CMS'S PROPOSED PART B DRUG PAYMENT MODEL

In a proposed rule issued on March 11, CMS formally unveiled plans for its Part B Drug Payment Model (the "Model"). The Model would significantly alter how Medicare pays for Part B drugs and biologicals. If finalized, the Model will affect hospital outpatient departments, physicians, nursing facilities and certain DME suppliers.

COMMENCEMENT AND DURATION OF MODEL

Phase I of the Model (noted below) would begin on or after August 1, 2016. Phase II (also noted below) would begin no sooner than January 1, 2017. As proposed, the Model would run for five years.

APPLICABLE DRUGS AND APPLICABLE PROVIDERS/SUPPLIERS

With certain limited exceptions, the Model would apply to all drugs and biologicals that are paid separately under Part B. All providers and suppliers furnishing any such drugs or biologicals would be subject to the Model.

GEOGRAPHIC DEPLOYMENT OF MODEL

The proposed rule identifies 7,048 primary care service areas ("PCSAs") throughout the country (excluding Maryland). PCSAs are clusters of ZIP codes that reflect primary care resources and utilization. Under the proposed rule, *each* of the PCSAs would be randomly assigned to either a "control group" or one of three "test arms" of the Model. The proposed rule does not indicate which PCSAs would be assigned to the control group or to one of the test arms. The control group and the three test arms are summarized as follows.

Control Group: Under the control group, drugs and biologicals are reimbursed under the current reimbursement methodology (i.e., average sales price plus 6 percent).

Test Arm #1: Drugs and biologicals are reimbursed at the average sales price plus 2.5 percent and, in addition, a flat fee of $16.80 per drug, per day administered. The flat fee amount would be increased annually based on the percentage increase in the CPI Medical Care for the most recent 12-month period.

Test Arm #2: Drugs and biologicals are reimbursed using the current methodology (i.e., average sales price plus 6 percent), subject to the application of certain value-based purchasing tools.[1]

Test Arm #3: Drugs and biologicals are reimbursed at average sales price plus 2.5 percent and a flat fee (initially $16.80 per drug per day administered, as noted above), subject to the application of the aforementioned value-based purchasing tools.

Whether a provider's or supplier's reimbursement would fall under the control group or one of the three test arms would be determined by the particular PCSA within which the provider or supplier is located. As mentioned earlier, a PCSA is a cluster of ZIP codes. CMS proposes to determine a provider or supplier's PCSA based on the service location ZIP code for physician drug claims, the beneficiary ZIP code for DME supply claims and the ZIP code for the address associated with the CMS certification number for hospital outpatient claims.

PHASES I AND II OF THE MODEL

Phase I of the Model would be limited to implementing the control group and test arm number 1 on or after August 1, 2016. Phase II of the Model would implement test arms numbers 2 and 3 on or After January 1, 2017.

OVERLAP WITH OTHER CMS INITIATIVES

In the proposed rule, CMS notes the likelihood that the Part B Drug Payment Model will overlap with other CMS initiatives, including the Bundled Payments for Care Improvement initiative, the Comprehensive Joint Replacement initiative, the Medicare Shared Savings Program, the Oncology Care Model and the Intravenous Immune Globulin Demonstration. For providers currently participating in any of these initiatives who are later determined to be located in PCSAs assigned to any of the aforementioned three test arms, it will be important for the providers to know: (1) whether they will be disadvantaged financially under the current initiatives as a result of the drug payments they receive under any of the test arms;[2] and (2) whether the combined administrative burden of any current initiative and the Part B Drug Payment Model will be excessive.[3] *Mindful of this, please note that CMS requests comments on the best approach for handling the overlap*

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between the Part B Drug Payment Model and the other CMS initiatives.

DEADLINE FOR COMMENTS TO CMS

Comments to CMS concerning the Model are due no later than May 9, 2016.

If you have any questions, please contact Tim Kennedy at tkennedy@hallrender.com or (317) 977-1436 or your regular Hall Render attorney.

[1] With regard to test arms number 2 and 3, the proposed rule merely describes, in general terms, certain value-based pricing strategies, including reference pricing, indications-based pricing, outcomes-based risk-sharing agreements and discounting or eliminating patient coinsurance amounts. In this regard, CMS proposes to gather additional information on these value-based purchasing tools and, thereafter, design and implement specific value-based purchasing tools for test arms number 2 and 3.

[2] This will be difficult to determine without knowing how CMS will specifically apply the value-based purchasing tools described above.

[3] This, too, will be difficult to determine without knowing how CMS will apply the value-based purchasing tools described above.

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