Overlapping Provisions in Major Healthcare Bills 2019

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Lawmakers came with big ambitions for 2019, but we are headed into 2020 with two major health policies left on life support and many healthcare programs nearing expiration. There has been much discussion about what policies can inch over the finish line given the political realities facing the House, Senate and White House, and the dwindling clock. Given the elephant in the room (ahem, the House impeachment inquiry), the question remains: What kind of healthcare legislation can lawmakers piece together this year?

That is the analysis we put together below. We looked at the Senate Health, Education, Labor and Pension (HELP) Committee legislation (S 1895), the Senate Finance Committee legislation (S 2543), House Speaker Nancy Pelosi's (D-CA) prescription drug bill (HR 3), and the various standalone bills that have been approved by the House Energy and Commerce Committee, and identified areas of overlap in provisions related to prescription drug pricing, surprise billing and health extenders. This chart is not a summary of all of the provisions in these bills. Rather, it highlights the policies that appeared in two or more of the four proposals. There is potential for a small package of bipartisan, "low-hanging fruit" proposals to be become law. The areas of overlap below point to those examples. However, costs and potential pay-fors are also a major player in policy negotiation, so we also note any official Congressional Budget Office (CBO) scoring if available.

Several items not listed in the chart below could also come into play. These include:

- ***Preserve Access to Affordable Generics and Biosimilars Act (S 64/HR 2375).*** These bills are sponsored by Senate Finance Committee Chairman Chuck Grassley (R-IA) and Amy Klobuchar (D-MN) in the Senate, and by House Judiciary Committee Chairman Jerry Nadler (D-NY) and Ranking Member Doug Collins (R-GA) in the House. The bills seeks to strengthen the Federal Trade Commission's (FTC) ability to challenge settlement agreements between large brand drug and generic drug companies in court. Otherwise known as "pay-for-delay," this tactic has long been an issue that lawmakers have wanted to address. Both bills are bipartisan, and HR 2375 has passed out of the House Judiciary Committee. CBO estimates that between fiscal year (FY) 2019 and FY2029, HR 2375 would reduce direct spending by $520 million and increase revenue by $93 million for a total of $613 million in deficit reduction.

- ***Site Neutral.*** While this is mainly a regulatory issue, a legislative fix has been rumored to be floating around since the last court ruling. In September 2019, a federal judge ruled that the Centers for Medicare and Medicaid Services (CMS) exceeded its authority in

extending a site-neutral payment policy to clinic visits performed at off-campus, provider-based hospital departments. If Congress is looking for a pay-for, this could be one. There is no CBO score because there is no legislation, but CMS estimated that the policy would lower reimbursement rates to hospitals by a total of $380 million in 2019 and $760 million in 2020.

- ***Transparency.*** There are many provisions in these bills that fall into the "transparency" bucket. Any overlap is included below, but we could see lawmakers picking and choosing from the large bucket of options.

While the chart below only includes policies that appeared in two or more of the four proposals, there are many other health extenders awaiting action that were not included in any of the four buckets. We believe that the healthcare extenders will get across the finish line by the end of 2019. It just a matter of how long programs are extended and how they are paid for.

Click here for our analysis on the extenders.

Chart 1. Overlapping Provisions Within Major Healthcare Bills 2019

Provision:	S 2543, Prescription Drug Pricing Reduction Act (Finance)	S 1895, Lower Health Care Costs Act (HELP)	HR 3, Lower Drug Costs Now Act (Pelosi)	Bills Passed Out of Energy and Commerce
PRESCRIPTION DRUG PRICING				
Pharmacy Benefit Managers (PBMs)				
Reporting on PBMs	**Sec. 142:** - Requires health plans or PBMs that manage prescription drug coverage to report aggregate information on prescriptions, price concessions and PBM payments to pharmacies. - Requires PBMs to report information on contracts with a state Medicaid program. - Removes exemption of reporting *bona fide* fees from the reporting of the aggregate amount of price concessions negotiated and reported by a PBM. - Allows the Secretary to share the information submitted by a PBM. - CBO estimates that section 142 would not affect federal spending or revenues between FY 2020 and 2029.	**Sec. 306:** - Requires that plan sponsors receive a quarterly report on the costs, fees and rebate information associated with their PBM contracts. Reporting will be structured to prevent the release of information that could lead to higher drug prices. - CBO estimates that section 306 would decrease the federal deficit by $1.7 billion over the 2019–2029 period.		

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Banning Spread Pricing	**Sec. 206:** - Bans spread pricing in Medicaid managed care contracts. - Aligns reimbursement methodologies across Medicaid to ensure payment is based on ingredient costs and professional dispensing fees and that such pharmacy reimbursement payments are passed through in their entirety by PBMs to the managed care organizations and state. - Makes changes to the national drug acquisition cost survey. - Requires the Secretary to submit a report to Congress on specialty drug coverage and reimbursement under Medicaid. - Requires public reporting of WAC cost for covered outpatient drugs under the MDRP. - CBO estimates that section 206 would decrease federal spending by $960 million over the FY 2020–2029 period.	**Sec. 306:** - Prohibits PBMs from engaging in spread pricing, or charging a plan sponsor, health insurance plan or patient more for a drug than the PBM paid to acquire the drug. - Includes reporting and pricing requirements for PBMs that own mail order, specialty or retail pharmacies. - Requires the PBM to pass on 100% of any rebates or discounts to the plan sponsor. - CBO estimates that section 306 would decrease the federal deficit by $1.7 billion over the 2019–2029 period.		

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Increasing Access to Generics and Biologics				
Preventing Blocking of Generic Drugs (BLOCKING Act)		**Sec. 205:** - Prevents first-to-file generic drug applicants from blocking, beyond a 180-day exclusivity period, the entrance of subsequent generic drugs to the market. - Triggers the start of first-to-file generic drug applicants' 180-day exclusivity when a subsequent applicant has been tentatively approved and no first-to-file applicant has received final approval within 33 months of submission of its application. - CBO estimates that enacting section 205 would decrease the federal deficit by $424 million over the 2019–2029 period.		**HR 938, BLOCKING Act of 2019:** - Prevents first-to-file generic drug applicants from blocking, beyond a 180-day exclusivity period, the entrance of subsequent generic drugs to the market. - Triggers the start of first-to-file generic drug applicants' 180-day exclusivity when a subsequent applicant has been tentatively approved and no first-to-file applicant has received final approval within 33 months of submission of its application. - CBO estimates that enacting HR 938 would decrease the deficit by $442 million over the 2019–2029 period.
Actions for Delays of Generic Drugs and Biosimilar Biological Products (CREATES Act)		**Sec. 214:** - Allows generic drug manufacturers to sue brand-name manufacturers for not selling them samples for testing. - Allows generic companies to use separate safety protocols than those in place for the branded drug.		**HR 965, CREATES Act of 2019:** - Allows generic drug manufacturers to sue brand-name manufacturers for not selling them samples for testing. - Allows generic companies to use separate safety protocols than those in place

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		- Courts would be authorized to award monetary damages sufficient to deter future gaming. - Clarifies the US Food and Drug Administration's (FDA's) discretion to allow generic manufacturers to operationalize equivalent safety protocols in a separate system. - CBO estimates that enacting section 214 would decrease the federal deficit by $3.7 billion over the 2019–2029 period.		for the branded drug. - Courts would be authorized to award monetary damages sufficient to deter future gaming. - Clarifies FDA's discretion to allow generic manufacturers to operationalize equivalent safety protocols in a separate system. - CBO estimates that enacting HR 965 would decrease the deficit by $3.9 billion over the 2019–2029 period
Transparency				
Biological Product Transparency (Purple Book Continuity Act)		**Sec. 201:** - Increases transparency of patent information for biological products by requiring information to be submitted to the FDA and published in the "Purple Book." - Codifies the Purple Book as a single, searchable list of information about each licensed biological product. - Requires the Secretary to publish a list of any holders of biological product licenses that failed to		**HR 1520, Purple Book Continuity Act of 2019:** - Increases transparency of patent information for biological products by requiring information to be submitted to the FDA and published in the Purple Book. - Codifies the Purple Book as a single, searchable list of information about each licensed biological product. - Requires the Secretary to publish a list of any holders of biological product licenses

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		submit such information. - CBO estimates that implementing section 201 would cost FDA about $3 million over the 2020–2024 period.		that failed to submit such information. - CBO estimates that implementing this bill would cost FDA about $3 million over the 2020–2024 period.
Orange Book Modernization (Orange Book Transparency Act)		**Sec. 202:** - Clarifies the information that FDA must include in the Orange Book about patents and exclusivities for drugs approved under Section 505 of the Federal Food, Drug, and Cosmetic Act. - Requires FDA to remove patents and patent claim information from the Orange Book when the US Patent and Trademark Office determines a patent or patent claim is invalid or inoperative to encourage drug development in the area no longer patented. - CBO estimates that implementing section 202 would cost $1 million dollars.		**HR 1503, Orange Book Transparency Act of 2019:** - Clarifies the information that FDA must include in the Orange Book about patents and exclusivities for drugs approved under Section 505 of the Federal Food, Drug, and Cosmetic Act. - Requires FDA to remove patents and patent claim information from the Orange Book when the US Patent and Trademark Office determines a patent or patent claim is invalid or inoperative to encourage drug development in the area no longer patented. - CBO estimates that implementing this bill would cost $1 million dollars.
Reporting on Prescription Drug Pricing	**Sec. 141:** - Requires manufacturers to report information, as determined by the Secretary, necessary to justify launch	**Sec. 215:** - Requires manufacturers to submit a report to the HHS Secretary for each price increase of certain drugs of		

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	prices and price increases for drugs, biologicals and biosimilars, as measured by the WAC, that meet certain criteria. The qualifying criteria for reporting would be that the drug is one of the following: o At least $10 per dose and had a price increase of at least 300% over five years or 100% over one year o In the top 50th percentile of net drug spending in the Medicare or Medicaid programs and had a price increase of at least 50% over five years or 15% over one year o A new drug with an initial launch price that is high enough that the cost of a year supply or full course of treatment would exceed total gross drug spending at the Medicare Part D annual out-of-pocket threshold. - CBO estimates that section 141 would not affect federal spending or revenues over the FY 2020–2029 period.	which the WAC increase is equal to 10% or more over a 12-month period or 25% or more over a 36-month period. - The report must be submitted no later than 30 days prior to the planned price increase date.		

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		Medicare		
Medicare Part B and Part D Rebate by Manufacturers for Drugs or Biologicals with Prices Increasing Faster than Inflation	**Sec. 106 and 128:** - Require manufacturers to pay a rebate for drugs and biologicals for which the ASP increases faster than inflation, as measured by the Consumer Price Index for all Urban Consumers (CPI-U), beginning in January 1, 2021. - CBO estimates that section 106 would reduce federal spending by $10.69 billion over the FY 2020–2029 period.		**Title II:** - Requires manufacturers that raise the price of a drug in Part B or D above the rate of inflation since 2016 to either lower the price or pay the entire price above inflation in a rebate back to the Treasury.	
Medicare Part D Benefit Redesign	**Sec. 121:** - Caps enrollee out-of-pocket costs at $3,100 in 2022 and indexed to per capita Part D spending thereafter. - Decreases federal reinsurance to 20% and increases plan reinsurance to 60%. - Ends existing manufacturer discount program in the coverage gap, but creates new manufacturer discount program in the catastrophic portion of the benefit, which would require 20% discounts on brand-name drugs. - CBO estimates that section 121 would reduce federal spending by $34.6 billion over		**Title III:** - Caps Part D beneficiaries' annual out-of-pocket costs at $2,000 and indexed to per capita Part D spending thereafter. - Decreases the government reinsurance from 80% to 20% and increase plan responsibility from 20% to 50%. - Requires manufacturers to pay 10% in the initial coverage phase and 30% in the catastrophic phase.	

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	the FY 2020–2029 period.			
Providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission with Access to Certain Drug Payment Information, Including Certain Rebate Information	**Sec. 122:** - Allows the Secretary to share Medicare Part D and Medicaid drug price and rebate data with the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC). - CBO estimates that section 122 would not affect federal spending or revenues over the FY 2020–2029 period.			**HR 1781, Payment Commission Data Act of 2019:** - Allows the Secretary to share Medicare Part D and Medicaid drug price and rebate data with MedPAC and MACPAC. - CBO estimates that HR 1781 would not affect federal spending or revenues over the 2019–2029 period.
HEALTHCARE EXTENDERS				
Extension for Community Health Centers, the National Health Service Corps and Teaching Health Centers that Operate GME Programs		**Sec. 411:** - Extends mandatory funding for community health centers, the National Health Service Corps and the Teaching Health Center Graduate Medical Education Program at current levels for each of fiscal years 2020 through 2024. - CBO estimates that enacting section 411 would increase direct spending by		**HR 2328, REACH Act:** - Extends mandatory funding for community health centers, the National Health Service Corps and the Teaching Health Center Graduate Medical Education Program at current levels for each of fiscal years 2020 through 2023. - CBO estimates that enacting section 101 of the REACH Act would increase direct spending by $17.7 billion

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		$22.2 billion over the 2019–2029 period		over the 2019–2029 period.
Extension for the Special Diabetes Program and Indian Health Service		**Sec. 412:** - Extends funding for the Special Diabetes Program and the Indian Health Service through 2024. - CBO estimates that section 412 would increase direct spending by $1.5 billion over the 2019–2029 period.		**HR 2328, REACH Act:** - Extends funding for the Special Diabetes Program and Indian Health Service through 2023. - CBO estimates that enacting section 102 of the REACH Act would increase direct spending by $1.2 billion over the 2019–2029 period.
		SURPRISE BILLING		
Payment Methodology for Addressing Surprise Billing Disputes		**Sec. 103**: - Insurers pay the out-of-network practitioner or facility based on the median in-network contracted rate for services in that geographic area in surprise billing situations. - CBO estimates that enacting title I of S. 1895 would decrease the deficit by about $24.9 billion over the 2019–2029 period.		**HR 2328, REACH Act**: - Insurers pay the out-of-network practitioner or facility based on the median in-network contracted rate for services in that geographic area in surprise billing situations. - Providers or insurers can appeal to an independent dispute resolution (IDR) entity in circumstances when the median in-network rate paid to doctors or hospitals exceeds $1,250. That threshold would take effect in 2021, with the dollar amount increasing each year in line with inflation. The non-prevailing party would

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				pay the costs of the IDR process for the prevailing party. - CBO estimates that enacting title IV of the REACH Act would reduce the deficit by about $21.9 billion over the 2019–2029 period.
Air Ambulance Surprise Billing Provisions		**Sec. 105**: - Patients are held harmless from surprise air ambulance bills. Patients' cost-sharing for out-of-network air ambulance services would be equal to the amount if such services were provided by an in-network practitioner. - Plans shall pay out-of-network air ambulance providers at the median in-network for that service in the same geographic area. - CBO estimates that lost revenues as a result of the mandate would average $5 million annually for public entities and $25 million annually for private entities in each of the first five years it is in effect.		**HR 2328, REACH Act:** - Requires air ambulance providers to separate out costs of air ambulance transportation and medical costs in claims submitted to plans. (Failure to do so will result in a $10,000 civil monetary penalty for each violation.) - CBO estimates that the mandate would impose small administrative costs related to compiling, aggregating and reporting the required information.

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