CMS hopes that a new, two-phase demonstration project will test whether certain changes to the way Medicare Part B pays for prescription drugs could cost less while preserving or improving quality of care. The Proposed rule, which will publish in the Federal Register on March 11, 2016, would create the Part B Drug Payment Model, would test alternative payment models for drugs furnished incident to a physician's services, drugs administered via a covered item of durable medical equipment (DME), and other drugs specified by statute. The first phase, which CMS hopes to begin in Fall 2016, would change Part B’s 6 percent add-on to Average Sales Price (ASP) to 2.5 percent plus a flat fee. The second phase, to start no earlier than 2017, would implement value-based purchasing (VBP) tools similar to those employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization.

Drugs under Part B. In general, drugs—including biologics and biosimilars—covered under Part B fall into three categories: (1) drugs furnished incident to a physician’s service in the office or hospital outpatient settings, which are not usually self-administered by the patient; (2) drugs administered via a covered DME item; and (3) other categories of drugs explicitly identified in the law. Part B generally pays physicians and hospital outpatient departments the ASP of a drug, plus a 6 percent add-on (ASP+6). The ASP is calculated as the manufacturer’s sales to all purchasers in the U.S. for such drug or biological in the calendar quarter divided by the total number of units of such drug or biological sold by the manufacturer in the quarter (Soc. Sec. Act §1847A(c)). The calculation is based on the amount of product included in a vial or other container as reflected on the FDA-approved label and without regard to any special packaging, labeling, or identifiers on the dosage form or product package.

Identified shortcomings in current payment model. According to a new issue brief released by HHS’ Office of the Assistant Secretary for Planning and Evaluation (ASPE), the ASP+6 payment method provides weak incentives for physicians to choose the lowest cost therapy to effectively treat a patient. The brief, titled Medicare Part B Drugs: Pricing and Incentives, determined that because Part B pays for most drugs separately, with no reference to other drugs of similar therapeutic effectiveness, there is no incentive to providers, suppliers, or patients to make high-value choices. Further, although commercial insurers—including Medicare Part D plan sponsors—commonly use pricing policies or formulary management practices to achieve better value for self-administered drugs, Part B has not applied similar policies to provider-administered drugs.

Another ASPE issue brief, titled Observations on Trends in Prescription Drug Spending, showed that expenditures on prescription drugs are rising faster than overall health spending, and are projected to continue doing so. There is an ongoing shift from brand-name prescription drugs to generic drugs, which is conferring substantial savings to the health care system. However, the ASP+6 methodology results in a larger add-on payment for more expensive drugs. For example, a physician administering a $100 brand-name drug would receive a $6 add-on payment from Part B, but only a 30-cent add-on payment for the $5 generic version of that drug. The proposed demonstration seeks to address this discrepancy to ensure that beneficiaries receive the most effective drugs at the lowest cost to the program.

Overview of proposed models. Section 3021 of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148) added section 1115A to the Social Security Act and established the Center for Medicare and Medicaid Innovation (CMMI). CMMI tests innovative payment and service delivery models to reduce program expenditures under the federal health care programs while preserving or enhancing the quality of care furnished to beneficiaries. The new payment models would be run under CMMI’s authority, and would test whether certain changes would be more cost-effective for Medicare. The demonstration would take place in two phases, and would address the ASP add-on as well as directly addressing the manufacturer’s ASP, which more directly affects costs than the add-on. It would last five years.
Phase One—changes to ASP add-on. The first phase would begin no sooner than 60 days after the rule is finalized; CMS hopes to begin in Fall 2016, suggesting a summer 2016 Final rule. The first phase would test an alternative to the ASP+6 model; CMS is proposing ASP+2.5 percent, plus a flat fee, but would like comments about additional alternative approaches from stakeholders. Phase One is designed to be budget-neutral, and would not test program savings but rather redistribution of the add-on. In a related fact sheet, CMS demonstrated its proposal as ASP+2.5, plus a flat fee of $16.80. Using the earlier example of a $100 brand-name drug versus a $5 generic drug, the model would pay $19.30 above ASP for the $100 drug and $16.93 above ASP for the $5 drug. The theory is that with a smaller discrepancy in the add-on payment, providers will have more incentive to prescribe less-expensive drugs than previously, without being penalized for using more-expensive drugs.

Phase Two—value-based purchasing. The second phase, which would begin no sooner than January 1, 2017, would base payments for certain drugs on VBP. CMS anticipates that Phase Two will take several years to fully implement. During the final three years of the demonstration, both phases will be operating at full-force. The proposed value-based pricing strategies include:

- discounting or eliminating patient cost sharing;
- feedback on prescribing patterns and online decision support tools;
- indications-based pricing;
- reference pricing; and
- risk-sharing agreements based on outcomes.

Provider and supplier participation. In order to determine whether the alternative payment models are effective, CMS will divide Part B providers and suppliers into two groups for Phase One based on geographic locations. All participating providers and suppliers in the chosen geographic areas will receive the modified ASP add-on, while those outside of the geographic areas will continue receiving ASP+6. Once Phase Two begins, each group will be subdivided, creating four reimbursement groups overall: ASP+6; ASP+6 with VBP; ASP+2.5+$16.80; and ASP+2.5+$16.80 with VBP. These divisions allow for control groups and study groups to test both payment models and the effects of the models both together and separately.

Comments requested. Comments on the proposed test models are due to CMS by May 9, 2016. In addition to the input on Phases One and Two, the agency would also like stakeholder comments on how to create VBP arrangements with manufacturers under Medicare fee-for-service (FFS) payment for drugs; whether CMS should consider implementing an updated version of the Competitive Acquisition Program (CAP); and whether the agency should pursue a more bundled or episode-based approach that moves beyond an FFS payment structure.

Early negative responses. Within hours of CMS’ announcement of the proposal, stakeholders began commenting on the model’s changes. The Republican chairs of three Congressional committees released a joint statement accusing the Obama Administration of “making decisions behind closed doors” and “with a complete lack of transparency and clear disregard” for Medicare beneficiaries. House Ways and Means Committee Chairman Kevin Brady (R-Texas), House Energy and Commerce Committee Chairman Fred Upton (R-Mich), and Senate Finance Committee Chairman Orrin Hatch (R-Utah) condemned the “proposed experiment,” saying that it will “disrupt how health care providers serve patients.”

The Pharmaceutical Research and Manufacturers of America (PhRMA) also issued a critical statement, calling the current Part B drug payment methodology “an effective, market-based pricing mechanism that works to control costs,” and pointing out that “Part B medicines represent a small and stable share of overall Part B spending.” The group concluded that the proposed demonstration project is “not the right approach.”

The American Society of Clinical Oncology said that the proposed demonstration will disrupt treatment for cancer patients. It noted, “Physicians did not create the problem of drug pricing and its solution should not be on their backs.” The Society sent letters to CMS Acting Administrator Andy Slavitt and HHS Secretary Sylvia Burwell asking them not to proceed with the demonstration.

Companies: Pharmaceutical Research and Manufacturers of America; American Society of Clinical Oncology

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