Monitoring and Evaluating the Access and Quality Implications of CMMI's Proposed Part B Drug Payment Model

Overview

The health care system is rapidly shifting from paying providers based on the volume of services they provide to payment models based on the value they demonstrate by controlling costs and enhancing quality. The Secretary of the Department of Health and Human Services (HHS) has committed to tying 50% of Medicare payments to alternate payment models (APMs) by 2018.[1] The Centers for Medicare & Medicaid Services (CMS) and their Center for Medicare and Medicaid Innovation (CMMI) have been leaders in value-based purchasing (VBP), with CMMI developing and testing new delivery and payment models. Consideration of appropriate patient safeguards has been a critical component of these efforts, as policy-makers and stakeholders seek to address and manage the potential for negative, as well as positive, impacts on patient access and care quality.

The Proposed Part B Drug Payment Model

In March 2016, CMMI released a proposed rule for a Part B Drug Payment Model, under which they intend to "test whether alternative drug payment designs will lead to a reduction in Medicare expenditures while preserving or enhancing the quality of care provided to Medicare beneficiaries." The five-year model, which is mandatory for providers receiving Part B reimbursement, includes two phases:

Phase 1: ASP + X (Fall 2016)	Phase 2: VBP (January 2017)
ASP+6% (Control)	ASP+6% (Control)
	ASP+6% with VBP Tools
ASP+2.5% and Flat Fee Drug Payment	ASP+2.5% and Flat Fee Drug Payment
	ASP+2.5% and Flat Fee Drug Payment with VBP Tools

- In Phase 1, the current Average Sales Price (ASP) plus 6% add-on will be changed to a 2.5% add-on plus a flat fee for half of the providers, while the other half will remain in a control group.
- In Phase 2, VBP tools for drug selection will be applied to half of the providers from each Phase 1 group. VBP tools may include reference pricing, indication-based pricing, outcomes-based risk sharing agreements, and discounting or eliminating patient coinsurance.

CMMI will compare the experience of providers under the new payment model and using VBP tools to one another and to a control group receiving payment under the existing ASP+6% structure. In the VBP Phase of the Part B Drug Payment Model, a participating provider may voluntarily access a Clinical Decision Support (CDS) tool to guide prescribing decisions and receive claims data reports and feedback on prescribing patterns. CMMI also added a Pre-Appeals Payment Exceptions Review process to allow providers, suppliers, or beneficiaries the opportunity to dispute payments under the model by requesting an exception to the pricing policy.

[1] US Department of Health and Human Services. "Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value." January 26, 2015. http://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html.

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Why Is Monitoring and Evaluation of VBP Important?

Risk for Inappropriate Care

Any policy initiative has the potential for both intended and unintended effects. VBP models are intended to increase providers' accountability for creating value through lowering cost and improving quality. However, the financial incentives built into VBP models inherently raise the risk of avoiding (or "stinting" on) necessary care to decrease costs,[2] particularly for relatively high cost specialty treatment and innovative care.

The Monitoring and Evaluation Imperative

Monitoring and evaluation of quality and cost of care outcomes and trends can detect whether unintended effects have occurred within VBP models. Given the potential for unintended effects of implementing a VBP approach such as the Part B Drug Payment Model, it is incumbent on CMMI to have effective strategies in place for *monitoring* the actions of providers participating in the model and *evaluating* the impact of the model. CMMI must balance cost control with the need to deliver high quality care, in terms of access and outcomes, to Medicare beneficiaries.

- **Monitoring:** In the shorter-term, detecting whether unintended effects have occurred and ensuring that beneficiaries in the program are not negatively impacted.
- **Evaluation:** In the longer-term, understanding trends in provider practice patterns and beneficiary outcomes that assess overall program impact and necessary adjustments.

Quality measures are important for both monitoring and evaluation. Appropriate measures help to balance the effect of financial incentives by holding providers participating in VBP arrangements accountable for quality, as well as cost, of care. Quality measurement, with additional analyses, should be used to monitor for any early warning signals that unintended effects have occurred, and to evaluate long-term trends in performance and outcomes.

How Does CMMI Propose to Assess the Part B Drug Payment Model?

How Is CMMI Proposing to Monitor for Unintended Effects?

In the proposed rule, CMMI does not adequately describe a monitoring approach for ensuring that beneficiaries will not be negatively impacted by either phase of the Part B Drug Payment Model. In previous policy initiatives, such as the Oncology Care Model (OCM), Comprehensive Joint Replacement (CJR) model, and the Accountable Care Organization (ACO) models, CMMI provided details about their intent to audit providers through claims analyses, medical record reviews, coding audits, site visits, surveys, and complaint reviews, among other activities, to detect unintended consequences.[3,4,5]

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[2] US Department of Health and Human Services, Office of the Inspector General. "2013 Top Management & Performance Challenges". December 1, 2013. http://oig.hhs.gov/reports-and-publications/top-challenges/2013/2013-tmc.pdf.

[3] 42 CFR 425.316 – Monitoring of ACOs.

[4] CMS. Oncology Care Model (OCM) Request for Applications (RFA) February 2015 (Updated 6/4/15).

[5] Federal Register. Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services. Published 11/24/15.

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How Is CMMI Proposing to Evaluate the Model?

Similar to other CMMI evaluations, a CMMI contractor will analyze questions about the model's impact on utilization and prescribing patterns, quality of care, access to care, timeliness of care, and patient experience, as well as potential unintended consequences. CMMI indicates the evaluation will be based mainly on secondary data sources, such as Medicare FFS claims, and they may consider a survey of beneficiaries, suppliers, and providers.

CMMI's Proposed Evaluation Questions

Payment	Is there a reduction in Part B drug spending, total Part B spending, or total Medicare program spending?
Prescribing Patterns	Are there changes in utilization and prescribing patterns?
Prescriber Acquisition Process	Is there any change in the prices at which providers and suppliers are able to obtain Part B drugs?
Outcomes / Quality	What is the impact on quality of care, access to care, timeliness of care, and the patient experience of care?
Unintended Consequences	Did the model result in any observable unintended consequences?
Variable Model Effects	Was each intervention tested more or less successful under some conditions compared to others?

Gaps and Risks in the Part B Drug Payment Model Design

Broad Scope and Complexity

CMMI models typically test new approaches on self-selected subsets of providers who are prepared and volunteer to experiment with new payment models. In contrast, the Part B Drug Payment Model is mandatory for providers who use Part B drugs, and may be confusing or disruptive to those who deliver highly complex patient care. Because CMMI assigns providers to each test group of the model, beneficiaries who want to keep their providers are also unable to opt out of the model.

The proposed Part B Drug Payment Model is far-reaching, and a broader population of providers and patients requires more significant investment in monitoring resources. Past CMS rulemaking for VBP initiatives has indicated program monitoring and evaluation could include analysis of financial and quality data; site visits; assessment and follow-up investigation of beneficiary and provider complaints; and audits of claims, medical charts, surveys, and physician coding. These efforts are expensive and time consuming, and the proposed rule does not describe the commitment of resources to adequately monitor such a broad demonstration.

Key Gaps in the Part B Drug Payment Model Proposal

Broad Scope	Far-reaching nature of the test will require immense resources for adequate monitoring and evaluation
Complexity	Mandatory participation requirement may disrupt already complex care delivery
Undefined Measures	Lack of necessary measures leaves questions about how CMMI will monitor and evaluate access and quality
Measurement Challenges	Few measures are available to capture patient-reported quality outcomes without significant reporting burden
Short Time Horizons	Trends in analyses over short time horizons may not capture true effect of incentives

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Quality Measure Use

Undefined Measures

The proposed rule for the Part B Drug Payment Model does not define the measures that CMMI will use to monitor provider practice patterns or evaluate whether the model maintained or enhanced quality of care over the long-term. In contrast, the OCM bundled payment model provides a detailed list of quality measures that may be part of quality monitoring or performance-based payment determinations, including clinical quality of care measures for the highest cost cancers. While the Part B Drug Payment model proposed rule does indicate that in Phase 2 some VBP tools and strategies (such as outcomes-based risk-arrangements) will include manufacturer-recommended outcome measures, it does not discuss the types of measures that will be included in monitoring and evaluation. Claims-based rates of hospital readmissions or emergency department visits may not tell the whole story, as limited access to treatment may cause longer-term adverse outcomes for patients.

Measurement Challenges

Patient-reported outcome (PRO) measures could reveal much about the effects of the Part B Drug Payment Model on changes in beneficiary health and experience with their health care. However, these measures are burdensome to collect and have not been widely adopted for clinical use. For example, while CMMI's Comprehensive Joint Replacement Model (CJR) encourages the collection of PRO data to test a measure of change in functional status following surgery, that measure was not yet ready to be included in the CJR measure set.

CMMI must be prepared to monitor and evaluate that beneficiaries are receiving the right care at the right time under the proposed Part B Drug Payment Model. However, measures of appropriate care processes are also challenging, because the evidence and clinical guidelines for many innovative therapies are changing quickly. As personalized medicine becomes more nuanced to meet individual needs, defining a standard of care becomes more difficult. Patients need treatment designed for their genetic profiles, risk levels, and ability to tolerate toxicity. Providers should be supported, not penalized, for making decisions that best meet the needs and preferences of their patients.

Short Time Horizons

The proposed rule indicates that the Part B Drug Payment Model will be tested for five years. Analyses of trends over that period may not adequately capture the total effect on beneficiary access and outcomes. The impact of the model on survival, quality of life, and ultimate outcomes for beneficiaries may require follow- up assessment over a longer term.

As Proposed, the Model Raises Questions about Access and Quality for Beneficiaries

While CMMI's aim to promote higher value health care is commendable, the impact that the proposed Part B Drug Payment Model would have on access and quality for affected beneficiaries is unknown. CMMI must be prepared to adequately monitor and evaluate for unintended effects, given the risks for provider stinting on necessary care under the proposed incentives. Models like the one proposed necessitate a plan for real-time monitoring to detect, and protect beneficiaries from, adverse effects, and a plan to comprehensively evaluate the longer-term impact of the program. Based on the detail provided in the proposed rule, CMS has not yet presented a monitoring and evaluation plan for the Part B Drug Payment model that will mitigate the risk of harm to Medicare beneficiary access and quality of care.

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