through a soft ceiling benchmarked on each drug's previous price and the consumer price index for urban consumers (CPI-U). This part of the program begins January 1, 2023 for Part B and October 1, 2022 for Part D, although the reporting requirements for the HHS Secretary for 2023 and 2024 plan years can be delayed until September 30, 2025, at least for Part B.

The inflation protections and rebates will be measured and calculated on a quarterly basis for Part B and an annual basis for Part D (running from October 1st through September 30th of the following year). The baselines are calculated using 2021 data. For Part B, the calendar quarter from July 1 to September 30 will be the "Payment Amount Benchmark Quarter" from which all future "Inflation-Adjusted Payment Amounts" will be based. For Part D, the 9 months from January 1, 2021 to September 30, 2021 will be used to calculate baseline costs. The comparison between the benchmark period and the measurement period for both Part B and Part D is at the manufacturer sale to wholesaler/pharmacy point in the process. This differs from the selected drug price guarantees, where the price guarantee is at the point-of-sale;

therefore, the protections do not guarantee that the inflation guarantee savings will be passed on to the member, only that the manufacturer cannot realize greater cost increases at the manufacturer point-of-sale than the CPI-U.

Part D Benefit Redesign

A major part of the legislation affecting health plans is the Part D benefit redesign. Changes to insulin copays begin in 2023, and while there are minor changes in 2024— such as the member's liability in the catastrophic phase becoming 0%—most of the major changes happen in 2025.

Low Income Subsidies

Beginning with the 2024 plan year, the act expands eligibility for full low-income subsidies to individuals who fall between 135% and 150% of the Federal Poverty Limit.

Insulin

For plan years 2023 and 2024, the maximum copay shall not exceed more than $35 for a 1-month supply for any covered insulin product, regardless of the phase the beneficiary is in, and the deductible is waived. Similarly in 2025, the maximum copay for insulin products is $35 for a month's supply, until the member reaches the Out-of-Pocket threshold. A covered insulin product is defined as an insulin product that is approved under is approved or licensed under sections 505 of the Federal Food, Drug, and Cosmetics Act or licensed under section 351 of the Public Health Service Act.

The copay maximum also applies to insulin furnished products covered under Part B, along with a waived deductible, however, it does not go into effect until 7/1/2023.

For plans years 2026 and each subsequent year, the maximum copay will be the lesser of:

- $35, or
- 25% of the maximum fair price, or
- 25% of the negotiated price.

The Act provides plan sponsors an opportunity to reimburse an enrollee within 30 days for any cost-sharing paid by such enrollee that exceeds the maximum cost sharing, during the period of January 1, 2023, through March 31, 2023.

Vaccines

Beginning in 2023, Adult vaccines, recommended by the Advisory Committee on Immunization Practices and in coordination with the Centers for Disease Control and Prevention shall be covered under Part B and Part D with no cost sharing and will not apply to the deductible.

Benefit Structure

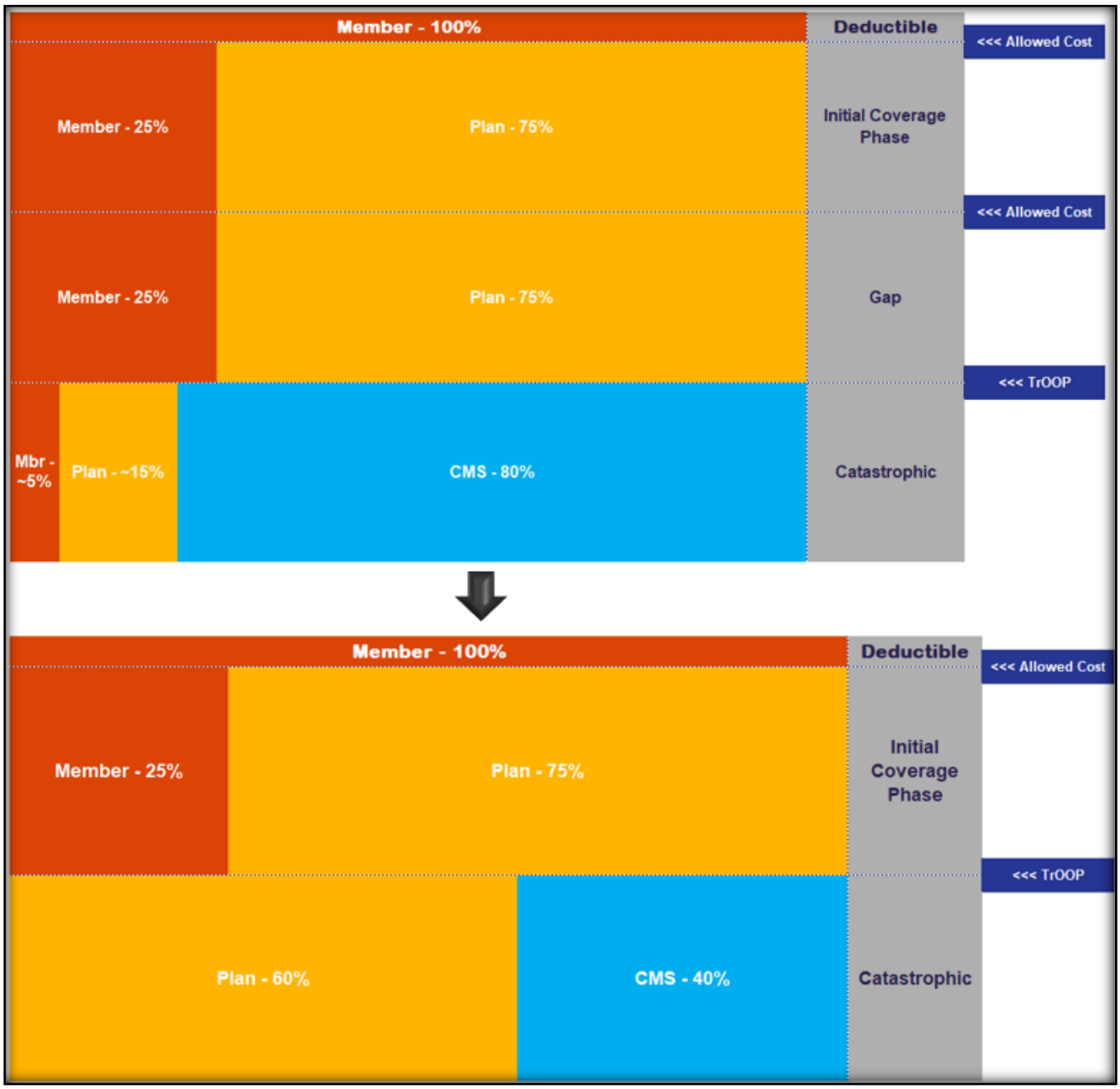
In 2025, the Part D basic benefit structure will change from a 4-phase benefit (Deductible, Initial Coverage Phase, Gap, and Catastrophic) to a 3-phase benefit (the Gap phase goes away). The deductible remains in place unchanged from the current version of the benefit. However, the gap will be eliminated, and the Initial Coverage Limit threshold that determines when the beneficiary leaves the Initial Coverage Phase (now going directly to the catastrophic phase of the benefit) will be determined by True Out-of-Pocket spend, not Gross Covered Drug Costs. Additionally, in the catastrophic phase of the benefit, the plan's liability increases from ~14-15% in 2023 to 20% in 2024, and to 60% in 2025 and beyond. CMS's liability in the catastrophic phase, in turn, decreases from 80% in 2024 to either 20% for applicable (Brand) drugs or 40% for non-applicable (Generic) drugs. Notably, this new TrOOP threshold that will determine when a beneficiary moves from the initial coverage phase to the catastrophic phase appears to be measured and calculated assuming all members are in a plan with a basic/defined standard benefit. In other words, plans with richer supplemental drug benefits will not experience an adverse leveraging impact of a rich benefit delaying the point at which the member hits the TrOOP threshold and enters the catastrophic phase of the benefit.

The Manufacturer Discount Program also changes significantly beginning in 2025. With the elimination of the gap phase of the benefit, the Manufacturer Discount Program must necessarily change, as through 2024 the entirety of the Coverage Gap Discount Program payments from manufacturers occurs in the gap phase, and only covered non-LIS beneficiaries. Beginning in 2025, the Manufacturer Discount Program will require participating manufacturers to pay 10% of ingredient costs for all applicable (Brand) drugs for non-LIS beneficiaries between the Deductible and the new TrOOP-based ICL, and 20% of ingredient costs for applicable drugs for non-LIS beneficiaries in the catastrophic phase. The application of the new Manufacturer Discount Program to non-LIS beneficiaries is consistent with the application of the current program, which only applied to non-LIS beneficiaries. For some drugs, the discount program will apply equally to LIS beneficiaries. However, beginning in 2025, there will be a gradual phase-in that will apply the manufacturer discount payments for certain drugs dispensed to LIS beneficiaries, instead of immediately requiring the full 10%/20% discounts these drugs for LIS beneficiaries. In both the initial coverage phase and the catastrophic phase of the benefit, manufacturers of applicable drugs dispensed to LIS beneficiaries will pay 1% of ingredient costs of the drug in 2025. The manufacturer percentage gradually increases from 1% in 2025 in both phases to 10% in 2029 in both phases. After 2029, the manufacturer percentage in the catastrophic phase continues to increase, to 15% in 2030 and 20% in 2031, at which point the manufacturer financial responsibility will be equal for LIS and non-LIS beneficiaries. However, for a manufacturer to qualify to "phase-in" to the discounts for LIS beneficiaries, the manufacturer needs to meet certain conditions established in the legislation. The manufacturer's total portfolio of "specified drugs" must be less than 1% of total expenditures for both Part D *and* Part B, *and* the manufacturer had to have participated in the prior Manufacturer Coverage Gap Discount Program that will sunset after 2024. Finally, there is a phase-in for specified small manufacturers for all beneficiary types if the manufacturer meets the condition that a single specified small manufacturer drug is greater than or equal to 80% of total expenditures of all drugs for that manufacturer (similar to the exclusion applied to small biotech firms in the Price Negotiation Program section of the legislation in Subtitle B/Part 1). For a manufacturer qualifying for this definition, the phase-in applies to all beneficiaries.

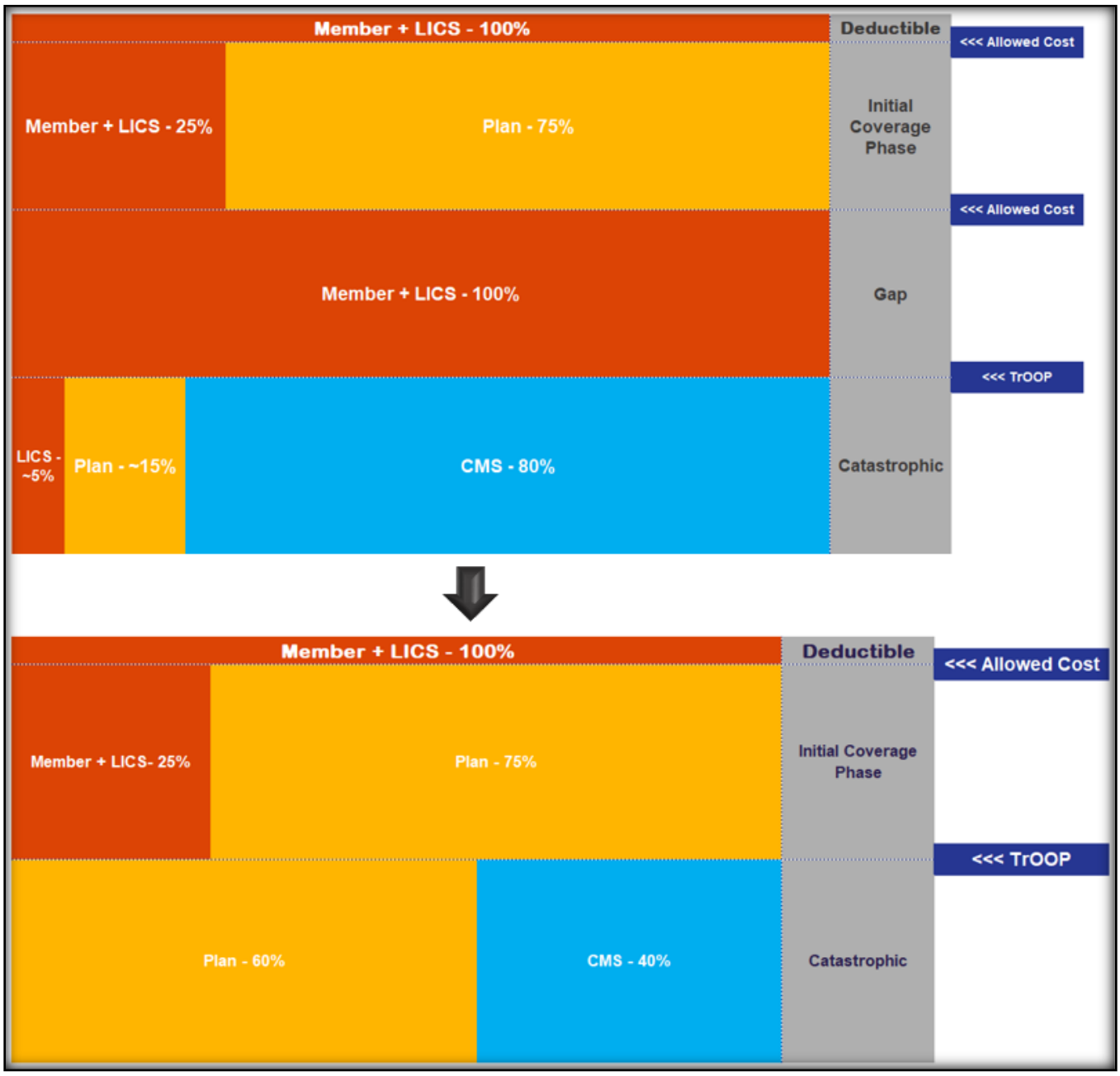
The final significant change to the benefit, particularly relevant to the member, is the option for the member to select into a Maximum Monthly Cap on cost-sharing payments. This provision in the legislation allows the member to evenly spread out their outstanding copayments from the incurred month to all remaining months in the plan year. The member can opt into the program at the beginning of the year *or in any month during the plan year*. This "any month" option for the member will require plans and PBMs to establish regular/monthly communications with their pharmacy networks to ensure the pharmacies appropriately adjudicate the claim at the point-of-sale. Per the legislation, we would expect the cash flow to function similarly to the current government subsidy cash flows, with the plan being invoiced the additional copayment cost foregone by the member at point-of-sale. The difference between the government subsidies and the maximum monthly OOP cash flows, however, is that for the member balances owed from the maximum monthly OOP selections, the plan incurs the responsibility to collect the liability, as well as any costs from unpaid balances. The plan can only prevent members with unpaid balances from selecting into the plan in future years (although the plan cannot prevent the member from switching plans the following year and selecting into the program in the new plan).

In aggregate, plan premiums are likely to increase for most plans due to the benefit restructuring. Additionally, there will likely be upwards premium pressure from the removal of pharmacy price concessions as a source of DIR in 2024. To prevent plan premiums from increasing too much and offsetting most or all of the member savings from the various provisions in the legislation meant to curb beneficiary drug expense, the legislation includes a provision that limits the increase of the base beneficiary premium to the lesser of the calculation as computed under the current formula, and a 6% increase from the prior year's base beneficiary premium. This limit takes effect in 2024 and remains in place until 2029. This limit will reduce basic premiums at the individual plan level by inflating the direct subsidy relative to the national average bid amount if the base beneficiary premium calculation yields an amount greater than 6% from the prior year. The higher direct subsidy would then be subtracted from each plan's standardized (1.0) basic bid amount, resulting in a lower basic premium at the individual plan level.

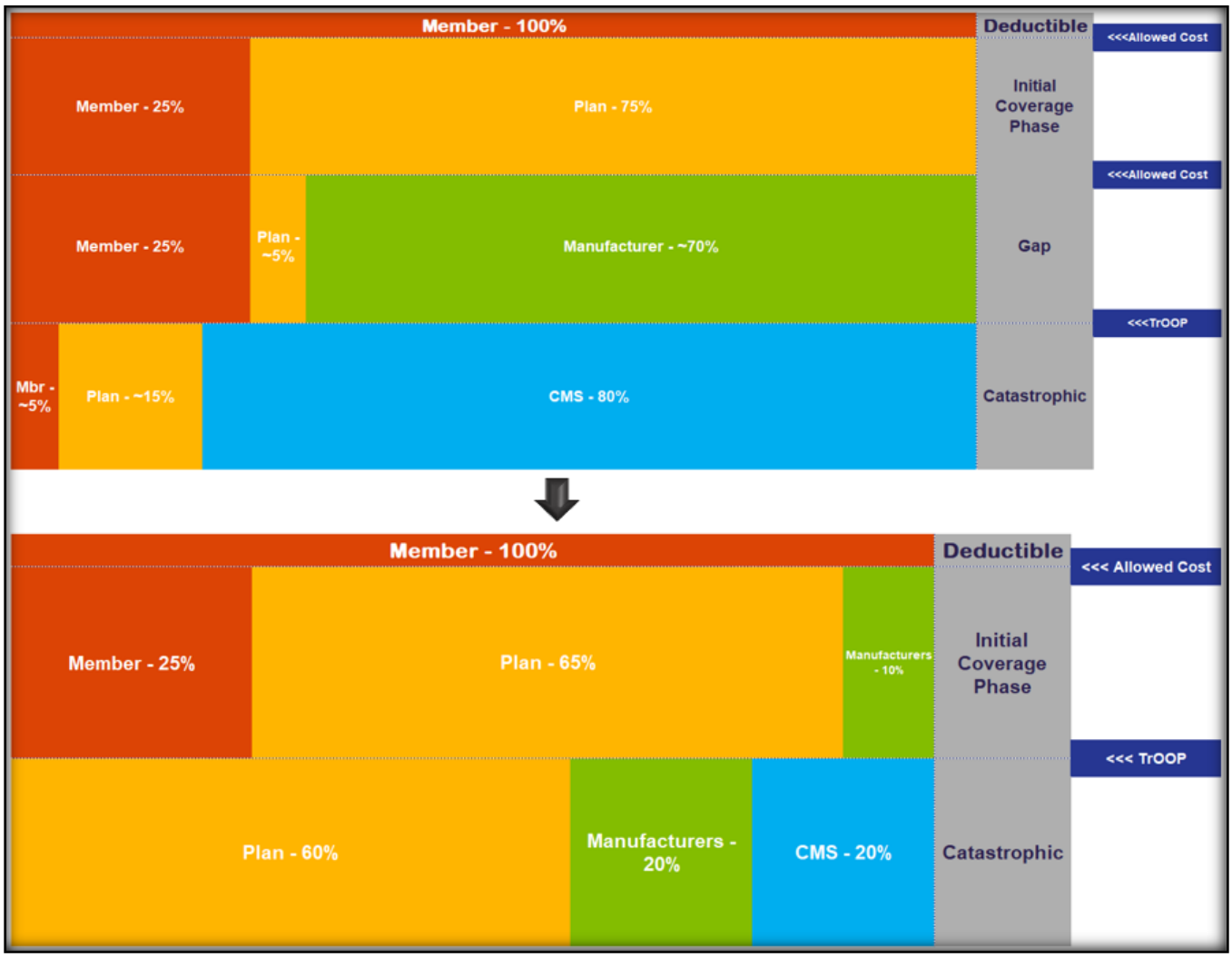
Changes to NLI Generics



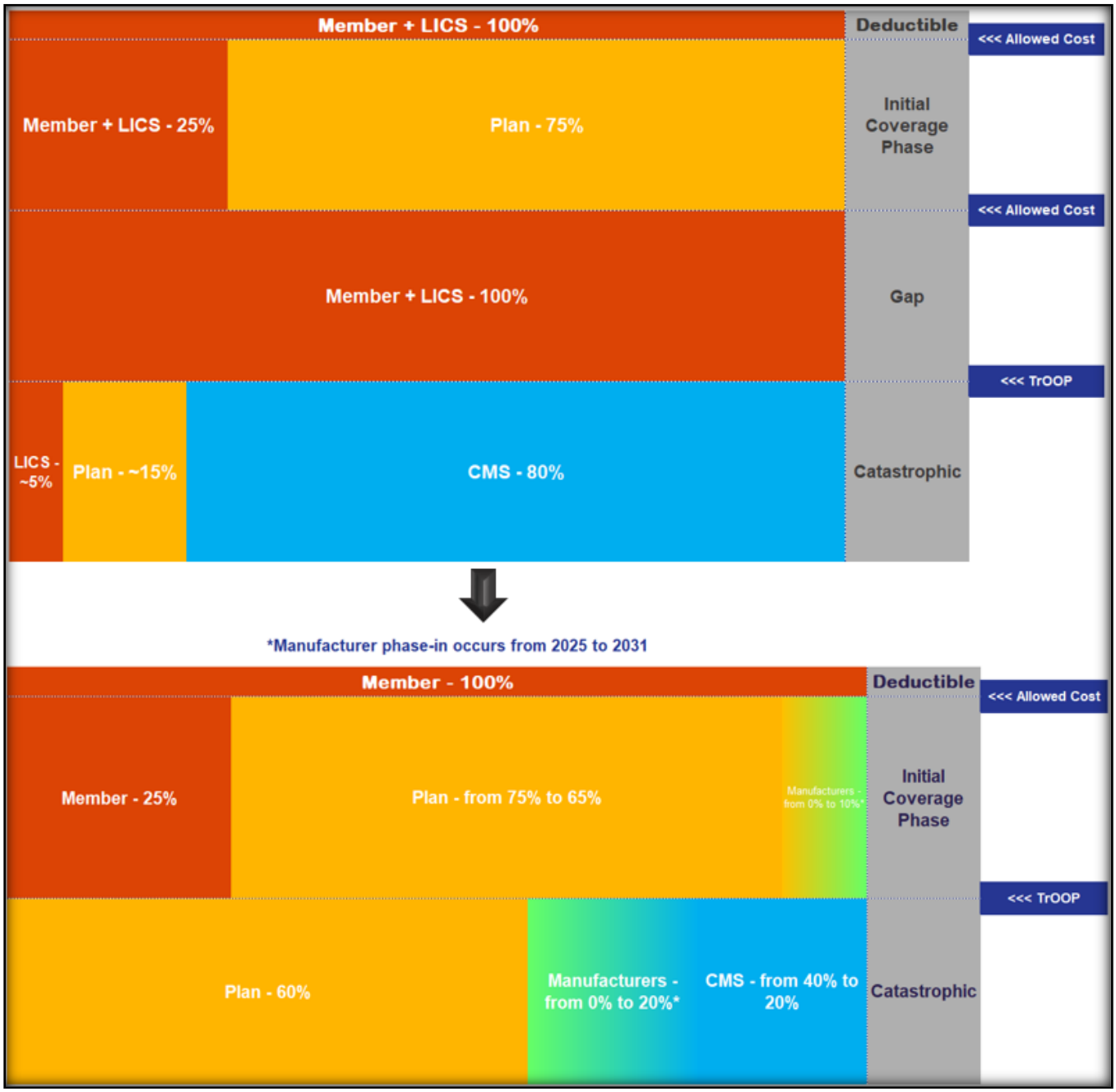
Changes to LI Generics



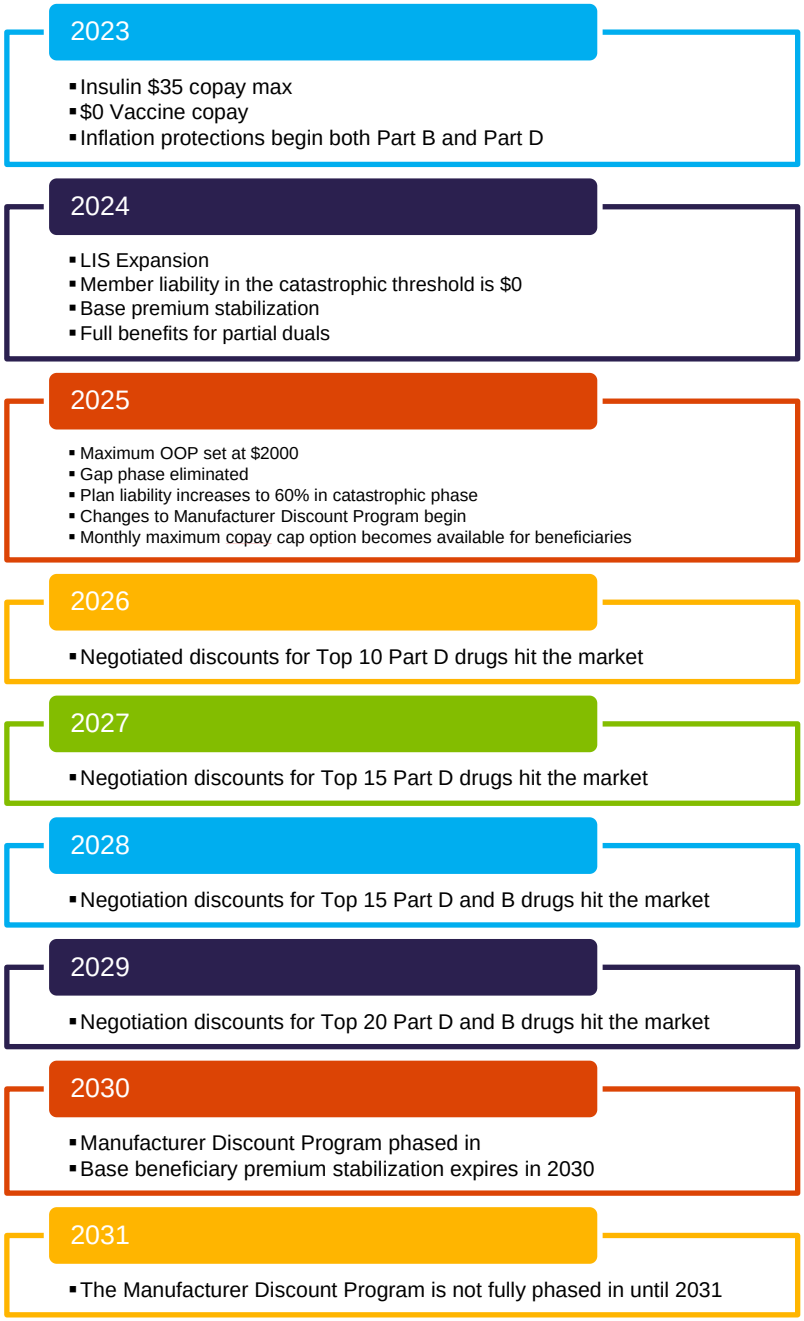
Changes to NLI Brand



Changes to LI Brand



Timeline


2023
Insulin $35 copay max
$0 Vaccine copay
Inflation protections begin both Part B and Part D
2024
LIS Expansion
Member liability in the catastrophic threshold is $0
Base premium stabilization
Full benefits for partial duals
2025
Maximum OOP set at $2000
Gap phase eliminated
Plan liability increases to 60% in catastrophic phase
Changes to Manufacturer Discount Program begin
Monthly maximum copay cap option becomes available for beneficiaries
2026
Negotiated discounts for Top 10 Part D drugs hit the market
2027
Negotiation discounts for Top 15 Part D drugs hit the market
2028
Negotiation discounts for Top 15 Part D and B drugs hit the market
2029
Negotiation discounts for Top 20 Part D and B drugs hit the market
2030
Manufacturer Discount Program phased in
Base beneficiary premium stabilization expires in 2030
2031
The Manufacturer Discount Program is not fully phased in until 2031

Conclusion

The changes to the Medicare Part D program in H.R. 5376 represent the most substantial alterations to the Part D program since the Medicare Modernization Act established the program in 2003. The transformative impact of the bill will be felt by all parties in the Medicare Part D space. Manufacturers, pharmacies, pharmacy benefit managers, and health plans will all experience significant changes to their business from the provisions of this bill. This initial paper summarizes the various important provisions of the bill that are relevant to Part D. Our next paper will address the expected impacts of the bill for all of the major players in the Part D space.

Please contact David Walters at david.walters@wakely.com or Wakely's Pharmacy team at Pharmacy@wakely.com with any questions or to follow up on any of the concepts presented here.

OUR STORY

Five decades. Wakely began in 1969 and eventually evolved into several successful divisions. In 1999, the actuarial arm became the current-day Wakely Consulting Group, LLC, which specializes in providing actuarial expertise in the healthcare industry. Today, there are few healthcare topics our actuaries cannot tackle.

Wakely is now a subsidiary of Health Management Associates. HMA is an independent, national research and consulting firm specializing in publicly funded healthcare and human services policy, programs, financing, and evaluation. We serve government, public and private providers, health systems, health plans, community-based organizations, institutional investors, foundations, and associations. Every client matters. Every client gets our best. With more than 20 offices and over 400 multidisciplinary consultants coast to coast, our expertise, our services, and our team are always within client reach.

Broad healthcare knowledge. Wakely is experienced in all facets of the healthcare industry, from carriers to providers to governmental agencies. Our employees excel at providing solutions to parties across the spectrum.

Your advocate. Our actuarial experts and policy analysts continually monitor and analyze potential changes to inform our clients' strategies – and propel their success.

Our Vision: To partner with clients to drive business growth, accelerate success, and propel the health care industry forward.

Our Mission: We empower our unique team to serve as trusted advisors with a foundation of robust data, advanced analytics, and a comprehensive understanding of the health care industry.

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