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Proposed Rule on Medicare Part B Drug Payment Models

OVERVIEW

On March 8th, the Centers for Medicare and Medicaid Services (CMS) released a proposed rule that would implement new Medicare Part B drug payment models and clinical decision support tools. The Center for Medicare and Medicaid Innovation would test the alternative payment models over a five-year period to assess the effect on beneficiary health outcomes and expenditures.

CMS proposes to group all Part B providers and suppliers according to their Primary Care Service Area (PCSA) and randomly assign PCSAs to participate in various models. There are 7,144 PCSAs nationwide, but PCSAs in Maryland would be excluded from the model tests due to the State's all-payer model. Of the 7,048 PCSAs that would be eligible to participate, approximately 5,350 would be randomly assigned to implement at least one of the proposed test models. The roughly 1,700 PCSAs that would be randomly assigned to control groups would not have to implement any of the test models.

The proposed rule coincides with a Department of Health and Human Services (HHS) report that was also released on March 8th. The report found that expenditures on prescription drugs are increasing faster than overall health care spending, and that expenditures for specialty drugs, including many Part B drugs, are increasing more rapidly than other prescription drugs.

CMS will accept comments on the proposed rule until May 9th. This document summarizes the payment models that CMS proposes to test. The proposed rule is available here. The HHS report is available here.

PHASE I: PAYMENT INCENTIVE MODEL

CMS currently reimburses providers for Part B drugs by paying the average sales price of the drug, plus a 6 percent bonus. The existing payment model may incentivize providers to prescribe more costly drugs because they receive a greater add-on payment for high-priced drugs than they do for low-priced drugs. CMS proposes to test a payment model that would change the add-on from 6 percent to 2.5 percent, plus a flat-fee of $16.80 per day. The flat-fee would be adjusted annually according to increases in the consumer price index for health care.

CMS proposes to include the majority of Part B drugs in this test models, but would exclude drugs that are billed separately by End-Stage Renal Disease facilities. CMS plans to begin testing this model by late 2016 in select PCSAs that will be identified in the final rule.

PHASE II: VALUE-BASED PRICING & CLINICAL DECISION SUPPORTS

CMS also proposes to implement the following models to test value-based pricing and clinical decision supports. The models would be tested in both PCSAs that have been selected to participate in the new payment incentive model and those that continue to receive the standard 6 percent add-on payment arrangement.

These models would be implemented no sooner than January 1, 2017 and would only apply to certain Part B drugs. CMS seeks comments on the Part B drugs that would be most appropriate for each of the following models.

Decreased Cost-Sharing

Medicare beneficiaries are currently responsible for paying for 20 percent of Part B services after their deductible is met. Under the proposed model, CMS would decrease or eliminate cost sharing for drugs that are determined to be high-value.

Indications-Based Pricing

Many drugs may be prescribed to treat multiple conditions, but are most effective at treating one condition. CMS proposes to test a model that would tie the payment of a drug to its effectiveness at treating a specific condition. The pricing would be based on the outcomes of clinical trials that test the effectiveness of various drugs in treating a specific condition.

Reference Pricing

Under the proposed model, CMS would establish standard payment rates for groups of therapeutically-similar drugs. In groups where one drug is more clinically effective than the other drugs in that group, the most effective drug would be paid a benchmark rate and the other drugs would be paid rates that are adjusted downward based on their effectiveness. Providers and suppliers would not be allowed to bill the beneficiary for any difference between the reference price and the cost of the drug.

Outcomes-Based Risk-Sharing

The proposed rule would authorize CMS to enter into voluntary agreements with drug manufacturers to tie the price of a drug to patient outcomes, rather than a predetermined price based on historical population data. Under this agreement, manufactures would provide rebates, refunds, or price adjustments to CMS when a drug does not meet patient outcome benchmarks.

Clinical Decision Support Tools

CMS would provide evidence-based clinical decision support tools to providers and suppliers to enhance their ability to prescribe the most appropriate drug for specific indications. Use of the tools would be voluntary and are not intended to replace the physician's medical judgment.

CMS also proposes to create an online source for participating providers to review their Part B drug claims and compare them to prescribing patterns on the local and national level. This information would not be publicly available.