Insight

Comparing the Recent Drug-Pricing Reform Proposals

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If lawmakers' desire to lower drug prices can be measured by the number of bills they introduce, it seems fair to say their desire is strong. In the past few days, a number of bills have either been introduced or re-introduced, while another will be formally considered this week. At least two of the bills have bipartisan support, and a third, while introduced only by Republican members of Congress, consists largely of provisions that have previously garnered bipartisan support. These bills include 70 distinct measures intended to reduce spending on prescription drugs in one way or another.

These bills are:

- S. 2543, the Prescription Drug Pricing Reduction and Health and Human Services Improvements Act, a bipartisan bill from the Senate Finance Committee;
- S. 1895, the Lower Health Care Costs Act, a bipartisan bill from the Senate Health, Education, Labor, and Pensions (HELP) Committee;
- H. R. 19, the Lower Costs, More Cures Act, from the House Republicans of the Energy and Commerce, Ways and Means, Education and Labor, and Judiciary Committees; and
- H. R. 3, the Lower Drug Costs Now Act, from Speaker Nancy Pelosi, which will be considered this week and which includes what would arguably be the most sweeping changes to how the United States pays for drugs to date—including implementing federal negotiation of drug prices.
- S. 3129, the Lower Costs, More Cures Act, from Sens. Crapo, Burr, Enzi, Tillis, and Barrasso, which largely mirrors H.R. 19.

This analysis compares these bills and notes the most significant reforms they are proposing. While there are unique parts to each bill, the bills' provisions overlap

significantly.

Past AAF Analyses of These Drug-Pricing Reform Proposals

A summary of the original version of the Senate Finance bill can be found here; aside from tweaks to the Medicare Part D benefit design reforms, the revised bill is largely similar to the original. A summary of the drug pricing provisions originally included in the Senate HELP legislation is here; this legislation also includes provisions to address surprise billing and a number of public health measures.[1] Most of the provisions included in H.R. 19 can be found in either the Finance or HELP packages or were included in various other bills previously considered by Congress. Further, many of the provisions in these bills are similar to proposals that the administration has put forward.

Most Notable Reforms

Federal Negotiation of Drug Prices

H.R. 3 includes new authorities for the Secretary of Health and Human Services to negotiate the price of drugs directly, using as a benchmark a weighted average of the international prices of such drugs, as explained here. This proposal is similar to a proposal from the administration to establish an International Pricing Index. The bill would authorize the secretary to negotiate prices on up to 250 drugs annually (the 125 most expensive drugs provided under each Medicare Part B and Part D).

Medicare Part B and Average Sales Price

Most of the Medicare Part B provisions focus on tweaks to the average sales price (ASP) payment methodology used for provider-administered drugs, with the changes seeking to encourage the use of lower-cost drugs, including biosimilars. One unique provision of note from H.R. 19 is section 103, which provides for variation in the Medicare Part B ASP payment rate based on the drug's price per beneficiary. If a drug's per beneficiary charge ranks in at least the 85th percentile, the Medicare payment would be reduced to 104 percent of ASP (rather than the currently standard 106 percent). For drugs ranked in the 70th to 84th percentiles, payment would continue to be 106 percent of ASP. For drugs in the 50th to 69th percentiles, payment would increase to 108 percent of ASP. Finally, for the half of drugs with the lowest per beneficiary charges, payment would increase to 110 percent of ASP.

The Benefit Structure of Medicare Part D

The most significant Medicare Part D provisions are those that would reform the benefit structure, similar to the proposal first put forward by AAF in 2018. S. 2543, H.R. 3, and H.R.

19 all include such a reform, with some differences. The key components included in each of these proposals include providing beneficiaries an out-of-pocket cap, reducing the government's reinsurance liability in the catastrophic phase, and requiring drug manufacturers to pay a share of the costs incurred in the catastrophic phase.

While each of the proposals sets slightly different parameters (which will result in substantial differences in the impact, particularly to the pharmaceutical industry), the various proposals are now more similar to each other than when originally introduced. The most significant change was a tweak to the Senate Finance bill which now would require drug manufacturers to cover a share of the costs in the initial coverage phase (7 percent) in addition to their liability in the catastrophic phase (now set at 14 percent). H.R. 3 would require manufacturers to cover 10 percent of costs in the initial coverage phase and 30 percent in catastrophic, while H.R. 19 would require a 10 percent manufacturer liability in both phases.

Other Notable Reforms

Finally, other measures include provisions aimed at increasing price transparency (including around discounts and rebates obtained by pharmacy benefit managers); increasing competition in the supply of drugs by making it easier for new products to come to market; and reforms to the Medicaid Drug Rebate Program.

Comparing Specific Provisions

Below is a comparison of the various bills showing, by section number, the significant overlap and few areas of uniqueness. Some of the areas where there is a lack of unanimous overlap is a function of a particular committee's lack of jurisdiction rather than a lack of support for such a provision. Shaded blocks (found in the attached PDF at the end) or bolded numbers (below) denote areas where the bills include similar, but slightly different, provisions; otherwise, the provisions are identical or nearly identical.

Provision	**Finance (S. 2543)**	**HELP (S. 1895)**	**Pelosi (H.R. 3)**	**House R's (HR 19)**	**S. 3129**
Medicare Part B					
Improving ASP reporting	10101				
Inclusion of manufacturer coupons in determining ASP	10102				

Revised payment for biosimilars during initial period	10103			501	106
Temporary increase in Part B payment for biosimilars	10104		601		
Improvements to site-of-service price transparency	10105			101	101
Part B price inflation rebate	10106		201		
Refunds for unused drugs	10107			102	102
OIG report on bona fide service fees	10108				
Establishing a maximum add-on payment for Part B drugs	10109			104	104
Treatment of drug admin services by certain off-campus providers	10110			105	105
GAO study on ASP	10111			502	108
Providing for variation in ASP add-on payment				103	103
Authority to use alternative payment models to prevent drug shortages	10112				
Government “negotiation” of drug prices via international reference pricing			101-102		
Medicare Part D					
Part D Redesign	10121		**301**	**121**	**111**
Maximum monthly OOP cap	10121A		**302**	**133**	**114**
$50 monthly cap on insulin costs				134	115
Requiring rebate pass-through at the point-of-sale	10121B	**206**			
Growth rate of OOP threshold (delaying OOP “cliff”)				135	116

Providing MedPAC/MACPAC drug pricing and utilization information	10122			141	205
Public disclosure of drug discounts and PBM provisions	10123			112	202
Public disclosure of DIR review and audits	10124				
Requiring increased use of real-time benefit tools	10125			116	117
Improving provision of A&B claims data to PDPs	10126				
Permanent reauthorization of retroactive Part D coverage for LIS beneficiaries	10127			131	112
Part D price inflation rebates	10128		202		
Prohibiting branding on Part D benefit cards	10129				
Requiring plans to report potential waste/fraud/abuse to HHS	10130			503	118
Establishment of standard pharmacy quality measures	10131		303	504	119
New star ratings for access to biosimilars	10132				
HHS study on influence of manufacturer 3rd party reimbursements hubs on prescribing practices	10133				
Allowing the offering of additional PDPs				132	113
Policies to lower costs for low-income beneficiaries			Title IV		
Miscellaneous					

Drug manufacturer price transparency	10141			114	201
PBM transparency	10142	**206**			
Drug pricing dashboards	10143	**212**			
Improving coordination between FDA/CMS	10144			505	402
Patient consultation in Medicare coverage decisions	10145			506	
GAO study on Medicare/Medicaid spending due to copay coupons	10146				
MedPAC report on shifting drugs from B to D	10147			507	403
Treaty obligations	10148				
Reporting on excessive price hikes	**10141**	412	501	111	
Study on pharmaceutical supply chain		**213**		113	
Making drug marketing sample info available				115	204
Requiring DTC ads to include truthful and non-misleading price information				508	404
Create Chief Pharmaceutical Negotiator at USTR				509	405
Waiving Medicare coinsurance for colorectal cancer screening				510	
Medicaid					
Medicaid P&T committee improvements	10201			202	
Improving reporting requirements and developing standards for use of drug review boards	10202				

GAO report on conflicts of interest in state P&T committees	10203			203	
Ensuring accuracy of price information in MDRP	10204			204	
Excluding authorized generics from AMP	10205				
Preventing use of spread pricing in Medicaid	10206	**206**		205	
T-MSIS data reports	10207			206	
Risk-sharing VBPs for outpatient drugs	10208			207	
Modification of maximum rebate under MDRP	10209			201	
Applying MDRP to drugs included in hospital bundled payments	10210			208	
FDA					
Purple Book reforms for patent transparency		401		331-332	
Orange Book modernization		406		341-342	
Streamlining transition to biologic products		403		361	
No new exclusivities for new biologics		402		391	
Biosimilars can show proposed indications have been previously approved for reference product		404		393	
Education on biosimilars		405		351	107
BLOCKING Act		407		321	
Clarifying meaning of new chemical entity		408		394	

Orphan Drug designation clarification		409		392	
New FDA authority for generic label safety information		410			
CREATES Act		411		301-303	
Pay-for-Delay prohibition				311-315	
OTC drug review regulations				370-382	

[1] The surprise billing provisions have been revised since this summary from AAF was written in July 2019 to reflect a bipartisan, bicameral compromise. The new provisions include the establishment of an in-network benchmark rate upon which patients' cost-sharing would be based, as well as the option for parties to use an independent dispute resolution (binding arbitration) for bills exceeding $750.