HHS Fall 2018 Regulatory Agenda

This week HHS published its Fall 2018 Regulatory Agenda, which reflects a number of potentially significant healthcare regulatory activities (proposed rules, final rules, request for information) over the coming months. Although HHS and its agencies may not pursue all of these regulatory actions and publication dates are not necessarily reliable, the Agenda reflects a continued focus by the Trump Administration on achieving a host of policy changes through the regulatory process. Some of the key items on the agenda include the following:

FDA

- Banning characterizing flavors in all cigars
- Increasing access to over-the-counter drugs through establishing new requirements for a drug product to be marketed as nonprescription
- Streamlining coverage of breakthrough technologies

CMS

- Modernizing the physician self-referral law, based on responses to an information request earlier this year
- Updating Medicaid Drug Rebate Program (MDRP) regulations to allow for value-based purchasing agreements between states and manufacturers, potentially through changing the "best price" requirement or waiving mandatory rebates
- Seeking comments on revising HIPAA to reduce barriers that limit or discourage coordinated care and case management, or otherwise impede value-based care
- Allowing flexibility for grandfathered ACA plans, and expanding the use of health reimbursement accounts (HRAs), health savings accounts (HSAs), and association health plans (AHPs)
- Streamlining the Medicaid and CHIP managed care regulatory framework, including to support state flexibility and innovation
- Permitting state Medicaid programs to require certain beneficiaries to pay premiums and copays
- Reissuing a rule requiring dialysis centers and charities that steer patients into private insurance to clarify what plans in their region will pay for and how it compares to Medicare or Medicaid