BAKU_RETSU/ISTOCK/GETTY IMAGES

POLITICS, POLICY & LAW

BACKING INTO VALUE WITH PART B

BY ERIN MCCALLISTER, SENIOR EDITOR

The Trump Administration's proposed revamp of Medicare Part B would cede value determinations to other countries by importing their cost-effectiveness standards on drug pricing. It could also lead to more experiments with alternative models for drug pricing and reimbursement.

The Oct. 25 proposal from HHS would create an International Pricing Index (IPI) and link it to Medicare reimbursement for infused drugs administered in a physician's office or outpatient hospital setting. It would also upend the existing buy-and-bill model by inserting third parties into the system to negotiate potentially lower prices, and by taking physicians out of the business of purchasing the drugs. Instead of receiving an add-on payment tied to the average sales price (ASP), physicians would be reimbursed a flat rate.

BIO, PhRMA and some physician groups see the move as detrimental, saying it imposes price controls and could put patients at risk (see "Trump's Divide and Conquer Part B Plan").

On first blush, introducing a cap to Medicare reimbursements appears to run counter to the administration's proposals to move towards "value-based" pricing and payment models (see "CMS's Verma Outlines New Drug Payment Options").

Stakeholders from physician, insurance and market access sectors see the issue as more gray than black or white.

Four of five KOLs who spoke to BioCentury disagree that it goes against the trend toward value-based pricing because nearly all of the countries included in the market basket rely on health technology assessments (HTAs) to define cost-effectiveness. The dissenting voice believes that the HTA processes in these countries don't take into consideration enough factors, such as quality of care and real-world patient outcomes, to be considered value assessment.

Three of the KOLs said the proposal could spur more novel drug payment models among commercial payers because it would introduce a value-based starting point, rather than an opaque manufacturer-determined price.

However, Peter Bach, director of the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center, thinks more changes are necessary to implement true value-based payment models for pharmaceuticals. Bach also serves as chair of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC).

Among other things, he thinks contracts should be more transparent and allow patients to share in the refund if the drug doesn't work.

IMPORTING VALUE

The IPI proposed by HHS Secretary Alex Azar could provide a back door to value-based pricing, which has yet to see broad adoption in the U.S.

According to Azar, HHS would calculate an IPI for each drug, then target the U.S. price at a certain percentage above the index. In public remarks, Azar has suggested that level would be 26% above the IPI.

In its proposal, HHS suggested the IPI could be based on prices in Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, the Netherlands, and the U.K.

With the exception of Japan, those countries have HTA bodies that determine the cost-effectiveness of a new drug, which is used either to set the reimbursement price or negotiate with the manufacturer.

Japan uses a cost-plus method to arrive at the launch price for a first-in-class drug and relies on reference pricing for next-in-class drugs (see "Access and Innovation in Japan").

In the U.S., some commercial payers have begun to incorporate assessments from the not-for-profit Institute for Clinical and Economic Review (ICER), but CMS cannot negotiate with drug companies for Part B treatments, meaning the government payer's hands are tied.

Introducing the IPI and third party negotiators would make CMS no longer hostage to drug companies' opaque pricing decisions and introduce value into the equation.

However, it would also mean CMS is relying on decisions made by international payers, rather than defining value for itself.

"This is in line with value-based pricing because they're piggybacking on these value assessments by taking all of the work they've done and building into the assessment," said Blase Polite, associate professor of medicine at the University of Chicago Medicine.

Bach agreed. "If you index price off European countries, you are backing into that assessment. The Trump Administration says it wants to end freeloading by these other countries, but this is essentially freeloading off of these other countries who are actually negotiating based on HTAs," he told BioCentury.

and it's unclear why the United States would offshore this important work to European nations that have very different health systems, contextual considerations, and budget priorities."

Ted Okon, executive director of the Community Oncology Alliance (COA) disagrees the HHS proposal would bring in true value-based pricing.

"What really bothers me with these models in other countries is that there's no real value in there. They're just looking at the cost consideration and not the quality and outcome consideration for the individual patients treated in the real world," Okon told BioCentury.

Mark Hamelburg, SVP of federal programs at America's Health Insurance Plans (AHIP) believes using the IPI could make the most difference where there is no competitive pressure to help negotiate prices down. "This is really zeroing in on drugs where there is only one manufacturer and it should help payers to create some sort of leverage," he said.

MORE TRANSPARENCY, MORE VALUE

If the IPI provides a more transparent value-based price, it could also usher in greater adoption of novel drug pricing models among commercial payers and CMS.

"THIS IS ESSENTIALLY FREELOADING OFF OF THESE OTHER COUNTRIES WHO ARE ACTUALLY NEGOTIATING BASED ON HTAS."

PETER BACH,MEMORIAL SLOAN KETTERING CANCER CENTER

Bach said there needs to be transparency in how prices are set, which ICER and the other countries' HTAs provide.

Jeffrey Berkowitz, CEO and director at reimbursement consultancy Real Endpoints LLC, said although value determinations in the other countries might not match the assessment by a group like ICER in the U.S. or other third parties, they are a step closer to value-based prices.

"Those entities are looking at their populations based on value and other factors they view as important. So it becomes a global index that reflects the value as seen by a number of different entities against all of other choices they need to make from a health delivery perspective," Berkowitz told BioCentury.

ICER was also lukewarm. In an emailed statement to BioCentury, spokesperson David Whitrap said that the group was "encouraged" by the proposal. However, he noted that "determining what an appropriate price for medicines should be is a nuanced, multi-stakeholder process,

Pay-for-performance and outcomes-based contracts have become more popular as a mechanism to gain better formulary access for both new and old drugs, and to link reimbursement to how a treatment performs in the real world (see "New Shops for Value-based Deals").

However, Bach and Hamelburg believe the transactions to date aren't truly value-based, in part due to the lack of transparency with how the initial price is set.

"Unless you can get to a clear and appropriate value, it's really hard to see in these existing contracts how they make a material impact," Hamelburg told BioCentury.

AHIP and Bach have both supported an expanded role for groups like ICER and tools such as the Drug Abacus from Bach's group to help set the starting price for negotiation in value-based contracts.

"There is an imbalance of information right now and when you don't have that information to determine the value it becomes too hard," Hamelburg said. He think the IPI could help add balance.

Bach, on the other hand, thinks the IPI won't have sufficient transparency to attach performance metrics to benefits the treatment provides to patients.

Bach said outcomes-based contracts could be "layered onto" drugs included in the pilot of the IPI, "but unless these are based on specific determinations of value they are just a distraction. Never mind that they are so burdensome they are not scalable."

> "IT BECOMES A GLOBAL INDEX THAT REFLECTS THE VALUE AS SEEN BY A NUMBER OF DIFFERENT ENTITIES AGAINST ALL OF OTHER CHOICES THEY NEED TO MAKE FROM A HEALTH DELIVERY PERSPECTIVE."
>
> JEFFREY BERKOWITZ, REAL ENDPOINTS

Bach and his colleague Anna Kaltenboeck have published commentaries in Morning Consult and the Journal of American Medical Association (JAMA) outlining what it would take to arrive at true value-based contracts. They argue that the contracts should be done in pilots that are transparent and objectively evaluated and disseminated, where the starting price and refund are likely to result in a value-based price and the refund is shared with the patient. They also note the collection of outcomes information shouldn't be overly burdensome to the patient. Kaltenboeck is the program director of the Center for Health Policy and Outcomes.

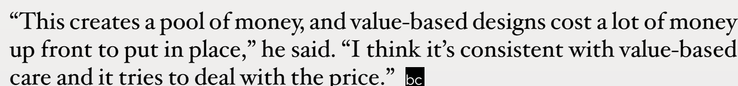
Berkowitz thinks that the ratcheting down of U.S. prices paid by Medicare would have a knock-on effect for commercial payers.

"I think that this mechanism will force the pharmaceutical companies to focus on the value of the products by looking at what benefits the treatment brings to the ecosystem and push more on the value they create for a better overall outcome for the patient and the system," said Berkowitz.

Roger Longman, chairman at Real Endpoints, added that there is increased interest from physicians to engage in more outcomes-based contracting. "We're involved in two value-based programs focused on providers who are themselves increasingly at risk and looking for other ways where they can directly benefit or not. I think as more attention is focused on Part B there will be other areas of the payer world that will surface to do these contracts, including the employers," he told BioCentury.

Polite added that eliminating buy-and-bill would remove physician risk for the cost of the drug and the proposed flat fee could create more bandwidth financially for physicians to implement novel payment arrangements.

"This creates a pool of money, and value-based designs cost a lot of money up front to put in place," he said. "I think it's consistent with value-based care and it tries to deal with the price." bc



COMPANIES AND INSTITUTIONS MENTIONED

American's Health Insurance Plans (AHIP), Washington, D.C.
Biotechnology Innovation Organization (BIO), Washington, D.C.
Centers for Medicare & Medicaid Services (CMS), Baltimore, Md.
Community Oncology Alliance (COA), Washington, D.C.
Institute for Clinical and Economic Review (ICER), Boston, Mass.
Memorial Sloan Kettering Cancer Center (MSKCC), New York, N.Y.
Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, D.C.
Real Endpoints LLC, Westport, Conn.
University of Chicago Medicine, Chicago, Ill.
U.S. Department of Health and Human Services, Washington, D.C.