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2019 White House and HHS Budgets Released: Key Changes to Drug Pricing and Reimbursement Proposed

February 15, 2018

On February 12, 2018, the White House Office of Management and Budget released an overview of the president's Fiscal Year (FY) 2019 Budget (the Budget), which makes, among many others, several proposals regarding drug pricing and payment reform. Concurrently, the Department of Health and Human Services (HHS) released the full FY 2019 Budget for HHS (the HHS Budget), which provides additional detail regarding such proposals. In presenting these proposals, the administration is seeking Congressional action; thus, the fate of these proposals is highly uncertain. Nevertheless, these proposals provide insight into the administration's – and particularly the new HHS Secretary Alex Azar's – thinking with respect to how the administration might go about fulfilling its frequent but often non-specific promise to precipitate such reform. A summary of some key proposals that are relevant to drug pricing and reimbursement is below.

New Medicaid Demonstration Authority to Test Medicaid Drug Coverage and Financing Reforms: "[T]he Budget calls for new Medicaid demonstration authority for up to five states to test drug coverage and financing reforms that build on private sector best practices," which would allow "Participating states . . . to determine their own drug formularies, coupled with an appeals process to protect beneficiary access to non-covered drugs based on medical need, and negotiate drug prices directly with manufacturers." The HHS Budget provides additional information regarding this proposed demonstration authority, stating that "the demonstration would exempt prices negotiated under the demonstration from best price reporting," and that, "[g]iven the interest among stakeholders to identify opportunities in outcomes-based purchasing (i.e. value-based purchasing) drug models, adhering to best price reporting can be a barrier for manufacturers to enter these models. This approach provides a pathway for testing changes to Medicaid drug coverage without the constraints in existing Medicaid authorities." We note that, even without this proposed demonstration authority, we are advising clients on ways in which the Centers for Medicare and Medicaid Services (CMS) may invoke its existing demonstration authority to enable a wider array of value-based arrangements that may potentially allow flexibility in coverage under Medicaid while minimizing best price implications.

Clarifying Definitions Under the Medicaid Drug Rebate Program (MDRP): The Budget calls for the clarification of definitions under the MDRP "to prevent inappropriately low manufacturer rebates." The HHS Budget elaborates that "[t]his proposal clarifies the Medicaid definition of brand and over-the-counter drugs as well as drugs approved under a biologics license application

by codifying existing regulations to ensure appropriate Medicaid drug rebates." It is unclear what specific revisions would be proposed to those definitions, but we note that the terms "brand" and "over-the-counter" have greater significance for purposes of Medicaid provider reimbursement provisions than for purposes of calculating drug rebates. Any revisions to the definitions underlying the MDRP could have potentially significant financial implications for manufacturers, and we will be following any related proposals closely.

Medicare Part D and Part B Drug Benefit and Payment Changes: With respect to drugs paid under Medicare Parts D and B, the Budget proposes the following key changes:

- **The Budget proposes to require Medicare Part D plans to pass-through a portion of rebates at the point of sale.** The HHS Budget clarifies that this proposal would require Part D sponsors to pass-through at least one-third of total rebates and other price concessions in the form of lower cost-sharing for beneficiaries at the point of sale. We note that CMS recently issued a Request for Information on this topic and believes it has authority to accomplish this without a need for additional legislation.

- **The Budget proposes to establish a beneficiary out-of-pocket maximum in the Medicare Part D catastrophic phase.** The HHS Budget clarifies that this proposal would increase Part D plan sponsors' liability for catastrophic coverage from 15 percent to 80 percent over four years, thus decreasing Medicare's reinsurance liability from 80 to 20 percent. Beneficiary coinsurance would decrease from 5 to 0 percent.

- **The Budget proposes to exclude manufacturer discounts from the calculation of beneficiary out-of-pocket costs in the Medicare Part D coverage gap.** Currently, amounts paid by manufacturers as coverage gap discounts count toward a beneficiary's out-of-pocket costs, for purposes of determining when catastrophic coverage begins. If enacted, this change would significantly increase the time it takes for a beneficiary to reach catastrophic coverage.

- **The Budget proposes to eliminate the requirement that Medicare Part D plans cover at least two drugs per therapeutic category or class.** According to the HHS Budget, this proposal would instead require plans to cover only a minimum of one drug per category or class and also would expand plans' ability to use utilization management tools for specialty drugs and drugs in the protected classes.

- **The Budget proposes to allow CMS to move drugs from Part B to Part D.** The HHS Budget explains that this proposal would allow CMS to move certain drug currently covered under Part B into Part D, where there are "savings to be gained from price competition." Such a change would be significant for manufacturers as well as providers, in light of the meaningful differences in how drugs are covered and paid for under the Part B and D programs, and might also impact the distribution channels under which the affected drugs are made available to patients.

- **The Budget proposes to establish an inflation limit for reimbursement of the ingredient cost of Part B drugs.** The HHS Budget clarifies that "this proposal limits growth of the Average Sales Price (ASP) portion of payment of Part B drugs to the Consumer Price Index for all Urban Consumers. Each quarter when CMS establishes the ASP +6 percent payment amounts, CMS would pay the lesser of (1) the actual ASP +6 percent or (2) the inflation-adjusted ASP +6 percent. The base for determining growth of a drug's price will be the initial ASP, or the first quarter of CY 2017 for drugs that had an ASP prior to the date of enactment." We note that the current Medicare Part B reimbursement system already functions to disincentivize large price increases given that the ASP the manufacturer reports

sets the reimbursement rate two quarters later. Because ASP is calculated net of commercial discounts (which often include a wholesaler prompt pay discount) and because the Medicare Part B payment rates are already further reduced by sequestration cuts, even a small percentage increase in a Part B drug's price in one quarter can cause providers two quarters later to be reimbursed close to or even less than acquisition cost. Any proposal to further limit ASP-based reimbursement may have significant implications for access to certain medications. It is not clear how this proposal would address billing and payment codes that contain multiple National Drug Code (NDC)-11 products (some of which might increase prices at a greater rate than others). It is also unclear whether implementation of this proposal would affect drugs under the hospital outpatient prospective payment system (OPPS) as well as the physician fee schedule.

Modifying Medicare Hospital Outpatient Reimbursement for 340B-Purchased Drugs: The Budget proposes to modify the recently implemented alternative payment methodology for certain 340B-purchased drugs reimbursed under the Medicare hospital OPPS. The HHS Budget clarifies that "this proposal allows CMS to apply savings from a reduction in payment to hospitals for drugs purchased under the 340B program in a non-budget neutral manner. Under a regulation that goes into effect CY 2018, hospital payment for 340B drugs is reduced from ASP +6 percent to the average sales price -22.5 percent to reflect the minimum average discount 340B hospitals receive. Statute requires the savings to be redistributed within the payment system in a budget neutral manner. Under this proposal, the savings from hospitals that provide uncompensated care equaling at least one percent of their patient care costs are redistributed based on their share of aggregate uncompensated care. Hospitals not meeting that threshold are not eligible for the redistribution, and the savings from their payment reduction will be returned to the Medicare Trust Funds." We note that CMS has existing authority to channel the savings to the contemplated class of hospitals, but not to channel a portion of the savings to the Medicare Trust Funds.

Limiting Medicaid Reimbursement to Government Providers to Cost: "To avoid the misuse of funds, the Budget also proposes to limit reimbursement to government providers to no more than the cost of providing services to Medicaid beneficiaries." The HHS Budget does not define "cost of providing services" or otherwise clarify this proposal. We note that states are already are generally required to reimburse for the ingredient cost of prescription drugs at "actual acquisition cost" as a condition to federal financial participation, so any reductions to services payments to a cost basis may be significant for providers dispensing or administering drugs.

Other Key Budget Proposals Include the Following:

- **"Improve manufacturers' reporting of average sales prices to set accurate payment rates."** The HHS Budget describes this proposal as requiring "all Part B drug manufacturers to report" ASP data, and providing for penalties "similar to penalties currently used in Medicaid, where if data is not reported within 30 days of the end of the quarter manufacturers face civil monetary penalties of up to $10,000 per day." We note that the current statutory ASP reporting obligation is within the Medicaid Drug Rebate Statute, and the proposal would be particularly significant to manufacturers of Part B drugs that do not have MDRP Rebate Agreements.

- **"Reduce Wholesale Acquisition Cost (WAC)-based payments."** This proposal would reduce payment from 106 percent of WAC to 103 percent of WAC, where WAC is used for Medicare Part B drug reimbursement. These changes could be significant for manufacturers of certain products (particularly newly-launched products), as WAC is used for setting reimbursement rates in some cases where ASP data is not available.

- **"Require coverage of all medication assisted treatment options [for opioid use disorder] in Medicaid."** The HHS Budget states that the coverage would include "associated counseling and other costs." We note that Medicaid is already required to make coverage available for products of manufacturers with MDRP drug rebate agreements in place as a condition of federal financial participation. It is not clear whether the proposal would extend coverage requirements to products not already subject to a drug rebate agreement, or might otherwise limit states' ability to restrict coverage of those products subject to a rebate agreement.
- **"Pay all hospital-owned physician offices located off-campus at the physician office rate."** Certain off-campus hospital outpatient departments are currently subject to exemptions from the hospital OPPS and are paid using the Medicare physician fee schedule. The HHS Budget explains that this proposal would eliminate all current exemptions for off-campus hospital outpatient departments, causing currently grandfathered off-campus hospital outpatient departments, emergency departments, and cancer hospitals to be reimbursed under the Medicare physician fee schedule. Because there are differences in how prescription drugs are reimbursed under the physician fee schedule as compared to the hospital OPPS (including without limitation, packaging policies and payment rates for drugs purchased under the 340B drug discount program), this proposal potentially shifts financial incentives for the affected outpatient departments.

While it will be important to monitor how Congress responds to these proposed changes in the Budget, it may be more important to monitor whether HHS identifies actions that it may take under its existing authority in these areas of apparent focus.

It is important to review the Budget and the HHS Budget in detail to identify any additional issues that may be relevant to your organization. Hogan Lovells will continue to monitor developments related to the Budget. Please feel free to contact us if you have any questions or would like to discuss these developments.

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