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Drug Pricing and Payment Policy: Key 2018 Developments and Potential 2019 Changes and Challenges

Following a number of drug pricing reforms implemented or proposed in 2018, 2019 likely will bring more action from HHS and Congress to reduce drug prices.

Key Points:

- In 2018, the Administration implemented and proposed several policy changes to reduce drug prices or spending, and Congress passed new legislation prohibiting health plans from preventing pharmacies from informing plan enrollees about lower-cost drugs.
- The most aggressive Administration proposal is the International Price Index (IPI) Model, a mandatory demonstration model that, if implemented, would apply to roughly half of all Medicare Part B drug expenditures and would reduce reimbursement for certain drugs to align with a composite price calculated from prices paid in other international markets.
- Additional and potentially significant new policy developments are likely in 2019. The Administration seeks to finalize proposals made in late 2018 and announce new policy changes, while new congressional leadership focuses on drug pricing ahead of the 2020 presidential election.

In 2018, the Trump Administration devoted significant attention to the issues of drug pricing and reimbursement. The Administration formally launched its drug pricing efforts in May 2018 when it published *American Patients First*, a "blueprint" for reducing drug prices and reducing out-of-pocket costs for American consumers. In connection with this blueprint, the Department of Health and Human Services (HHS) implemented and/or announced a number of proposals this past year aimed at reducing drug prices and reimbursement across a variety of government programs, including the 340B discount drug pricing program and Medicare Parts B, C (Medicare Advantage), and D.

Many industry observers believe 2019 will be even more consequential, expecting the implementation of additional regulatory proposals and possible legislative action, as the leadership in Congress — particularly in the new Democratic majority US House of Representatives — shares the Administration's goal to reduce drug prices. Stakeholders of all types (providers, manufacturers, distributors, and insurers) should monitor government announcements closely.

Overview of 2018 Changes and Proposals

2018 was an extremely active year for drug pricing and reimbursement policy. The Department of Health and Human Services (HHS) implemented or proposed a number of new policies aimed at (1) reducing

Medicare and Medicaid spending on drugs, and (2) incentivizing providers and health plans to use lower-cost drugs. Congress also passed legislation banning private and public health plans from preventing pharmacies from informing enrollees about lower-cost drug options, which President Trump signed into law in October. The past year's most significant drug pricing and reimbursement changes are summarized below:

- **Medicare Reimbursement Cuts Under the 340B Drug Pricing Program**
  - As a part of the Centers for Medicare and Medicaid Services' (CMS') 2018 Hospital Outpatient Prospective Payment System (OPPS) final rule, the Agency reduced payment rates for drugs purchased under the 340B drug pricing program, effective January 1, 2018. Under previous policy, 340B drugs reimbursed through Medicare Part B were eligible for the same payment rate as other drugs: an amount equal to the Average Sales Price (ASP) of the drug, plus 6% of that drug's ASP. As of January 1, 2018, many hospitals' claims to Medicare for 340B drugs (which certain healthcare providers can purchase at discounted rates) were subject to a new payment amount equal to 77.5% of ASP (or ASP minus 22.5%).[1] CMS stated that it adopted this change "[t]o address recent trends of increasing drug prices, for which some of the cost burden falls to Medicare beneficiaries."[2] The change was projected to reduce Medicare drug payments by US$1.6 billion.[3]

  - In response to a lawsuit challenging this payment change, the D.C. District Court held in December 2018 that CMS exceeded its statutory authority in implementing these cuts.[4] The Court did not vacate the 2018 rule or enjoin the cuts from being applied in CY 2019, but the parties were asked to submit briefs on an appropriate remedy and path forward.

- **Changes to the Medicare Part D "Donut Hole"**
  - On February 9, 2018, Congress passed the Bipartisan Budget Act of 2018, which included three policy changes to Medicare Part D aimed at expanding beneficiary coverage and reducing out-of-pocket costs.[5] These changes, which were estimated by the Congressional Budget Office to reduce government expenditures by approximately US$11.8 billion, largely shifted costs from health plans to pharmaceutical manufacturers through the following:
    - Increasing the discount that pharmaceutical manufacturers must provide in the Coverage Gap Discount Program from 50% to 70% of the negotiated price of applicable drugs, while reducing the plan's share of costs from 25% to 5%
    - Closing the coverage gap for 2019, one year earlier than scheduled, which reduces beneficiary cost-sharing in the coverage gap from 35% to 25% of a drug's cost
    - Eliminating the exclusion of certain biosimilars from the Coverage Gap Discount Program

- **The Administration's Drug Pricing Blueprint**
  - On May 11, 2018, the Administration published a high-level blueprint summarizing its policy approaches to lower drug prices and reduce consumers' out-of-pocket costs. The blueprint identified a number of actions that could be implemented quickly, as well as potential actions for which the Administration was soliciting feedback. These actions were focused around four main policy goals, with many policies already implemented or moving toward implementation in 2019:
    - **Improved Competition**
      1. Encouraging branded manufacturers to provide generic manufacturers with product samples needed for generic drug development, including preventing the "gaming" of regulatory processes such as Risk Evaluation and Mitigation Strategies (REMS)
      2. Developing proposals to stop Medicaid and Affordable Care Act plans from raising prices

- **Better Negotiation**
  1. Experimenting with value-based purchasing in federal programs
  2. Reforming Medicare Part D to give plans more negotiating power with drug manufacturers
  3. Working across the Administration to assess the problem of foreign free-riding on American innovation
- **Incentives for Lower List Prices**
  1. Requiring manufacturers to include list prices in advertising
  2. Reforming and/or restricting the use of rebates
  3. Reforming the Medicaid Drug Rebate Program and 340B drug pricing program
- **Lowering Out-of-Pocket Costs**
  1. Prohibiting Part D plans from preventing pharmacists from telling patients when patients could pay less by not using insurance
  2. Exploring measures to inform Medicare Parts B and D beneficiaries about lower-cost alternatives

- **Ban on Pharmacy "Gag Clauses"**
  - On October 10, 2018, the President signed legislation prohibiting prescription drug plans from restricting pharmacies' ability to inform plan enrollees of any difference between the price, copayment, or coinsurance of a drug under the plan and a lower price of the drug without health-insurance coverage.[6] The two bills, one that applies to Medicare and Medicare Advantage (MA) plans and the other that applies to private plans, implement a policy proposed in the Administration's drug pricing blueprint.

- **CMS Proposal to Include Drug List Prices in TV Advertisements**
  - On October 18, 2018, CMS published a proposed rule that would require drug manufacturers to include the Wholesale Acquisition Cost (WAC), or list price, in direct-to-consumer television advertisements for drugs and biologics covered by the Medicare and Medicaid programs.[7] This policy is consistent with the proposal included in the Administration's drug pricing blueprint.

- **HHS Proposal of the International Price Index Model for Medicare Part B Drug Reimbursement**
  - On October 30, 2018, HHS and CMS published an Advance Notice of Proposed Rulemaking describing a demonstration model that would reinvent the distribution model and reimbursement formula for certain physician-administered drugs and biologics under Medicare Part B.[8] The Agency sought feedback on a mandatory model that would apply to clinics and hospitals representing 50% of overall Part B drug spending and include three primary components:
    - **Third-Party Vendor:** Part B drugs included in the Model would be sold to third-party vendors who would be responsible for purchasing and distributing the drugs.
    - **IPI Target Price:** The Model would reimburse the vendor, rather than the provider that administers the drug, an amount equal to a "Target Price" plus a flat add-on fee, with the Target Price determined by an "International Price Index," a composite of prices for those drugs in 16 countries.
    - **Alternative Add-On Payment:** Providers would receive an alternative add-on payment, calculated on a budget-neutral basis, rather than 6% of the drug's ASP.

  - The model would have a proposed net impact of US$17.9 billion in reduced federal spending over five years. Following its review of comments submitted on the proposal, the Agency will consider issuing a proposed rule in the spring of 2019, with a potential model implemented starting in spring 2020.

- **HHS Expands Formulary Controls for Medicare Advantage and Medicare Part D Plans**
  - On November 30, 2018, HHS and CMS issued a proposed rule that would give health plans under MA and Medicare Part D greater flexibility in how those plans cover and pay for certain drugs.[9]
    - **Medicare Advantage:** The proposed rule would allow MA plans, beginning in 2020, to use step therapy for Medicare Part B drugs, meaning plans could limit coverage for more expensive Part B drugs until a more cost-effective option is attempted (*e.g.*, starting on a low-cost biosimilar before moving to a more costly biologic).
    - **Part D:** The proposed rule would change Medicare Part D's "protected class" policy, under which plans must cover all available drugs in one of six therapeutic classes of drugs, to allow greater flexibility in managing their formularies. In addition, Part D plans would be required, by January 1, 2020, to adopt a provider tool that would provide prescribers with real-time formulary and benefit information (including cost, formulary alternatives, and utilization management requirements). CMS also announced that it is considering for a future year, which could be as soon as 2020, a proposal to re-define a drug's "negotiated price," which is the price used to calculate beneficiary cost-sharing and generally adjudicate the Part D benefit, to include pharmacy price concessions (which are currently excluded from the definition).

  - The proposed rule solicits public comment on a number of policy proposals summarized above, with a public comment period ending on January 25, 2019.

Potential Drug Pricing and Reimbursement Changes On the Horizon in 2019

Following a flurry of activity in 2018, the Administration will likely continue to propose and implement policies aimed at reducing drug prices and federal healthcare program spending on drugs in 2019. As summarized above, HHS issued two proposals in late 2018 that it may seek to finalize in 2019: a sweeping mandatory model for Part B drugs, and a proposal to change the price and formulary coverage of drugs under MA and Medicare Part D. Both proposals offered fairly high-level policy changes that the Agency will further develop as it reviews and responds to public comments in advance of anticipated implementation in 2020. Consistent with the *American Patients First* blueprint, the authors expect HHS will announce new policy proposals aimed at increasing competition, incentivizing lower drug list prices, and improving CMS' power to negotiate for lower drug prices.

Additionally, new leadership in key Congressional committees may increase the likelihood that Congress will consider new legislation to lower drug prices and increase price transparency. While Republicans maintain the majority in the Senate, Senator Charles Grassley becomes Chairman of the Senate Finance Committee in the new Congress, taking over for retiring Senator Orrin Hatch. Senator Grassley has long been critical of certain aspects of the pharmaceutical industry, including on the issue of drug pricing. Also, the new Democratic leadership of the House Ways & Means Committee, Energy & Commerce Committee, and Oversight and Reform Committees, among other committees, may prioritize drug pricing reforms. Finally, some of the potential Democratic presidential candidates currently serving in Congress have been outspoken on the issue of drug pricing and may seek to introduce legislation addressing the topic.

As both the Administration and Congress consider a variety of changes to drug pricing and reimbursement — both within and outside of federal healthcare programs — manufacturers, providers, and other stakeholders must continue to play an active role in the policymaking process. Given the breadth and complexity of the changes, and the demonstrated interest in this topic from the White House, HHS, CMS, and Congress, the authors anticipate stakeholders will have a number of opportunities to

offer input on proposed policy changes, and should remain active and engaged as these policies are debated and implemented.

If you have questions about this *Client Alert*, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:

Stuart S. Kurlander
stuart.kurlander@lw.com
+1.202.637.2169
Washington, D.C.

Daniel Meron
daniel.meron@lw.com
+1.202.637.2218
Washington, D.C.

Eric C. Greig
eric.greig@lw.com
+1.202.637.3330
Washington, D.C.

Barrett J. Tenbarge
barrett.tenbarge@lw.com
+1.202.637.2288
Washington, D.C.

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Endnotes

1 HHS, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 59355 (Dec. 14, 2017), *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1678-FC.html.

2 CMS, CMS Issues Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs Changes for 2018 (CMS-1678-FC) (Nov. 1, 2017), *available at* https://www.cms.gov/newsroom/fact-sheets/cms-issues-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-payment.

3 *Id*.

4 *American Hospital Association, et. al. v. Azar* (#18-2084), Memorandum Opinion (Dec. 27, 2018).

5 Pub. L. 115-123, "Bipartisan Budget Act of 2018" (Feb. 9, 2018)

6 Pub. L. 115-262, S.2553, "Know the Lowest Price Act of 2018" (Oct. 10, 2018); Pub. L. 115-263, S.2554, "Patients Right to Know Drug Prices Act" (Oct. 10, 2018).

7 Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency, 83 Fed. Reg. 52789.

8 HHS, Medicare Program; International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546.

9 HHS, Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62152 (Nov. 30, 2018), *available at* https://www.govinfo.gov/content/pkg/FR-2018-11-30/pdf/2018-25945.pdf.