CMS proposes to test new Medicare Part B prescription drug models to improve quality of care and deliver better value for Medicare beneficiaries.

The backlash against the proposal that changes physician reimbursement for Part B drugs was swift. Several strongly worded letters were sent to the Centers for Medicare & Medicaid Services (CMS) protesting the change, including one from more than 60 cancer care groups representing nearly every state in the country. The CMS proposal doesn’t impact most prescriptions Medicare beneficiaries receive through their pharmacies.

Prescription Drugs under Medicare Part B

Medicare Part B covers prescription drugs administered in a physician’s office or hospital outpatient department under physician supervision, such as cancer medications, antibiotics, anti-inflammatory, or eye care treatments.

Drugs paid under Medicare Part B generally fall into three categories:

1. Drugs furnished incident to a physician’s service in the office or hospital outpatient setting,

2. Drugs administered via covered durable medical equipment, and

3. Other categories of drugs explicitly identified in the law.

Today, Medicare Part B generally pays physicians and hospital outpatient departments 80 percent of the average sales price (ASP) of a drug, plus a 6 percent add-on to the ASP. The remaining 20 percent of the ASP is paid by beneficiaries who manage such costs through a Medigap or employee sponsored retiree health plan, but 10 percent or six million Medicare beneficiaries lack such coverage.

The proposed model would test whether changing the ASP add-on payment to 2.5 percent plus a flat fee payment of $16.80 per drug, per day will change prescribing incentives and lead to improved quality and value. CMS would update the flat fee at the beginning of each year by the percentage increase in the consumer price index for the most recent 12-month period. The change would begin no earlier than 60 days after the rule is finalized.

Because physicians often choose among several Part B drugs to treat a patient, let’s consider two drugs each prescribed for a similar condition, with similar patient outcomes, but with widely varying prices. The average sales price for Drug A is $5, and for Drug B it’s $100. Today, the physician is reimbursed for both drugs at 80 percent of the average sales price plus an upcharge of 6 percent for a total of $4.30 for Drug A and $86 for Drug B.

Under the new Part B drug proposal, Medicare would reimburse both Drug A & B at 80 percent of the ASP plus a flat fee payment of $16.80 and an upcharge of 2.5 percent for a total of $20.92 for Drug A and $99.30 for Drug B.

Note: Not all physicians pay the ASP for the drugs prescribed to patients, but rather receive a wholesaler discount for volume purchasing.

In both scenarios, the remaining 20 percent is the Medicare patient’s responsibility. In 2017, Part B changes will also include additional strategies to lower drug costs including discounting or eliminating patient cost sharing.
According to CMS, if the proposed reimbursement changes for Plan B evolve into policy, the change may mean up to 40 percent more in reimbursement for family physicians who administer relatively inexpensive drugs such as injectable steroids and vitamins, while specialists such as oncologists, rheumatologists and ophthalmologists could see reimbursements fall for high-cost drugs. According to Avalere Health, Part B drugs costing less than $480 per day on average will boost revenue for clinicians while drugs with more than a $480 a day price tag would earn them less.

<table>
<thead>
<tr>
<th>Drug Payment: Current Part B Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Sales Price (ASP)</td>
</tr>
<tr>
<td>$5</td>
</tr>
<tr>
<td>$10</td>
</tr>
<tr>
<td>$100</td>
</tr>
<tr>
<td>$1000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Payment: Proposed Part B Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Sales Price (ASP)</td>
</tr>
<tr>
<td>$5</td>
</tr>
<tr>
<td>$10</td>
</tr>
<tr>
<td>$100</td>
</tr>
<tr>
<td>$1000</td>
</tr>
</tbody>
</table>

Nathan Downhour, Pharm.D, executive vice president of strategic programs for Avella Specialty Pharmacy in Phoenix has a broader perspective on the problem of rising drug costs in Part B, “I’m not sure we are attacking the correct area of cost savings by focusing only on the spend,” he said. “Medication costs have risen up to $26B on pricing increases which is outpacing the market.”

Downhour explained that a speaker at a conference last week said, ‘Evidence based medicine is now reimbursement based medicine’. “Yes, we need to reduce the pricing but we need to reduce the overall spend and mitigate the rise in the spend as well,” said Downhour. “We need to reduce the overall costs, not just the reimbursement [to physicians].”

Kaiser Health News recently discussed reducing costs by implementing a reference price approach for drugs to reduce costs. The Part B proposal allows Medicare to earmark “therapeutically similar” drugs and set a benchmark, or “reference price,” that it would pay for all drugs in that category. That amount might be the cost of the drug the agency considers the most effective in the group, or some other measure. It’s aimed at narrowing the wide variability — often hundreds or thousands of dollars a year — in what is paid for similar drugs. It was suggested using this approach for drugs is more complex than using it for tests or procedures since medications can have widely differing effects based on the genetic makeup of patients. Also, critics note that it would put Medicare — or some other group — in charge of determining which products are similar.

“The last thing I want to see is Centers for Medicare & Medicaid Services trying to make decisions on the relative value of drugs,” said Dr. Scott Gottlieb, a resident fellow at the American Enterprise Institute, who previously served as a deputy commissioner at the Food and Drug Administration and as a senior adviser to Medicare.

Changing the formula Medicare Part B uses to reimburse doctors and hospitals when they provide chemotherapy and other drugs has also drawn opposition from physician groups.

“\textit{It’s a pretty explosive document [the Medicare Part B Rule proposal]: There’s a hot-button in it for everyone. The biggest thing is that it’s seen as a bow to the government setting prices for drugs.}”

\textit{Dan Mendelson, President of Avalere Health}

More than 1,300 comment letters were submitted about the proposal before the May 9 deadline.

According to Joel V. Brill, MD FACP, chief medical officer at Predictive Health, LLC in Phoenix, “The proposal contains serious deficiencies that will undermine patient access to essential treatment for important conditions,” he said.

“The Medicare Payment Advisory Commission (\textit{MedPAC}) has already examined this issue thoroughly and concluded that there was little evidence to support the notion that physicians select drugs based on the current reimbursement methodology. CMS has provided no evidence to indicate that care provided to Medicare beneficiaries is compromised under the current reimbursement methodology. The proposed model would cut reimbursement for uniquely effective therapeutic medications, while arbitrarily creating enormous windfalls for other drugs, purely to achieve budget neutrality. If finalized, the demonstration will have the
exact opposite effect of its stated goal. Rather than reducing overall health care costs, the demonstration will result in even more care shifting into the higher-cost hospital setting.”

The Pharmaceutical Research and Manufacturers of America — the drugmakers’ trade group — submitted a 45-page comment letter citing a variety of objections to the proposal, from its scope to methods such as reference pricing.

“PhRMA is disappointed that [Medicare] chose to … pursue imposition of policies for price regulation based on government value judgments,” the letter says.

“PhRMA is disappointed that [Medicare] chose to … pursue imposition of policies for price regulation based on government value judgments,” the letter says.

Support for the proposal has come from AARP, which said it won’t affect patients’ access to medications and might even lower their costs.

“This project is a thoughtful, measured approach to modernizing the way that Medicare pays for what are often incredibly expensive drugs.”

Nancy LeaMond
Chief Advocacy Engagement Officer
AARP

Other groups including the Medicare Rights Center and the American Academy of Family Physicians (AAFP) also support the Part B drug proposal.

“The AAFP believes that all physicians should be paid accurately for the clinical services they provide and that delivery systems should not favor certain drugs or medical devices over others,” said AAFP President Dr. Wanda Filer. “This proposed rule offers the opportunity to test program changes that may be an important step in this direction and the AAFP looks forward to providing CMS with a full reaction prior to the comment deadline.”

Health insurers, who blame rising drug prices for causing premiums to go up, have also added their voice to the discussion.

Aetna said the proposal would “incentivize providers to choose less expensive drugs when they are able to do so.” America’s Health Insurance Plans, the industry’s lobbying arm, was more qualified. The proposal highlights “a fundamental concern about the affordability of prescription drugs,” AHIP said, but warned that it might result in shifting costs to other parts of Medicare.

Given the controversy, many observers say it’s hard to tell what the final version will look like. In recent weeks, Medicare’s Chief Medical Officer, Dr. Patrick Conway has sounded open to adjusting the overall proposal.

Revisions may be made, but it’s likely something of the broad regulation will remain intact, said Gottlieb. For his part, he would like to see reference pricing removed and the sheer size of the experiment scaled back.

“It’s a grab bag of policy prescriptions related to drug pricing,” he said. “They threw in some good ideas and some very problematic ideas.”

The Hertel Report, will continue to monitor this issue and bring you, our valued readers and members, updates as this much-debated proposal winds its way through the Medicare proposal process.