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Client Alert

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Medicare Part B Payment Redux

Another Presidential Administration Attempts to Change Part B Payment for Physician-Administered Drugs

On October 25, 2018, the Trump Administration released an Advance Notice of Proposed Rulemaking ("ANPRM") entitled "International Pricing Index Model for Medicare Part B Drugs," soliciting comments on a proposal to reset Medicare Part B drug payment rates to more closely align with international "prices" for the drugs paid by other countries.[1] Comments on the proposal are due by **December 31, 2018**.

The proposal, which would be implemented as a demonstration project through the Center for Medicare and Medicaid Innovation ("CMMI"), would operate for five years, during which time certain Part B drug payment rates to both physicians and hospital outpatient departments would be lowered to some proportion of a product's "Average Sales Price" and its newly created "Target Price" based on its "International Pricing Index" value. In doing so, the Administration aims to further two of its policy goals—(1) the Medicare program should not be faced with higher drug prices compared to drug prices in other countries where national health systems directly negotiate prices with drug manufacturers; and (2) the United States government should not directly negotiate Part B drug prices with manufacturers. In addition, the proposal seeks to modify the statutory +6% "add-on payment" that allegedly creates incentives for providers to prescribe more expensive drugs, and to reduce physician financial burden inherent in a "buy and bill" system by enabling private sector vendors to purchase and distribute Part B drugs.

Importantly, the Administration's announcement is only an "Advance Notice" seeking public comments on the proposed concept—the Centers for Medicare & Medicaid Services ("CMS") must still issue a Proposed Rule outlining the precise parameters of the demonstration project for further comment prior to issuance of a Final Rule and launch of the model. Although CMS anticipates issuing a Proposed Rule in Spring 2019 and

running the model between 2020 and 2025, it may be many months, if not years, before a Proposed Rule is issued and the changes described in the ANPRM are effectuated. Moreover, the issuance of this ANPRM just a few days before the 2018 mid-term elections has led to speculation that the Administration may have timed the proposal for political reasons. Either way, the proposal raises issues that are of significant interest to stakeholders involved with access to physician-administered drugs (in both the Medicare and Medicaid programs), including manufacturers, physicians, hospitals, patient groups, State Medicaid programs, and entities that may be interested in becoming private sector vendors under the proposed model.

BACKGROUND

Prior to 2005, the Medicare payment amount for Part B drugs and biologicals was based on 95% of a published price known as "Average Wholesale Price" or AWP (which is still published today by certain commercial drug price compendia). Due to concern that AWP was not an actual market price, in 2003, Congress changed the basis for payment to "Average Sales Price," or ASP—generally, the actual volume weighted average sales price that manufacturers charge to commercial purchasers and payers.[2] Effective January 1, 2005, drugs and biologicals not paid on a cost or prospective payment basis were paid based on the ASP methodology, with payment to providers at a statutory rate of ASP+6% (or 106% of the ASP) for each drug or biological. The ASP methodology uses quarterly drug pricing data submitted to CMS by drug manufacturers. There is a two-quarter lag between the sales period for which ASPs are reported and the effective date of the payment amounts (for example, sales and discounting data from the first quarter of 2018 were used to establish payment amounts for the third quarter of 2018).

There are two important features of the current system relevant to the ANPRM—first, and contrary to many of the statements made by the Administration, ASP is a true market price for drugs and biologicals, as it is calculated using actual sales prices net of discounts, rebates and chargebacks. Second, CMS makes Medicare Part B payments for drugs and biologicals to providers—physicians and hospitals—who themselves have to purchase the drugs on the open market. To account for the fact that providers have overhead costs related to purchasing these drugs, and may not be able to purchase them at or below ASP, Congress directed that payment be set at ASP+6%.

Unfortunately, many policymakers misunderstand the purpose of the "+6%" add-on payment, wrongly believing it to be purely incentive to providers to use more expensive drugs. To remove that incentive, in March 2016, the Obama Administration proposed a demonstration project using CMMI authority that would have converted the percentage add-on payment to "+2.5%" and an additional fixed dollar amount.[3] The proposal resulted in such a firestorm of criticism from Republicans in Congress, providers and patient groups, that the Obama Administration withdrew the proposal in October 2017.[4]

In addition to concerns about ASP-based payment, the Trump Administration has also criticized the fact that Medicare Part B drugs are less expensive in foreign countries, where national health systems directly negotiate pricing with manufacturers. This disparity has long existed, but CMS has not previously focused on this issue, which is complicated by the general aversion to having the United States government directly negotiate with drug manufacturers over prices. Thus, until the ANPRM, CMS has not offered any suggestions for ways to align Medicare Part B payments with the lower amounts that foreign governments pay for the same drugs and biologicals.

THE ANPRM PROPOSAL

To tie these issues together, the ANPRM proposes a demonstration project that would modify Medicare Part B payment rates, including add-on payment rates, as well as the structure of the "buy and bill" purchasing framework, in certain geographic areas of the country (yet to be determined, although the total areas would encompass 50% of Medicare Part B spending on separately payable Part B drugs). Within these geographic areas, all physician practices and hospital

outpatient departments (and potentially other categories of providers and suppliers) would be required to participate in the demonstration project for certain Medicare Part B drugs and biologicals.

Which drugs and biologicals will be part of the demonstration project?

The ANPRM proposes to initially include in the demonstration project single source drugs, biologicals (including biosimilars), and multiple source drugs with a single manufacturer that are administered "incident to a physician's services" for which there are reliable sources of international pricing data. In the hospital outpatient setting, separately payable drugs and biologicals, including those on pass-through payment status, would be included. Excluded from the demonstration project are: (1) drugs identified by the FDA to be in short supply; (2) drugs paid under "miscellaneous" or "not otherwise classified" codes, including compounded drugs; (3) radiopharmaceuticals; (4) End Stage Renal Disease ("ESRD") drugs; and (5) drugs that are packaged in Medicare's Hospital Outpatient Prospective Payment System ("the OPPS").

How will the new Medicare Part B payment rate be calculated?

The five-year demonstration project would set Medicare Part B payment rates for drugs and biologicals based on a descending blend of ASP and a "Target Price" based on a new International Pricing Index ("IPI") figure. Specifically, in the first year of the demonstration, the payment amount would be determined using 80% ASP and 20% Target Price, in Year Two it would be 60% ASP and 40% Target Price, in Year Three the payment amount would be 40% ASP and 60% Target Price, in Year Four it would be 20% ASP and 80% Target Price, and in Year Five it would be 100% Target Price.

The Target Price for a particular drug or biological is derived from the IPI, which is based on the ratio of Medicare spending for the product using ASP prices to the estimated spending for the product using international prices. The international prices are proposed to be based upon drug prices in countries that have economies comparable to the United States or countries that are included in Germany's market basket for reference pricing for their drug prices: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands and the United Kingdom. Indeed, hours before the ANPRM was announced, the HHS Office of the Assistant Secretary for Planning and Evaluation ("ASPE") issued an extensive report documenting the payments in many of these countries for the top 50 most expensive drugs in the Medicare Part B program.[5] CMS is considering whether to rely on existing data sources for international prices or implement a manufacturer data collection and reporting system—similar to the ASP reporting system—whereby manufacturers report to CMS international sales data for prices and units of product sold. CMS anticipates that payment amounts in the demonstration would be updated on a quarterly basis.

Administration officials have broadly suggested that this tie to international drug prices will cause manufacturers to "adjust their global pricing strateg[ies],"[6] presumably raising their foreign prices to avoid a reduction in domestic Medicare reimbursement. How this result would reduce domestic drug prices is unclear.

How will the "buy and bill" system be modified?

The ANPRM also addresses a fundamental structural difference between European countries that negotiate drug prices directly, and the Medicare system of reimbursement to providers who purchase Part B drugs. The Trump Administration acknowledges that foreign governments can negotiate drug prices with manufacturers because they are able to leverage the volume of patients in the country in their negotiations. The Medicare system has no such leverage—all CMS can do is announce that it will reimburse providers at a lower rate, and hope that manufacturers will lower drug prices in response to pressure from providers. To create market leverage in the Medicare Part B program, the ANPRM proposes to select through a competitive process a group of at least three national "vendors" who would negotiate with manufacturers to reduce drug prices on behalf of providers who enroll with those vendors. The providers would pay the vendors for distribution services, and the vendors would bill and receive payment from the Medicare program for drug

and biological products administered by the enrolled providers. The vendors, not providers, would purchase and take title of drug products, but the vendors would not be required to take physical possession of those products. Providers would collect beneficiary deductible and coinsurance amounts, and would bill supplemental insurers. The ANPRM does not suggest that vendors would have any authority to impose formulary restrictions, potentially undermining their ability to demand and obtain price concessions from manufacturers.

It is likely that pharmacy benefit managers ("PBMs") will be best situated to become vendors in the demonstration project given that they already have experience negotiating drug prices with manufacturers and know how to aggregate entities to create market leverage. The ANPRM suggests that other entities may also qualify, including wholesalers, distributors, group purchasing organizations, specialty pharmacies, individual or groups of physicians or hospitals, and Medicare Part D sponsors. This is a change from the Competitive Acquisition Program ("CAP") that was briefly in effect during the 2000s, in which only specialty pharmacies could qualify as vendors. Providers would be encouraged to enroll with at least one, but preferably, multiple vendors in order to obtain drugs from the vendor offering the most cost-effective arrangement.

We note that sales to these vendors would not be excluded from Medicaid Best Price calculations. Exempting such sales would be one way to further the success of the demonstration project, however, such an exemption would need to be made by statutory change.

What changes to the add-on payment are proposed?

The ANPRM also proposes that physicians and hospitals participating in the demonstration project would be paid a set payment amount per encounter or per month for a drug rather than a percentage add-on payment (+6%) per drug product, which CMS believes creates incentives to administer more costly drug products. The set payment could be based on a class of drugs, a physician specialty, or a particular physician practice or hospital. The set payment amount would be calculated annually based on the +6% of ASP revenue that the demonstration participants would have garnered without sequestration in the most recent year of claims data. CMS is also considering whether to create a "bonus pool" through which physicians can achieve bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization.

ESTIMATED COST SAVINGS FROM THE PROPOSAL

The Trump Administration estimates that the proposal to modify the Medicare Part B drug payment rate, if implemented, would result in $12.5 billion in savings over the five years of the demonstration project, with an additional $9.2 billion of savings through the Medicare Advantage program (totaling $21.7 billion of savings). Taking into account an expected $4.8 billion in physician add-on payments, the overall net savings for the Medicare program is estimated to be $16.3 billion. In addition, there are also some highly speculative expected Medicaid savings (due to a lower Best Price which would increase the Medicaid rebate for some products, although reduced Average Manufacturer Price may offset this) of approximately $1.6 billion. These figures assume no changes in utilization, although we expect that involvement of the vendors almost certainly guarantees that utilization would change. In addition, Medicare beneficiaries who do not have supplemental coverage and would otherwise be responsible for a 20% coinsurance for Part B drugs would also save funds as a result of the proposed demonstration project.

THE ADMINISTRATION'S AUTHORITY FOR THIS DEMONSTRATION

Because the ASP-based payment methodology was created by Congress and codified into law since 2003, many have questioned whether the demonstration project can be implemented without statutory change. The Administration's position is that it possesses authority through the CMMI to create and operate the demonstration. Section 1115A of the Social Security Act permits Medicare to enact demonstration programs to test payment models that would reduce costs

without harming care. This authority contains a broad waiver of *any* provision of the Medicare statute (Title XVIII of the Social Security Act), including the ASP payment methodology and OPPS provisions. The CMMI authority also permits waiver of specific provisions of the Medicaid statute—not including the Medicaid Best Price requirements—which means that lower Medicare Part B payment rates may result in lower Medicaid Best Price figures for certain products, which would yield the Medicaid savings noted above.

The very same Section 1115A authority was relied upon by the Obama Administration for its proposed Part B demonstration, however, many accused the Obama Administration of not meeting certain key requirements of the statute, including that a demonstration project must not be national in scope and must be limited in both geography and time. The statute also requires that the demonstration program save funds while not reducing quality of care; the Obama Administration demonstration was intended only to be budget neutral. While the Trump Administration appears to have been more careful in its adherence to the Section 1115A requirements, these conditions have never been tested in a court and it is unclear how they would be construed. Notwithstanding the judicial review limitations in Section 1115A, if the Trump Administration proceeds with the demonstration, we should expect a legal challenge to the program as exceeding CMS's lawful authority, potentially buttressed by constitutional challenges to the statute itself, which purports to delegate substantial authority to CMS to waive statutory requirements and exercise what would appear to be legislative power.

STAKEHOLDER REACTION

As noted above, the Obama Administration proposal, which was more modest in scope, drew extensive opposition from physicians, hospitals, drug manufacturers, and patient advocates. The Trump Administration proposal will be sure to draw no less ire, and we anticipate an even more heated debate in Congress and in the media over the proposal. Although groups like the American Medical Association have issued cautious statements,[7] others like PhRMA were swift and strong in their objections to the proposal.[8] If history is any guide, opposition is expected to mount in the coming weeks and months as providers and patients internalize the change to payment rates and to access that could be impacted by the proposal.

Curiously, the Trump Administration's own words may be used against the proposal. In May 2018, the Administration published its drug pricing "Blueprint" in which it addressed in detail the international pricing scheme, but noted that using "the price of a medicine in one or several countries to derive a benchmark or reference price" would effectively be implementing "price controls [that] prevent drug companies from charging market rates for their products, while delaying the availability of new cures to patients living in countries implementing these policies."[9]

Manufacturers may already be thinking about options to avoid lower Medicare Part B payment amounts. One simple idea would be to shift Part B products into the Part D program by creating self-administration delivery mechanisms such as auto-injectors. (It is important to know that the Trump Administration is intending to publish a Part D Drug Pricing proposed rule in the next few weeks, which may address this issue.) In another approach, manufacturers could license core intellectual property to European subsidiaries who could create "new" drugs with minor differences that could be "approved" in foreign countries, but that would be distinct drugs from those used in the United States such that they would not be used to calculate an IPI value. European countries would likely have an interest in facilitating the approvals of these "new" drugs for use in countries measured for the IPI value, given that manufacturers otherwise may increase drug prices in these countries in order to maintain higher Medicare payment rates in the United States.

NEXT STEPS

The ANPRM was published in the Federal Register on October 30, 2018, and interested stakeholders are invited to submit comments by December 31, 2018. Following submission of the comments, it will likely take the Trump Administration several months to analyze the comments and issue a formal Proposed Rule, following which another

round of comments would be submitted. Undoubtedly, we expect an intense internal debate within the Trump Administration over the proposal, and whether and how to implement it. Moreover, even if the demonstration program is finalized, it is unclear whether any vendors will seek to participate in the program, and if vendors that do participate will be able to negotiate drug prices that are low enough to offer to providers in their networks.

King & Spalding is ready to assist you in considering what the proposal and ensuing developments mean for your company, as well as preparing comments for submission to CMS. For more information, please contact any of the team members on the first page of this Client Alert.

[1] *See* Centers for Medicare & Medicaid Services, Advanced Notice of Proposed Rulemaking with Comment, "Medicare Program; International Pricing Index Model for Medicare Part B Drugs," 83 Fed. Reg. 54,546 (October 30, 2018), *available at* https://www.gpo.gov/fdsys/pkg/FR-2018-10-30/pdf/2018-23688.pdf.

[2] Section 303(c) of the Medicare Modernization Act of 2003 ("MMA") amended Title XVIII of the Act by adding section 1847A, which established a new ASP drug payment system. *See* 42 U.S.C. § 1395w-3a; 42 C.F.R. § 414.800, *et seq*.

[3] *See* Centers for Medicare & Medicaid Services, Proposed Rule, "Medicare Program; Part B Drug Payment Model," 81 Fed. Reg. 13,230 (March 11, 2016), *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05459.pdf.

[4] *See* Centers for Medicare & Medicaid Services, Withdrawal of Proposed Rule, "Medicare Program; Part B Drug Payment Model; Withdrawal," 81 Fed. Reg. 46,182 (October 4, 2017), *available at* https://www.gpo.gov/fdsys/pkg/FR-2017-10-04/pdf/2017-21420.pdf.

[5] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Report, "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures" (October 25, 2018), *available at* https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf.

[6] *See* Dan Best (Senior Advisor to the Secretary for Drug Price Reform), HHS.gov Blog Post, "Answering Your Questions About the IPI Drug Pricing Model" (October 30, 2018), *at* https://www.hhs.gov/blog/2018/10/30/answering-your-questions-about-the-ipi-drug-pricing-model.html.

[7] American Medical Association, "Statement on President's Plan for Prescription Drugs" (October 25, 2018), *at* https://www.ama-assn.org/ama-statement-president-s-plan-prescription-drugs.

[8] Pharmaceutical Research and Manufacturers of America, Press Release, "Statement on HHS Speech and Part B Proposal" (October 25, 2018), *at* https://www.phrma.org/press-release/phrma-statement-on-hhs-speech-and-part-b-proposal.

[9] "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" (May 2018) at 15, *available at* https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.