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BULLETIN:
CMS TO CHANGE MEDICARE PART B

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In a teleconference with reporters, Patrick Conway, MD, Acting Principal Deputy Administrator and Chief Medical Officer for the Centers for Medicare and Medicaid Services (CMS), announced that CMS is planning a series of tests that would make major changes to Medicare Part B (drugs administered in a physician's office or hospital outpatient clinic), incorporating "value-based pricing." The proposal is open for public comment until May 9, 2016. Then, CMS may tweak the six proposals, issuing a final rule. Within 60 days of the final rule, a series of pilots will begin in different geographic regions. The pilots will run for five years. Based on the outcome of the pilots, CMS will propose permanent changes to Part B.

It was a short call and light on details, but this is what is known. Dr. Conway insisted, "Nothing in the proposed payment model will prevent doctors from prescribing exactly the treatment they think their patient needs. Nothing in this proposed test will tell doctors and other clinicians what to prescribe and when." But he also said it would eliminate pressure on doctors by health systems to choose a higher cost drug.

Six Part B proposals

1. **Change the ASP** (drug add-on fee doctors get) from 6% to 2.5% + $16.80 per drug per day. CMS' goal is to remove any financial penalty doctors experience for prescribing lower cost drugs.
2. **Eliminate patient drug cost-sharing.**
3. **Provide evidence-based clinical decision support tools** to doctors and suppliers about safe and appropriate use for selected drugs and indications. Examples could include best practices in prescribing or information on a clinician's prescribing patterns relative to geographic and national trends.
4. **Pay for a drug based on its clinical effectiveness for different indications.** If a drug works better in one approved indication than another approved indication, then CMS would pay more for the indication with the better results. CMS did not give this example, but it comes to mind: If a TNF inhibitor was more beneficial in rheumatoid arthritis (RA) than psoriasis, the reimbursement would be higher in RA than in psoriasis (or vice versa). This seems rather complicated, and CMS said it is not going to issue annual ratings on drug effectiveness in various conditions. But Dr. Conway did indicate CMS will look at levels of evidence, perhaps (though he didn't say this) those listed in medical society guidelines.
5. **Set a standard payment rate** (reference pricing) or benchmark for a group of therapeutically similar drug products.
6. **Allow CMS to enter risk-sharing agreements with drug companies based on outcomes.** *This is what Novartis has been pushing with Entresto (sacubitril + valsartan) for heart failure, though CMS did not cite that example.*

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Where will the pilots take place? There was no detail on this, but Dr. Conway did say, "We will test in different geographic regions across the country. So, there will be areas with no changes (control areas), other areas that may just have ASP changes, and others with ASP + value-based payment arrangements. We are testing this in different geographic areas because that is a strong evaluation design." He did not indicate how many beneficiaries would be affected.

Asked why there will be any ASP percentage at all, Dr. Conway said, "That was the input we received prior to the proposal from diverse sources."

Asked if high priced specialty drugs will be affected, Dr. Conway said, "This proposal will include almost all Part B drugs. There are a few categories excluded. It would include many specialty drugs. The vast majority of drugs are included, including specialty drugs." Dr. Conway did not give any examples of drugs that will not be affected.

Asked how CMS will determine whether or not drugs are being used in an appropriate way for a suggested condition, Dr. Conway said only, "Physicians and clinicians will be making the prescribing decisions. There is nothing in this model that restricts their ability to prescribe the most appropriate medication. In the value-based model we will be providing information around what are the best uses of drugs based on clinical evidence. We also will be working in a number of value-based areas…[This] will roll out over time…We are open on the way to reward and incentivize."

Asked if CMS will publish on an annual basis what are the clinically effective uses for a drug and which are not recommended, Dr. Conway said, "No, we believe clinicians and physicians should make prescribing decisions. What we could do, for example, is if a drug is used for a condition with better evidence, that can be rewarded financially. That still allows a clinician to make decisions on how a drug is used…We fundamentally believe clinicians and physicians should be making decisions."

Asked how much savings CMS hopes to achieve, Dr. Conway said the proposals are budget neutral.