RIPARIAN

February 29, 2020

Inflation-Based Rebates for Medicare Part B and Part D Covered Drugs

Distinctions Between Congressional Bills H.R.3 and S.2543

For:
Clients and Friends of Riparian, LLC

RIPARIAN

Leadership

Monica Tsao Kim

Contributors

Susan Dunne, Cynthia Hwang, Don Russell, Alvin Cheng

In an effort to lower pharmaceutical drug costs, two bills are pending vote in the Senate.

H.R.3 – aka Elijah E. Cummings Lower Drug Costs Now Act passed on the Floor of the House of Representatives on Thursday, December 12, 2019. The final vote was 230 Yeas (228 Democratic + 2 Republican) to 192 Nays (191 Republican + 1 Independent), mostly along party lines. The bill has now gone to the Senate for vote.

S. 2543 – aka Prescription Drug Price Reduction Act ("PDPRA"), passed through the Senate Finance Committee with bipartisan support (19 Ayes to 9 Nays) on July 25, 2019 and is pending vote for passage in the Senate.

Of note, there are similar provisions in both the House and the Senate committee bills. Relevant to pharmaceutical manufacturers, both bills introduce an inflation-based rebate using the Consumer Price Index- Urban ("CPI-U") for both Part B and Part D covered drugs. This paper provides a comparison of these rebate provisions, along with mathematical examples illustrating those differences. This analysis is not intended to offer legal or regulatory advice and is based on our general experience in the industry. Our interpretations may differ from the views and intentions of the lawmakers that authored the relevant legislation.

1. Comparison of Part B Inflation Rebate

The design of the provisions for a Medicare Part B inflation rebate are similar between the two bills. Both bills measure an ASP Payment Amount and require a rebate if the ASP Payment Amount increases at a rate faster than CPI-U. The main differences between the bills lie with the periods that are compared to determine whether an inflation rebate is owed, and handling of subsequently approved drugs.

Key Provisions:

Category	House Bill, H.R.3	Senate Committee Bill, PDPRA
Rebatable Drugs	Part B Covered Drug EXCEPT vaccines and drugs/biologicals where average total allowed charged per year per individual is less than $100.	Part B Covered Drug EXCEPT vaccines and biosimilars.
Pricing Basis for Rebate	ASP Payment Amount	ASP Payment Amount
Rebate Calculation Cadence	Quarterly	Quarterly
Rebate Effective Start Period	Q3 2021	Q1 2021

Category	House Bill, H.R.3	Senate Committee Bill, PDPRA
Benchmark Period CPI-U	For Products Launched Before July 1, 2015: July 2015 For Products Launched After July 1, 2015: First Month of First full calendar quarter after First Marketed Date	For Products Launched Before January 1, 2019: July 2019 For Products Launched After January 1, 2019: First Month of First full calendar quarter after First Marketed Date Until First Month of First full calendar quarter for which an ASP Payment Amount is computed
Benchmark Payment Amount Period	For Products Launched Before July 1, 2015: Q1 2016 For Products Launched After July 1, 2015: 3rd calendar quarter after First Marketed Date	For Products Launched Before January 1, 2019: Q3 2019 For Products Launched After January 1, 2019: First full calendar quarter after First Marketed Date Until First full calendar quarter for which an ASP Payment Amount is computed (WAC is measured until an ASP Payment Amount is established)
Rebate Period CPI-U	Greater of: (a) Benchmark Period CPI-U (b) CPI-U for the first month of the calendar quarter that is two calendar quarters prior to the rebate period	Last month of the calendar quarter that is two calendar quarters prior to the rebate period
Civil Monetary Penalties	125% of Rebate	125% of Rebate

When comparing the two bills, manufacturers should note the following distinctions:

1. Limitation on applicable drugs: The Senate committee bill, PDPRA, does not limit "Part B Rebatable Drugs" based on spend as the House bill, H.R.3, does, so there would be manufacturers that may owe inflation rebates if the PDPRA passes but would not if the provisions of H.R.3 pass. "Part B Rebatable Drugs" described in H.R.3 are covered drugs and biologicals, excluding vaccines, that have an average individual spend per year of $100 or

more. There were approx. 350 non-vaccine drugs/ biologicals reported that have a per-patient spend in excess of $100 out of the approx. 521 non-vaccine Part B drugs/biologicals reported by CMS in 2018 (i.e., approx. 67%)[1]. Thus, the manufacturers of the remaining non-vaccine drugs/ biologicals with a per-patient spend less than $100 may prefer the House bill of the two bills as there would be less rebate obligations.

2. CPI-U: There are differences in the month for which the CPI-U represents a quarterly period between the two bills[2]. The House bill, H.R.3, specifies that CPI-U for the first month of the quarter is used for comparison between benchmark and rebate periods. The Senate committee bill, PDPRA, has a disconnect between its benchmark and rebate periods. For the Benchmark Period CPI-U, the PDPRA uses the first month of the calendar quarter but for the Rebate Period CPI-U, it specifies the last month of the calendar quarter that is two calendar quarters prior to the rebate period.

3. CPI-U Comparison Periods: The Benchmark CPI-U in the House bill, H.R.3, is earlier: the H.R.3 benchmark timing is as early as July 2015 for drugs marketed prior to July 2015, while the Benchmark CPI-U for the Senate committee bill, PDPRA, is July 2019 for drugs marketed prior to January 2019. Both provisions provide for inflation rebates applied beginning in 2021, but depending on market entry date, the CPI-U comparison could span as much as 6 years for H.R.3, while the PDPRA would be a CPI-U comparison spanning only 2 years. As demonstrated mathematically in the below examples, the difference in benchmark periods can lead to significant impacts on the rebate amount. Manufacturers of older products introduced prior to July 2015 may prefer the Senate committee bill which may have a more favorable rebate outcome due to there being a shorter period between benchmark and rebate periods for comparison.

The House bill also recognizes that the ASP Payment Amount for a given quarter is determined on the basis of sales and discounts in the quarter that begins six months (i.e., two quarters) prior to the ASP Payment Amount (i.e., ASP Payment Amount for Q1 is determined based on transactions in the prior year Q3). Thus, the Benchmark CPI-U for products introduced prior to July 2015 is the CPI-U for July 2015 and the benchmark quarter for the ASP

[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB

[2] The CPI-U used to represent a quarterly period differs between the House bill, the Senate committee bill, and what is used for determining the additional rebate based on inflation for Medicaid. The introduction of inflation rebates for Medicare seems to borrow from the concept employed by the Medicaid Drug Rebate Program, so it is worth noting that the definitions differ. The ACA Final Rule (42 CFR § 447.502 Medicaid Program; Covered Outpatient Drugs; Final Rule) identifies the CPI-U for quarterly comparison as "the month before the beginning of the calendar quarter".

Payment Amount is Q1 2016 in H.R.3. The Senate committee bill, PDPRA, seemingly ignores this two quarter lag connection and links the benchmark measurement quarters for CPI-U and ASP Payment Amount to be the same quarter: for products introduced prior to January 1, 2019 the benchmark quarter for both CPI-U and ASP Payment Amount is Q3 2019. However, the PDPRA does seem to acknowledge the two quarter lag with the Rebate Period CPI-U, which is described as the last month of the calendar quarter that is two quarters prior to the rebate period. This creates a mathematical disconnect between the CPI-U and the period for which the payment is being calculated.

4. Subsequently Approved Drugs: In the House bill, H.R.3., manufacturers would not be subject to the provisions of a Part B inflation rebate for newly marketed drugs until a minimum of six calendar quarters have passed, while the Senate committee bill, PDPRA, provides for a Part B inflation rebate as early as the following quarter. With this difference, manufacturers of newly approved drugs may prefer the House bill, so they would not be subject to inflation rebates as immediately.

a. For the House bill, H.R.3, if a new drug is approved and marketed today, the Benchmark CPI-U period would be the first month of the first full calendar quarter after today, and the Benchmark ASP Payment Amount would be subject to the CPI-U difference from then until the third full calendar quarter after today. An inflation rebate for subsequent quarters would not be due until the later of the 6th full calendar quarter after today or July 1, 2021.

b. For new drugs approved and marketed today, the Senate committee bill, PDPRA, would establish the Benchmark period CPI-U to be the first month of the first calendar quarter after the drug is first marketed, and wholesale acquisition cost ("WAC") would be measured immediately to determine whether WAC exceeded the rate of inflation in each subsequent quarter until an ASP Payment Amount is established. Once an ASP Payment Amount is established, the Benchmark CPI-U becomes the first month of the first calendar quarter for which ASP was computed and manufacturers will continue to be subject to inflation rebates in each subsequent quarter.

The following mathematical examples illustrate the potential difference between different market entry dates and CPI-U periods outlined in the two bills:

Example 1: Product with a First Marketed Date Prior to July 2015, subject to annual WAC increase of approx. 3% with ASP approx. 20% lower than WAC:

This example illustrates a potential outcome of an older product for inflation rebates due for Q3 2021 (the period in which the House bill, H.R.3, inflation rebate goes into effect; the Senate committee bill, PDPRA, inflation rebate is effective for Q1 2021). Under H.R.3, this product

would be subject to a price increase comparison with CPI-U across a six-year period, whereas under the PDPRA the product would be subject to a comparison across a roughly two-year period of time instead. As a result, the outcome under H.R.3 could be more costly for manufacturers (vs. PDPRA) for older products.

Ref	Component	H.R.3	PDPRA
A	Benchmark CPI-U Period	July 2015	July 2019
B	Benchmark CPI-U	238.654	256.571
C	Benchmark WAC	100	120
D	Benchmark ASP	80	96
E	Benchmark ASP Period	Q1 2016	Q3 2019
F	Rebate Effective Period	Q3 2021	Q3 2021
G	Rebate Effective Period CPI-U (estimated at rate of +1.10 period-over-period from values in Q4 2019)	262.844 (i.e., estimated CPI-U for January 2021*)	262.472 (i.e., estimated CPI-U for March 2021*)
H	Rebate Effective Period WAC	128	128
I	Rebate Effective Period ASP	102	102
J = (G-B) ÷ B	Change in CPIU	10.1360%	2.2999%
K = (J×D) + D	Inflation Adjusted Benchmark ASP	88.1088	98.2080
L = I – K	Rebate Owed Per Billing Unit	13.8912	3.7920

* The House bill, H.R.3, specifies that a quarterly period's CPI-U is determined by the first month of the calendar quarter. The Senate committee bill, PDPRA, also uses the first month of the calendar quarter for Benchmark CPI-U but specifies the last month of a calendar quarter is used in determining the Rebate Period CPI-U. Estimated CPI-U values are extrapolated at a rate increase of 1.1 per quarter from Q4 2019.

Example 2: Product with a First Marketed Date of November 15, 2018:

For a product similar to the first example, but with a market entry date after the benchmark period described in the House bill, H.R.3, and before the benchmark period described in the Senate committee bill, PDPRA, the outcome under H.R.3 may be less costly for manufacturers (vs. PDPRA). This example illustrates a Benchmark ASP Period coincident with the Rebate Period under both bills. H.R.3 would compare CPI-U changes to pricing from January 2019 to January 2021 (24 months) in this example, whereas the PDPRA would compare pricing changes to the CPI-U change from July 2019 to March 2021 (20 months). In this scenario, where the Benchmark ASP and Rebate Period ASP values are the same, the rebate amount due under the Senate committee bill, PDPRA, is greater.

Ref	Component	H.R.3	PDPRA
A	Benchmark CPI-U Period	January 2019	July 2019
B	Benchmark CPI-U	251.712	256.571
C	Benchmark WAC	120	120
D	Benchmark ASP	96	96
E	Benchmark ASP Period	Q3 2019	Q3 2019
F	Rebate Effective Period	Q3 2021	Q3 2021
G	Rebate Effective Period CPI-U	262.844 (i.e., estimated CPI-U for January 2021*)	262.472 (i.e., estimated CPI-U for March 2021*)
H	Rebate Effective Period WAC	128	128
I	Rebate Effective Period ASP	102	102
J = (G-B) ÷ B	Change in CPIU	4.4225%	2.2999%
K = (J×D) + D	Inflation Adjusted Benchmark ASP	100.2456	98.2080
L = I – K	Rebate Owed	1.7544	3.7920

* The House bill, H.R.3, specifies that a quarterly period's CPI-U is determined by the first month of the calendar quarter. The Senate committee bill, PDPRA, also uses the first month of the calendar quarter for Benchmark CPI-U but specifies the last month of a calendar quarter is used in determining the Rebate Period CPI-U. Estimated CPI-U values are extrapolated at a rate increase of 1.1 per quarter from Q4 2019.

Example 3: Product with a First Marketed Date of May 15, 2020:

For a product similar to the first two examples, but with a market entry date after the benchmark periods for both bills and before 2021 (when the inflation rebates go into effect), the outcome under the House bill, H.R.3, could be less costly for manufacturers (vs. the Senate committee bill, PDPRA). The rebate period under evaluation, Q3 2021, is less than six quarters after the product is first marketed and thus, no inflation rebate is due under the House bill, but there is a rebate due under the Senate committee bill.

Ref	Component	H.R.3	PDPRA
A	Benchmark CPI-U Period	July 2020 (i.e., first month of first full quarter after first marketed date)	January 2021 (i.e., first month of first full calendar quarter for which an ASP Payment Amount is computed)

Ref	Component	H.R.3	PDPRA
B	Benchmark CPI-U	260.645 (i.e., estimated CPI-U for July 2020*)	262.844 (i.e., estimated CPI-U for January 2021*)
C	Benchmark WAC	124	124
D	Benchmark ASP	100	100
E	Benchmark ASP Period	Q1 2021	Q1 2021
F	Rebate Effective Period	Q3 2021	Q3 2021
G	Rebate Effective Period CPI-U	262.844 (i.e., estimated CPI-U for January 2021*)	262.472 (i.e., estimated CPI-U for March 2021*)
H	Rebate Effective Period WAC	128	128
I	Rebate Effective Period ASP	102	102
J = (G-B) ÷ B	Change in CPIU	0.8437%	-0.1415%
K = (J×D) + D	Inflation Adjusted Benchmark ASP	100.8437	99.8585
L = I – K	Rebate Owed	0.0000 (Rebate not due until six quarters after product is first marketed)	2.1415

* The House bill, H.R.3, specifies that a quarterly period's CPI-U is determined by the first month of the calendar quarter. The Senate committee bill, PDPRA, also uses the first month of the calendar quarter for Benchmark CPI-U but specifies the last month of a calendar quarter is used in determining the Rebate Period CPI-U. Estimated CPI-U values are extrapolated at a rate increase of 1.1 per quarter from Q4 2019.

Of course, the Part B inflation rebate has the potential to have a significant impact on manufacturer discount obligations. Due to different provisions between the House bill, H.R.3, and the Senate committee bill, PDPRA, manufacturers with emerging products or manufacturers of products with a low per-patient annual cost may be subject to lower rebates under the House bill while manufacturers with older products (marketed prior to July 2015) may be subject to lower rebates under the Senate committee bill.

The Payment Amount described in both bills may be referencing the ASP payment limit which includes the mark-up of 6% and sequestration, if applicable[3]. If this is the intent, in cases

[3] https://www.cbo.gov/publication/55995 CBO estimates that sequestration will not be required for 2020.

where manufacturers share a J-Code it seems a manufacturer could be subject to inflation penalties due to actions of other manufacturers of products assigned the same J-Code.

In light of the impending effective date of the proposed Part B inflation rebate in both bills (i.e., Q1 2021 under the Senate committee bill or Q3 2021 under the House bill), manufacturers may want to carefully evaluate any pricing and discount decisions that may impact ASPs for existing products beginning in 2021, and incorporate ASP inflation rebates into their gross-to-net forecasts in anticipation of the passage of either bill.

2. Comparison of Part D Inflation Rebate

The differences in the design of the Part D inflation rebate are more significant between the two bills as compared to the differences in the Part B inflation rebate between the two bills because the differences are more fundamental: the two bills use different bases for the rebate and they differ in their scope/coverage of drugs.

Key Provisions:

Category	House Bill, H.R.3	Senate Committee Bill, PDPRA
Rebatable Drugs	Part D covered drug EXCEPT drugs/biologicals where average total cost per year per individual is less than $100.	Part D covered drug EXCEPT generic drugs and biosimilars
Pricing Basis for Rebate	Annual Manufacturer Price	Unit-Weighted Average Wholesale Acquisition Cost ("WAC")
Rebate Calculation Cadence	Annual	Semi-Annual (i.e. each six-month period beginning January 1 and July 1)
Rebate Effective Start Period	2022	January 2022
Benchmark CPI-U Period	For Products Launched Before January 1, 2016: January 2016 For Products Launched After January 1, 2016: January of the first year after First Marketed Date	For Products Launched Before July 1, 2019: July 2019 For Products Launched After July 1, 2019: First month after the last day of the six-month period that begins on the day on which the drug was first marketed

Category	House Bill, H.R.3	Senate Committee Bill, PDPRA
Benchmark Payment Amount Period	For Products Launched Before January 1, 2016: Calendar Year 2016 For Products Launched After January 1, 2016: First calendar year after First Marketed Date	For Products Launched Before July 1, 2019: July 2019 For Products Launched After July 1, 2019: Six-month period beginning on the day which the drug was first marketed
Rebate Period CPI-U	January of the applicable year	Last month of the rebate period
Civil Monetary Penalties	125% of Rebate	125% of Rebate

When comparing the two bills, manufacturers should note the following distinctions:

1. **Limitation on applicable drugs**: "Part D Rebatable Drugs" described in the House bill, H.R.3, are Part D covered drugs and biologicals, that have an average individual spend per year of $100 or more. There were approx. 5,430 Part D covered drugs/ biologicals reported that have a per-patient spend in excess of $100 out of the approx. 9,116 Part D covered drugs/biologicals reported by CMS in 2018 (i.e., 60%)[4]. The Senate committee bill, PDPRA, does not limit to "Part D Rebatable Drugs" based on spend, but does specify that the Part D inflation rebate is only applied to brand drugs/ biologicals; thus there are different populations of drugs and manufacturers affected by the proposed rebates as noted below. Depending on where a manufacturer's products fall in the below matrix, one bill's passage may be more favorable than the other.

	Annual Average Spend Per Beneficiary	
Part D Covered Drug	< $100	>= $100
Brand Drug/ Biological	PDPRA	PDPRA and H.R.3
Generic Drug/ Biosimilar	N/A	H.R.3

2. **Benchmark Period distinctions**: Another distinction between bills is the designation of benchmark periods for purposes of measuring inflation for existing and subsequently approved drugs. For newer drugs, the benchmark rebate period in the Senate committee bill (for drugs approved by the FDA after July 1, 2019), is the six months starting with the market entry date. The Benchmark CPI-U Period is the first month after the benchmark rebate period

[4] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD

(i.e., the six months starting with the first marketed date), which may be offset from the ongoing six month rebate periods (defined as beginning January 1 and July 1). In the House Bill, the benchmark rebate period is longer, one year vs six months, and starts the calendar year following launch. The Benchmark CPI-U Period is then always that January following launch and new drugs are those launched after January 2016. There is also a disconnect between the ongoing CPI-U periods and the Benchmark CPI-U Period compared for determining inflation changes under the Senate committee bill, PDPRA; Benchmark CPI-U Periods are the first month of the benchmark period and the rebate CPI-U periods are the last month of the rebate periods.

3. Basis for the Rebate: The House Bill, H.R.3, bases its rebate on the Annual Manufacturer Price (determined using Average Manufacturer Price[5]), whereas the Senate committee bill, PDPRA, uses a unit-weighted average WAC[6] as the basis for the rebate.

   The Senate committee bill, PDPRA, describes a "weighted average price" (i.e. weighted average WAC) for each package size as being calculated by taking each WAC price multiplied by the ratio of number of days for which each WAC price is applied during the six-month rebate period over the total number of days in the rebate period. The unit-weighted average WAC is determined by the sum product of the weighted average WAC and the ratio of the total units of each package size dispensed in the rebate period to the total number of units of the dosage form and strength dispensed during the rebate period. See the following example calculation for a given dosage form and strength:

Package Size 1 – Weighted Average WAC

Six Month Period	WAC Price/ Unit	Days	Days %	Weighted Average
A	*B*	*C*	*D = C ÷ sum(C)*	*E = D x B*
WAC 1	100	120	66.67%	66.67
WAC 2	120	60	33.33%	40.00
			Weighted Average WAC	106.67

[5] Defined in the House bill, H.R.3, as having the same meaning as the "term in section 1927(k)(1), with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927".

[6] The Senate committee bill, S.2543 references a "unit weighted average price" and defines "price" to be: "with respect to a rebatable covered part D drug, the wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) for such drug." Sec.128 (a)(4)(E). Where applicable, references of such "price" has been substituted with "WAC" for clarification purposes.

Package Size 2 – Weighted Average WAC

Six Month Period	WAC Price/ Unit	Days	Days %	Weighted Average
A	*B*	*C*	*D = C ÷ sum(C)*	*E = D x B*
WAC 1	100	135	75.00%	75.00
WAC 2	120	45	25.00%	30.00
			Weighted Average WAC	105.00

Unit Weighted Average WAC

Six Month Period	Weighted Average WAC	Units	Unit %	Weighted Average
A	*B*	*C*	*D = C ÷ sum(C)*	*E = D x B*
Package Size 1	106.67	3000	75.00%	80.00
Package Size 2	105.00	1000	25.00%	26.25
			Unit Weighted Average WAC	106.25

The House Bill, H.R.3, is based on the Annual Manufacturer price, which is described as being calculated by taking the quarterly Average Manufacturer Price ("AMP") multiplied by the ratio of total units dispensed for the dosage form and strength in the quarter over the total units dispensed for the dosage form and strength in the calendar year. The introduction of the Annual Manufacturer Price raises a number of questions including:

- Would the "total units dispensed" include units that were treated as ineligible in the AMP calculation?
- Would this be based on the calculated AMP (which could be a negative or zero value) or the reported AMP value?
- In the event AMP is restated after an inflation rebate for the period, would there be an adjustment?

The following mathematical examples illustrate potential different outcomes based on provisions for Part D outlined in the two bills upon the start of the rebates in 2022. The examples are a comparison between Annual Manufacturer Price across a one-year period under the House bill, H.R.3, to unit weighted average WAC in a six month period under the Senate committee bill, PDPRA, for an existing product with a first marketed date prior to January 1, 2016 that has only one package size and wholesale acquisition cost ("WAC") is constant for the entire calendar year:

Example 1: Product with a First Marketed Date Prior to January 1, 2016, with AMP approx. 15-20% lower than WAC and subject to annual WAC increase closely aligned with CPI-U:

This example illustrates a potential outcome of an older product. The product would be subject to a comparison of price increase to CPI-U across a six-year period under the House bill, H.R.3, verses only a roughly three-year period of time under the Senate committee bill, PDPRA. As a result, H.R.3 may be more costly for manufacturers (vs. PDPRA) for older products. With regard to the distinction in basis for the rebate (Annual Manufacturer Price vs WAC), AMP has different levers that can affect its value outside of WAC price changes, so the potential variability is higher under the House bill because a manufacturer's weighted average prices can change more than the rate of inflation year-over-year even when WAC does not.

Ref	Component	H.R.3	PDPRA
A	Benchmark CPI-U Period	January 2016	July 2019
B	Benchmark CPI-U	236.916	256.571
C	Benchmark Unit Weighted Average WAC	102	110
D	Benchmark Annual Manufacturer Price	87	N/A
E	Rebate Effective Period	2022	January - June 2022
F	Rebate Effective Period CPI-U	267.242 (i.e., estimated CPI-U for January 2022*)	268.854 (i.e., estimated CPI-U for June 2022*)
G	Rebate Effective Period Unit Weighted Average WAC	115	115
H	Rebate Effective Annual Manufacturer Price	100	N/A
I = (F-B) ÷B	Change in CPIU	12.80032%	4.787369%
J	Inflation Adjusted Benchmark Amount	98.136276	115.266106
	Formula	*=D+ (I × D)*	*= C+ (I × C)*
K	Rebate Owed	1.863724	0.000000
	Formula	*=IF(H-J <0,0,H-J)*	*=IF(G-J <0,0,G-J)*

* Rebate Period CPI-U for the Senate committee bill, PDPRA, is based on the CPI-U of the last month of the rebate period, while the House bill, H.R.3, specifies January of the calendar year. Estimated CPI-U values are extrapolated at a rate increase of 1.1 per quarter from Q4 2019.

Example 2: Product with a First Marketed Date Prior to January 1, 2016, with AMP approx. 15-20% lower than WAC and subject to annual WAC increase not aligned with CPI-U:

This example is similar to the first example but having WAC that is not closely aligned with CPI-U. In this scenario, it seems both bills lead to more rebate liability for manufacturers of older products, but the House bill, H.R.3, is still more costly. Depending on the timing and aggressiveness of price changes, the amount due under the Senate committee bill, PDPRA, could potentially be less for older products where weighted average prices are tied to WAC.

Ref	Component	H.R.3	PDPRA
A	Benchmark CPI-U Period	January 2016	July 2019
B	Benchmark CPI-U	236.916	256.571
C	Benchmark Unit Weighted Average WAC	102	125
D	Benchmark Annual Manufacturer Price	87	N/A
E	Rebate Effective Period	January 2022	January – June 2022
F	Rebate Effective Period CPI-U	267.242 (i.e., estimated CPI-U for January 2022*)	268.854 (i.e., estimated CPI-U for June 2022*)
G	Rebate Effective Period Unit Weighted Average WAC	135	135
H	Rebate Effective Annual Manufacturer Price	115	N/A
I = (F-B) ÷B	Change in CPIU	12.80032%	4.787369%
J	Inflation Adjusted Benchmark Amount	98.136276	130.984211
	Formula	*=D+ (I × D)*	*= C+ (I × C)*
K	Rebate Owed	16.863724	4.01579
	Formula	*=IF(H-J <0,0,H-J)*	*=IF(G-J <0,0,G-J)*

* Rebate Period CPI-U for the Senate committee bill, PDPRA, is based on the CPI-U of the last month of the rebate period, while the House bill, H.R.3, specifies January of the calendar year. Estimated CPI-U values are extrapolated at a rate increase of 1.1 per quarter from Q4 2019.

Example 3: Product with a First Marketed Date Prior to January 1, 2016, subject to an annual WAC increase not aligned with CPI-U (same as Example 2) and Product is Mostly Sold to Non-Wholesalers/Non-Distributors at Pricing Below WAC:

This scenario is similar to the first two examples, but where the distribution model is such that WAC has less influence over AMP eligible sales. It seems likely that the Annual Manufacturer Price will align with inflation and little or no inflation rebate would be due under the House bill. The inflation rebate is likely higher in this example, however, under the Senate committee bill with its WAC-based rebate because, as is typical, WAC increased at a rate faster than CPI-U resulting in a heavy rebate impact, even when the manufacturer has a sales mix that does not have a high percentage of sales at a WAC price.

Ref	Component	H.R.3	PDPRA
A	Benchmark CPI-U Period	January 2016	July 2019
B	Benchmark CPI-U	236.916	256.571
C	Benchmark Unit Weighted Average WAC	102	125
D	Benchmark Annual Manufacturer Price	87	N/A
E	Rebate Effective Period	January 2022	January – June 2022
F	Rebate Effective Period CPI-U	267.242 (i.e., estimated CPI-U for January 2022*)	268.854 (i.e., estimated CPI-U for June 2022*)
G	Rebate Effective Period Unit Weighted Average WAC	135	135
H	Rebate Effective Annual Manufacturer Price	98	N/A
I = (F-B) ÷B	Change in CPIU	12.80032%	4.787369%
J	Inflation Adjusted Benchmark Amount	98.136276	130.984211
	Formula	*=D+ (I × D)*	*= C+ (I × C)*
K	Rebate Owed	0.000000	4.01579
	Formula	*=IF(H-J <0,0,H-J)*	*=IF(G-J <0,0,G-J)*

* Rebate Period CPI-U for the Senate committee bill, PDPRA, is based on the CPI-U of the last month of the rebate period, while the House bill, H.R.3, specifies January of the calendar year. Estimated CPI-U values are extrapolated at a rate increase of 1.1 per quarter from Q4 2019.

Depending on the distribution model of the manufacturer and whether the manufacturer sells Part D Rebatable Drugs at a price consistent with WAC or sells largely at prices that are not tied to WAC, there will be different outcomes. The key for manufacturers to understand is that by measuring inflation rebates based on an Annual Manufacturer Price (using AMP for purposes of determining an inflation rebate for Part D Rebatable Drugs), the inflation rebate

proposed by the House bill, H.R.3, while higher in general for older products, is subject to the levers that affect AMP, and therefore fluctuates with the variability of price concessions to AMP eligible entities. Manufacturers participating in the Medicaid Drug Rebate Program ("MDRP") are likely already monitoring and taking actions to manage fluctuations in AMP against MDRP baseline AMP values. In contrast, under the Senate committee bill, PDPRA, rebate liability is tied to WAC changes and will fluctuate based on WAC price increases. Considering that WAC changes typically are not evaluated as closely for impact on compliance costs and revenue leakage, and that balanced pricing committees that weigh costs and market factors (with stakeholders from GP as well as marketing, sales, trade and finance) have less influence over WAC change decisions, manufacturers may find less comfort in the Senate committee bill.

3. Considerations:

Forecasting: Manufacturers will need to consider their pricing strategies and how those may be impacted by these inflation rebate provisions. The provisions in the House bill, H.R.3, and the Senate committee bill, PDPRA, provide for Part B inflation rebates that will go into effect in 2021 and Part D inflation rebates that will go into effect in 2022. Therefore, their impact on pricing and contracting strategies as early as 2020 will need to be considered as lagged discounts may affect ASPs and AMPs reported in 2021.

Resources: With the inflation rebates for Part B and Part D described in both bills, passage of either bill would require manufacturers to assign resources to accrue for and adjudicate rebates due and consider how those additional rebates should influence future pricing and discounting decisions.

Mergers and Acquisitions: As manufacturers are performing due diligence for mergers and acquisitions, both of these bills (especially the House bill, H.R.3), make it especially important for manufacturers to consider pricing reported for periods as far back as 2016 and consider whether its pricing strategies would be affected by potential inflation penalties.

Riparian offers a wide range of consulting and managed services. We believe that solutions originate when we listen, understand, and deliver together as one team. Let our team of Technology and Subject Matter Experts be an extension of your team. For additional information, email info@riparian.com.