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Proposed Medicare Part B Payment Methodologies Will Impact Drug Manufacturers, Physician Practices and Hospital Outpatient Departments

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On March 11, 2016, the Centers for Medicare & Medicaid Services announced a proposed two-phase demonstration project to test new Medicare Part B payment models (CMS-1670-P; 81 Fed. Reg. 13,230, March 11, 2016). The proposed changes to the current system are intended to eliminate the perceived incentive inherent in the average sales price (ASP) ''add-on'' model (ASP plus 6%) for providers to purchase higher priced drugs and biologics, and to create incentives to purchase lower priced drugs and biologics (collectively drugs). Comments on the Proposed Rule are due May 9, 2016. The genesis of the Proposed Rule is a concern that many drugs administered by physicians in outpatient settings and paid by Medicare Part B are very expensive specialty drugs, and that the current Part B payment rate for drugs encourages providers to purchase and bill Medicare for higher priced drugs.

To reduce the cost of prescription drugs, CMS, using authority to test innovative payment and service delivery models granted by section 3021 of the Affordable Care Act, proposes a two-phase initiative in which it would first test a model that substitutes a lower percentage add-on to ASP plus a fixed fee per drug per day for the current ASP + 6% payment rate. In Phase II, it would test application of value based factors to the current rate and another model that combines the value based method with the alternative add-on in addition to the Phase I model.

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PHASE I – CHANGES TO ASP + 6%

In the first phase, CMS is proposing to reduce the add-on component to 2.5% and adding a flat fee of $16.80 per drug per day. The value of the flat fee will be increased annually for inflation based on the Consumer Price Index for Medical Care and could be revised in the final rule depending on CMS' analysis of more recent claims data. CMS selected 2.5% as an amount sufficient to cover prompt pay discounts to wholesalers that are not passed through to providers, because CMS believes any reimbursement exceeding the provider's cost is incentive for overusing more expensive drugs. However, unlike average manufacturer price (AMP), discounts to wholesalers are included in ASP, and ASP does not reflect the price wholesalers charge providers, which depresses the value of the add-on. Reducing the percentage to 2.5% of ASP, may cause more providers to be under water even with the fixed fee as there is little leeway for those paying more than the average to recoup the difference. Moreover, in situations where a physician needs to administer a larger dose to a patient, the effect of the alternate payment model would be exacerbated as one fee would be paid on the total volume of the drug administered to the patient in a single visit. CMS is con-

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sidering variations such as tiers of flat fees and other means of further breaking down the payment, although it is concerned that the effect could be a huge mark-up over the lowest cost drugs. It is soliciting comments on these concepts and justification for higher payments such as special handling and similar contributors to higher costs.

CMS proposes to apply the rule to Medicare Part B providers nationwide and to include all drugs covered by Part B, whether reimbursed as stand-alone drugs or under the Outpatient Prospective Payment System, with few exceptions. CMS also proposes to use Medicare Part B Primary Care Service Areas to define the geographic areas for the control group (paid at the current statutory rate), the alternative add-on plus fixed fee rate, and the Phase II value based model and combination model. Providers in these Service Areas would be randomly assigned to one of the payment model groups. A ''G-Code'' would be assigned to geographic regions and used to bill for the flat fee portion.

PHASE II – DEVELOPING TOOLS TO ASSESS VALUE

In Phase II, CMS proposes to develop tools for evaluating patient outcomes (improved clinical results and quality of care) and cost effectiveness as a basis for payment instead of sales volume, and to assess the suitability of particular drugs for application of these various tools. CMS does not intend to apply all of these strategies to every drug. Rather, it intends to implement them for specific Healthcare Common Procedure Coding System (HCPCS) codes after notice and comment and an evaluation of the appropriateness of the tools to specific Part B drugs.

Among the tools it is considering for implementing value-pricing is equal payment for therapeutically similar drug products using reference pricing, i.e., setting a benchmark payment using either the average price for drugs in a group of therapeutically similar drug products, the most clinically effective drug in the group, or some other reference point, and pay all drugs in the group the same amount. CMS would determine whether a particular therapeutic class was a candidate for reference pricing, and assess the characteristics of the group of drugs, such as relative effectiveness, before selecting a benchmark rate. A single payment amount would apply to each HCPCS code within the group if they are determined to be therapeutically equivalent, or if they differ in effectiveness, the reference price could be the price of the most clinically effective drug with payment for other products in the group adjusted downward based on their effectiveness in comparison to the benchmark drug. CMS would not permit providers who paid more for the selected drug than the reimbursement amount to hold patients responsible for the difference as a disincentive for purchasing the more expensive drug.

CMS is also proposing indication-based pricing where payment for a drug might differ by indication depending on evidence-based outcomes data. For this tool, CMS recognizes that high quality evidence and measured outcomes is necessary. As part of this strategy, CMS is proposing to enter into voluntary agreements with manufacturers through outcome-based risk sharing agreements in which payment is linked to patient health outcomes, and the final price is adjusted based on achievement of targeted outcomes. Additionally, CMS is proposing a cost-sharing strategy that would reduce or eliminate high-value patient copayments for such drugs, because Part B beneficiaries' percentage share of expensive drugs is often a hardship. This proposal could benefit providers who would no longer have to collect the co-payments. Although the proposed rule doesn't expressly address steering concerns underlying the prohibition against provision of co-pay assistance to Medicare patients and providers, CMS is concerned that reducing co-payment costs could create competitive advantages for similar drugs that are paid under different HCPCS codes, and it is seeking comments on how to avoid this effect.

POTENTIAL IMPACT

The alternative proposed models are intended to and could influence the selection of drugs administered to Part B beneficiaries. As noted, providers paying more than the average are more likely to be undercompensated. Many industry and professional associations have strongly criticized the proposal as unnecessary, because there are many factors taken into consideration in selecting a drug therapy, and harmful to older patients with serious conditions who could potentially lose access to the most appropriate medication for them. Others believe the payment changes will shift certain types of care from physician practices to hospital outpatient departments. Further, because of the significant difference between 340B drug discount program acquisition cost and ASP, particularly for expensive brand drugs with significant inflation penalties, the existing disparity in the cost of administering drugs and biologics between 340B hospitals and physician practices would be exacerbated, and could lead to more practice acquisitions and affiliations.

On March 17, 2016, 316 national and regional medical organizations wrote a letter to Senate and House leadership from both parties objecting to the limited opportunity CMS gave stakeholders before announcing drastic changes to the payment system, reminding Congress that CMS has already cut reimbursement for Part B drugs by 2% due to sequestration imposed by the Budget Control Act, and requesting that Congress take action to stop the agency from proceeding with its initiative. At the same time, managed care organizations have weighed in supporting CMS' reform efforts.

Regardless of whether the proposal is withdrawn, private health plans are showing interested in new approaches to payment for expensive drugs, and it's possible that CMS' ideas, especially the value based approach, will gain traction with managed care even if not implemented for Medicare Part B. For some drugs,

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where risks are manageable and metrics are available for assessing patient outcomes and cost savings, manufacturers may consider risk-sharing arrangements preferable to traditional discounting practices.