Issue	Blueprint Recommendations	Party	Action Steps	Milestones
Better Negotiation	Direct CMS to develop demonstration projects to test innovative ways to encourage value-based care and lower drug prices. These models should hold manufacturers accountable for outcomes, align with CMS priorities of value over volume and siteneutral payments, and provide Medicare providers, payers and states with additional tools to manage spending for high-cost therapies.	CMS	CMS <u>proposed its "International Pricing Index" demonstration model</u> which, if finalized would test the feasibility of reducing Medicare payment rates for certain drugs to levels approximating those paid in international markets.	+ Released 10/30/18 + Comments due 12/31/18 + Proposed rulemaking ~Q1 2019
	Allow Part D plans to adjust formulary or benefit design during the benefit year if necessary to address a price increase for a sole source generic drug. Presently, Part D plans do not contract with generic drug manufacturers for the purchase of generic drugs, and generally are not permitted to change their formulary or benefit design without CMS approval in response to a price increase. This change could ensure Part D plans can respond to a price increase by the only manufacturer of a generic drug.	CMS	CMS instructed Part D sponsors that, beginning January 1, 2019, plans may apply step therapy to control the utilization of services in a manner that does not create an undue access barrier for beneficiaries. This may include the use of a Part D covered drug before a Part B covered drug.	+ Released 8/7/18 + Effective 1/1/19
	Allow Part D plans to better manage overall spending particularly on certain categories of high-cost drugs. Presently, Part D plans are unable to negotiate lower prices for high-cost drugs without competition. This change could allow Part D plans to use utilization management tools like those used by private payers to negotiate more favorable pricing for these drugs.	CMS	CMS <u>proposed three exceptions</u> to this protected class policy that would allow Part D sponsors to: (1) implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications; (2) exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.	+ Released 11/30/18 + Comments due 1/25/18
		CMS	CMS is <u>considering future regulatory changes</u> that would change the definition of "negotiated price" to mean the lowest amount that a pharmacy could receive from the plan. This amount would be net of all adjustments, contingent payments to the pharmacy and incentive fees.	<ul><li>+ Released 11/30/18</li><li>+ Comments due 1/25/18</li><li>+ Requires future regulatory action</li></ul>
		CMS	CMS is considering defining "price concession" to include all forms of discounts, subsidies and rebates.	<ul> <li>+ Released 11/30/18</li> <li>+ Comments due 1/25/18</li> <li>+ Requires future regulatory action</li> </ul>
		CMS	CMS announced plans for a <u>new Part D payment modernization</u> model taking effect for the 2020 plan year. This voluntary, 5-year program will require selected participating Part D plans to take on greater risk for spending in the catastrophic phase of Part D in return for additional flexibility, including rewards and incentives designed to lower the cost of Part D drugs. The model intends to create incentives for Part D plans, patients and providers to choose drugs with lower list prices.	<ul> <li>+ Request for Applications release 1/18/19</li> <li>+ To be effective 1/1/20</li> </ul>
	Allow Medicare to pay different prices for different uses of the same drug. Presently, Part D plans must cover and pay the same price for a drug regardless of the indication for which it was prescribed. This change could permit Part D plans to choose to cover or pay a different price for a drug, based on the indication.		HHS solicited comments on ways to apply lessons learned from commercial insurers to an indications-based payment system under Medicare and Medicaid.	+ Released 5/16/18 + Comments due 7/16/18
		CMS	CMS <u>instructed Part D sponsors</u> that, beginning in 2020, plans may negotiate formulary coverage based on specific indications and may include only certain indications on-formulary.	+ Released 8/29/18 + Effective 1/1/20
	Send the President a report identifying particular drugs or classes of drugs in Part B where there are savings to be gained by moving them to Part D.			
	Take steps to <b>leverage the authority created by the Competitive Acquisition Program</b> (CAP) for Part B Drugs & Biologicals.	CMS	CMS solicited feedback from stakeholders in the CY 2019 OPPS proposed rule on how a CAP could be structured in such a way as to increase competition, strengthen negotiation and create incentives for lower list prices.	<ul><li>+ Released 7/31/18</li><li>+ Comments due 9/24/18</li><li>+ Would require future rulemaking</li></ul>
	Address the disparity between the drug prices in America and other developed countries.		H.R. 6958 would have required CMS to report on the feasibility of basing payment rates for prescription drugs under Medicare and Medicare Advantage on the average price of such drugs in countries that are members of the Organization for Economic Cooperation and Development (an intergovernmental organization focused on global economic development).	<ul> <li>+ Introduced 9/27/18</li> <li>+ Referred to E&amp;C and W&amp;M</li> <li>+ Needs to be reintroduced</li> </ul>
		CMS	CMS <u>proposed its "International Pricing Index" demonstration</u> model which would test the feasibility of reducing Medicare payment rates for certain drugs to levels approximating those paid in international markets.	+ Released 10/30/18 + Comments due 12/31/18 + Proposed rulemaking ~Q1 2019