

CMS Part B Drug Models Challenged

A proposed rule released by the Centers for Medicare & Medicaid Services (CMS) on March 8 with a range of potential changes affecting reimbursement for medications, such as cancer medications, injectables, and eye care treatments, administered in physicians' offices has met with protest in the medical community. The proposed rule would create a 5-year plan including a range of changes that would be tested to identify cost savings and quality improvements in Medicare Part B prescription drug payments. In a press release, CMS indicated that the proposed rule was "designed to test different physician and patient incentives to do 2 things: drive the prescribing of the most effective drugs, and test new payment approaches to reward positive patient outcomes." Among the approaches to be tested are "the elimination of certain incentives that work against the selection of high performing drugs, as well as the creation of positive incentives for the selection of high performing drugs, including reducing or eliminating patient cost sharing to improve patients' access and appropriate use of effective drugs."

The proposed rule sought comment on 6 alternative approaches to Part B, listed under the following headings:

- (1) Improving incentives for best clinical care: This proposed model would assess whether changing the add-on payment to physicians from 6% plus the average sales price of a drug (known as the ASP + 6% formula) to 2.5% plus a flat-fee payment of \$16.80 per drug per day.
- (2) Discounting or eliminating patient cost sharing.
- (3) Feedback on prescribing patterns and online decision support tools: This proposed model would test the effects of evidence-based clinical decision support tools as a resource for providers and suppliers; for example, with information on best practices in prescribing or information on a clinician's prescribing patterns relative to geographic and national trends.
- (4) Indications-based pricing: This model would test the effect of varying payment for a drug based on its clinical effectiveness for different indicators.
- (5) Reference pricing: This model would assess the practice of setting a standard payment rate (benchmark) for groups of therapeutically similar drug products.
- (6) Risk-sharing agreements based on outcomes: This proposed test would allow CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.

The announcement of the proposed models was met with immediate protest from physicians and professional health care associations. The American Society of Clinical Oncology (ASCO) estimated that, on average, practices would lose \$30,000–\$35,000 per physician FTE (the exact amount would vary depending on patient mix, geography, setting, and other factors). ASCO noted in a statement urging members to contact their Congressional representatives that "Physicians did not create the problem of drug pricing, and its solution should not be on their backs." PhRMA, an advocacy group for the pharmaceutical industry, released a statement on March 10 saying that "Proposing sweeping changes to Medicare Part B drug reimbursement without thoughtful consideration and stakeholder input is not the right approach and puts Medicare patients who rely on these medicines at risk." More than 300 professional organizations expressed their concerns about the changes in a joint letter to Congress on March 17. At the same time, patient advocacy groups came out in favor of the changes and their potential for consumer cost savings.

The public comment period for the proposed rule ended on May 9. If finalized, changes relative to the current ASP + 6% formula would go into effect in late 2016, with the other proposed models implemented no earlier than January 1, 2017. For more information on the proposed rule, see <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-03-08.html>.

Centers for Medicare & Medicaid Services