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Get ready for big changes in Medicare drug pricing

Medicare To Experiment With Tying Drug Costs to Effectiveness

Why CMS’s Crazy Plan to Remake Medicare Part B Won’t Work

Drug pricing wars, Part B

Medicare Tries an Experiment to Fight Perverse Incentives

Oncologists Blast New Medicare Part B Drug Plan

Critics push back against new Medicare Part B payment proposals

Biopharma, Republicans and doctors dig in for fight against new CMS cancer-drug cuts

Groups Scrutinize White House Plan to Cut Drug Costs in Medicare
GOP Lawmakers Blast Part B Drug-Pay Demo As 'Experiment On Seniors'
Inside Health Policy
March 9, 2016

Medicare official defends controversial drug plan
The Hill
March 9, 2016

New Medicare Drug Payment Scheme Will Need Help From Doctors
Morning Consult
March 9, 2016

Battle Lines Drawn Over Medicare Pricing Proposal
U.S. News
March 9, 2016

Proposed Payment Change for Part B Drugs Draws Fiery Response
Bloomberg BNA
March 9, 2016

CMS wants to overhaul Part B drug payments. Oncologists call the plan 'absurd.'
Modern Healthcare
March 8, 2016

Medicare considers overhaul of doctors’ payments for drugs
The Washington Post
March 8, 2016

Medicare Seeks New Ways to Pay for Part B Drugs
Bloomberg Government
March 8, 2016

CMS Proposes Revamping ASP Formula At First, Followed By More Aggressive Policies
Inside Health Policy
March 8, 2016

Medicare Officials Propose Drug Payment Change
CQ Roll Call
March 8, 2016

CMS to overhaul Part B drug payments
Patient advocates are joining Republicans in opposing a major proposal from the Obama administration to change Medicare reimbursements to doctors.

The backlash to the Obama administration's proposal is growing, with more than 300 patient care and advocacy groups across the country slamming it. The move comes as several GOP lawmakers have complained about it.

The Centers for Medicare and Medicaid Services announced a proposal about two weeks ago that would enable the agency to conduct a series of experiments on Medicare Part B payment models. The idea is to get doctors to prescribe more effective, lower-cost drugs and sidestep expensive products. CMS officials have said that the intent is to ensure a doctor can choose the right pharmaceutical for a patient.

A doctor currently gets a lower payment from Medicare Part B if he prescribes a lower-cost drug. For instance, a doctor or hospital gets an additional 6 percent of the average sales price for more expensive drugs.

The agency is concerned that doctors may be prescribing more expensive products to get that additional payment.

Medicare Part B pays for drugs delivered in a doctor's office or outpatient facility as opposed to a pharmacy. Chemotherapy and cancer drugs are among those affected, which is why several cancer groups are opposing any changes.
Patient and cancer groups believe the experiments could have unintended consequences.

"There are too many assumptions and too few safeguards in the recent proposal to alter the payment rules for Part B drugs," said Julie Vose, president of the American Society of Clinical Oncology, during testimony before a congressional panel last week. The society advocates for oncologists and receives financial support from several pharmaceutical companies.

Vose said she is worried about whether any effort to revise the oncology payment system will hinder access to treatments for cancer patients.

A group of more than 300 medical groups, which included many cancer centers across the country, echoed the same concern in a letter released last week.

"There is no evidence that the payment changes contemplated by the model will improve quality of care, and may adversely impact those patients that lose access to their most appropriate treatments," according to the letter sent to congressional leaders in both parties.

The comments come about the same time several GOP lawmakers denounced the experiments.

Rep. Tom Price, R-Ga., said the rule could disrupt the level of care that seniors receive by "limiting the level of treatments providers may offer despite what a patient's health conditions demand." Price is chairman of the House Budget Committee.

The administration has pushed back hard against such criticism, saying the proposal won't prohibit access to treatments for patients.

A few weeks ago it shared comments from several healthcare experts praising the models.

"Part B drug payments are generally not based on value, or on the competitive approaches that have helped bring a value focus to Part D drug payments," according to a statement from Mark McClellan, a former CMS director under the Bush administration and now with the Brookings Institution.

"While not all of these ideas will work out, testing new Part B drug payment models and finding more effective ways to encourage drug innovation while avoiding unnecessary costs is very important for Medicare," he added.

The proposed rule is available for public comment until May 9.

**Politico Prescription Pulse: Dispatch From the Part B Wars**

Politico

Update: more than 300 groups are urging House and Senate leadership to press CMS to “permanently withdraw” the Innovation Center experiment to overhaul payments for Part B drugs. The letter last week came from many of the same groups that appealed to CMS before it formally proposed the rule. Now they’re trying their luck with lawmakers, where indications are they’ll find a more receptive audience.

... The American Society of Clinical Oncologists weighed in separately, calling the Part B proposal a “significant, independent threat” in comments to the House Energy and Commerce Committee mainly focused on MACRA. “This new demonstration not only continues to erode practice resources necessary for the care of patients with cancer, it imposes additional administrative burdens by making participation in this experiment mandatory,” ASCO President Julie Vose wrote.

... The Institute for Clinical and Economic Review published a white paper on different models for indications-based pricing, which CMS wants to test in Part B. The paper.

Cancer Care Groups Vocalize Opposition to Medicare Drug Payment Proposal
Health Leaders Media

Jacqueline Fellows, March 21, 2016

Oncologists have been the most vocal group opposing CMS's proposal to restructure Part B drug reimbursement because they believe patients have the most to lose—namely access to care.

The backlash against a new Medicare proposal that reduces physician reimbursement for Part B drugs has been swift. Several strongly worded letters were sent to the Centers for Medicare & Medicaid Services protesting the change, including one from more than 60 cancer care groups that represent nearly every state in the country.

Zon has held several leadership positions with American Society of Clinical Oncology (ASCO), one of many cancer organizations that believe restructuring Part B reimbursement from ASP plus 6% to a flat fee of $16.80 plus 2.5% will reduce patient access to cancer care.

Reimbursement Affects Patient Access

National Patient Advocate Foundation CEO Alan Balch, PhD, says the proposal will hit Medicare patients in rural areas. "Most cancer patients are still getting care in a community setting, especially in rural areas," he says. "Cutting reimbursement may mean providers won’t take
Medicare or they'll sell [their practice] to a hospital, which pushes patients to a setting that is further away.

Transportation is a major concern for the more than 20,000 patients NPAF helps annually, 50% of which are Medicare beneficiaries. Cancer care at a hospital is also more expensive. A Community Oncology Alliance study in 2012 on cost of cancer care by site showed that the cost of chemotherapy treatment in a hospital-owned outpatient office was 34% higher when compared to the same treatment in an independent oncology practice.

Vice President of Texas Oncology, Debra Pratt, MD, says she is equally concerned about the potential impact on cancer patients in rural areas. Texas Oncology has more than 165 community-based cancer clinics in Texas and Oklahoma, some are in rural areas. Pratt calls the CMS proposal a "blunt instrument" with no consideration of oncologists and the cancer community.

"The natural consequences of this will be that Medicare patients will not have access, there will be further hospitalization, and increases to the cost of care," Pratt says.

The CMS proposal to change Part B drug reimbursement is described by the agency as budget-neutral. Some critics have charged that the current reimbursement model gives physicians an incentive to choose drugs with higher costs. But Zon says most oncologists are following clinical care pathways to do what's best for their patients. Plus, she says, the current model doesn't pay enough now.

"We are already in a situation where Medicare was not keeping up with the cost of drugs," Zon says. "ASP plus 6% was never updated quickly enough for physicians, and the sequester (2%) really made it ASP plus 4%. It’s some desperate attempt to try and control drug costs. The problem is we have done nothing to cause the cost of drugs to escalate."

Independent oncologists also say there isn't a level playing field between them and hospitals. "[Hospitals] have bigger discounts on drugs," Pratt says.

The debate over drug costs is at a near-tipping point. Two studies out this month point to double-digit cost increases and billions of dollars wasted. The costs impact Medicare beneficiaries, too. Zon's practice has hired financial counselors to help patients figure out how to afford treatment. "It's taking a personal toll on them," Zon says. "Patients are coming in crying."

**Cancer Treatment Outlook**

What's gotten lost in the debate over adequate reimbursement, say Zon and Pratt, is that patients with cancer are living longer in part because of better drug treatments. ASCO's State of Cancer Care in America: 2016 report celebrates some of those advancements but also warns that access to care in rural areas is a critical issue.
"It came out of nowhere," says Robin Zon, MD, FACP, vice president at Indiana-based Michiana Hematology Oncology.

According to the report, only 5.6% of oncologists practice in rural areas—where 11% of cancer patients live. "In the last decade, there's been wonderful advancement," she says. "The eye is on the wrong ball. We need comprehensive payment reform. Don't make the doctors carry the burden of the rising drug costs when we had nothing to do with it."

Other organizations believe CMS's proposed payment change is an end-run around Congress. Community Oncology Alliance Executive Director Ted Okon questions why CMS is using the Center for Medicare & Medicaid Innovation to test a new payment model.

"This is using the mandate that Congress gave CMS in creating and funding CMMI," Okon says. "That allows CMS to use CMMI to overturn any law dealing with Medicare that Congress has made. We're testing a mandatory national initiative. That's flat-out wrong."

COA has taken an aggressive stance against the proposal. It has threatened legal and legislative action to stop the proposal from moving forward. Okon says the reimbursement changes are at cross purposes with the Oncology Care Model, CMMI's model that's been three years in the making. Its aim is to improve cost, care coordination, and quality by using performance-based incentives.

"It's designed to address the clinical side of care and give practices the opportunity to improve, but we've been waiting for four months to find out which practices and payers are going to get to participate," Okon says. "I suspect the reason that's been delayed is because of this [new proposal]."

Other specialists are also against the policy change, include rheumatologists and gastroenterologists. The American College of Rheumatology issued a statement criticizing a Medicare reimbursement rate that is already too low.

"It is our hope that the proposed payment methodology changes would not exacerbate the existing access problem and force more patients to receive biologic therapies in the hospital setting, where they will be faced with higher copayments, more expensive facility fees, longer travel times, and administration of complex therapies without the supervision of their rheumatologists."

**Editorial: Medicare's big drug test**
Chicago Tribune
March 21, 2016

Federal officials poked a medical hornet's nest recently with an ambitious attempt to do what many American taxpayers — and patients — demand: tame rising prescription drug costs in Medicare.

Officials at the Centers for Medicare and Medicaid Services rolled out a proposal to test new ways of reimbursing doctors who administer drugs in their offices and in hospital outpatient departments. These drugs include cancer medications, antibiotics and certain eye care treatments — about $19 billion a year in Medicare spending. (This does not include prescription drugs that seniors take on their own; that's a different part of Medicare.)

How would this proposal work? Right now, Medicare pays providers the average price of a drug plus 6 percent to cover their costs. So the higher the price, the more the doctor earns. Patrick Conway, chief medical officer for CMS, calls that a "perverse incentive" that could encourage doctors to select more expensive medications when cheaper ones could be just as effective.

Under the proposal, there would be different pricing tests in different parts of the country. In one test, Medicare would reduce that 6 percent payment to 2.5 percent plus a flat daily fee for some doctors, to see if that alters the drugs they choose to administer; other doctors would see no change. Talk about Mediscare ... for doctors taking the cut.

Another phase of tests would peg reimbursements to a drug's demonstrated effectiveness for different conditions. Or set benchmark prices for a group of similar drugs, steering doctors and patients to choose the lowest priced alternative.

CMS says the five-year trial would push doctors to prescribe the most effective drugs, not necessarily the most expensive.

Not surprisingly, doctors groups and other critics blast this proposal as dangerous government meddling in a doctor's decision about what to prescribe.

"This experiment is a misguided government intrusion on the treatment of seniors with cancer and a very dangerous precedent in severing the sacred physician-patient bond," wrote Bruce Gould, president of the Community Oncology Alliance, a nonprofit group that advocates for independent oncology practices.

The Pharmaceutical Research and Manufacturers of America, which represents the drug industry, says the proposal could cut patient access to treatments and "create uncertainties that could discourage investment in future treatment advances."

Curbing drug costs has been a Medicare Holy Grail for years.

But most Americans don't favor — nor do we — allowing government regulators to decide
which drugs patients should receive and which are too expensive. That smacks of rationing.

Under this proposal, doctors in the test group would still get paid for the drugs they administer, including a 2.5 percent bump for overhead costs. They just wouldn't get the 6 percent to which they're accustomed. So yes, some doctors that prescribe expensive meds may see their bottom lines wilt a little. We don't blame them for howling.

But if the cheaper medicine is just as good as the expensive one, then nudging doctors in that direction will save patients — and taxpayers — money.

If the proposal is finalized — public comments are due by May 9 — the changes probably wouldn't begin until later this year; the other phase of tests would follow, likely starting in 2017. An incoming administration, Democratic or Republican, may have other, better ideas to accomplish this mission. But we see value in testing these ideas.

We'll know by 2022 if these tests save money and improve health. Medicare officials will have to monitor them closely. If evidence emerges that the changes are damaging patients' health, the feds should pull the plug fast.

CMS Should Pull Drug Pay Model, Lawmakers Told
Bloomberg BNA
https://www.bgov.com/core/news/#!/articles/O498AO3H0JK0?ni_name=NewsAlert&ni_source=AlertEmail

By Mindy Yochelson | March 18, 2016 5:42PM ET

Letter to Hill on Part B Demo

Main Point: Groups want Congress to stop proposed payment rule.

Another View: Managed care association commends agency for “thoughtful” proposals.

March 18 (BNA) -- Hundreds of regional and national medical groups are asking Congress to prevail upon the Medicare agency to permanently withdraw a proposed rule that would test alternative approaches to paying for drugs, such as chemotherapy, that are administered in a physician's office.

Congress should ensure that the “nation's oldest and sickest patients continue to be able to access their most appropriate drugs and services,” according to the March 17 letter to Republican and Democratic congressional leaders from 316 organizations.

Proposed by the Centers for Medicare & Medicaid Services earlier this month (CMS-1670-P; RIN: 0938-AS85), the model would test six approaches for Part B drugs (See previous story,
03/09/16). In 2015, Medicare Part B spent $20 billion on outpatient drugs administered by physicians and hospital outpatient departments.

Targeted Methods First

“We believe these types of initiatives should be initially implemented in a targeted, patient-centered and transparent way that accounts for the unique needs of Medicare beneficiaries,” the letter said. “We are very deeply concerned, therefore, that CMS’ proposed Part B Model would be applied on a nationwide basis—to all states except Maryland, due to its all-payer model—and would include the ‘majority’ of Part B drugs.”

Among the signatories were the Alliance of Specialty Medicine, Alzheimer’s and Dementia Alliance of Wisconsin, American Academy of Allergy Asthma and Immunology, American College of Rheumatology, American Gastroenterological Association, National Alliance on Mental Illness, and Healthcare Leadership Council.

Bad Timing

In a separate statement, the American Society of Clinical Oncology said that Congress should enact legislation directing the CMS to forgo implementation of the plan.

The group said it's particularly problematic “to place additional strain on the oncology infrastructure at a time when significant administrative burdens are likely to arise” due to implementation of the Medicare Access and CHIP Reauthorization Act that will install a new Medicare physician payment system.

However, the Alliance of Community Health Plans, which represents about two dozen health plans and provider groups, commended the agency for “a thoughtful set of proposals” to address the high cost of drugs though a “multi-pronged approach that addresses reimbursement, pricing, benefit design and evidence-based decision tools.”

Asked about the strong level of opposition, ACHP President and CEO Ceci Connolly told Bloomberg BNA that “it’s important to not let the perfect be the enemy of the good.”

It's also important to have “constructive dialogue on this very complex issue,” she said, and it's “a bit disappointing we don't see more coming to the table with ideas to get lifesaving therapies to patients at an affordable price.”

Comments Due in May

The CMS is accepting comments on the proposed rule through May 9.

The CMS would test the alternatives through a comparison of a control group of physicians and outpatient departments that would be reimbursed under the current 106 percent of the
average sales price (in other words, ASP plus 6 percent), versus a study group reimbursed at 102.5 percent of ASP plus a $16.80 flat payment per drug.

This would begin no earlier than 60 days after the final rule.

In the second phase, no earlier than January 2017, the CMS would test value-based purchasing arrangements, such as varying the payment for a drug based on its clinical effectiveness for different conditions.

Inaccurate Assumption

In the proposed rule, the CMS expressed concern that the current 106 percent of ASP payment “may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs,” the groups’ letter said.

“This assumption fails to take into account the fact that providers’ prescribing decisions depend on a variety of factors, including clinical characteristics and the complex needs of the Medicare population,” the groups said. “Most importantly, there is no evidence indicating that the payment changes contemplated by the model will improve quality of care, and may adversely impact those patients that lose access to their most appropriate treatments.”

Healthcare, patient groups speak out against Medicare Part B proposal
Healthcare Finance News

March 18, 2016

Healthcare and patient advocacy groups sent a letter to Senate, House leaders urging them to press CMS to withdraw reduced Part B drug payment model.

Susan Morse, Associate Editor

Over 300 healthcare and patient advocacy organizations sent a letter to Senate and House leaders on Thursday urging them to press the Centers for Medicare and Medicaid Services to permanently withdraw a reduced Part B drug payment model from consideration.

CMS has proposed testing the new model, recommended by the Medicare Payment Advisory Commission, to lower the 6 percent add-on payment to Part B prescription drugs to 2.5 percent and to include a flat fee of $16.80 per drug per day.

The move is seen as a way to counter the rising costs of prescription drugs.
In the proposed rule, CMS expresses concern that the 6 percent average sales price add-on payment may encourage the use of more expensive drugs because they generate more revenue.

Opponents have said the rule would adversely affect beneficiaries, push cancer care delivery into the more expensive hospital setting, result in drug reimbursement below the average sales price, and is based on the faulty assumption that oncologists practice medicine solely by financial incentives.

Medicare Part B covers drugs administered in a physician's office or hospital outpatient department, such as cancer medications, injectables like antibiotics, or eye care treatments.

Part B expenditures remain relatively stable and Part B drugs account for just 3 percent of total program costs, according to Thursday's letter from 316 physician groups and other organizations nationwide.

More than 60 signers sent a similar letter earlier this month to Department of Health and Human Services Secretary Sylvia Burwell.

Medicare patients with cancer, macular degeneration and other complex conditions must often try multiple prescription drugs and/or biologics before finding the appropriate treatment, the organizations said in the letter.

"... They should not face mandatory participation in an initiative that may force them to switch from their most appropriate treatment," the letter states. "Medicare beneficiaries with life-threatening and/or disabling conditions would be forced to navigate a CMS initiative that could potentially lead to an abrupt halt in their treatment."

The signers also said they were disappointed that CMS only provided a limited opportunity for stakeholders to give input before announcing the sweeping proposed changes to Medicare Part B drug payments.

Since the Centers for Medicare and Medicaid Innovation is statutorily required to ensure initiatives target deficits in care, it is unclear what CMS is attempting to address given the success of the current Part B reimbursement methodology, the letter said.

"We believe these types of initiatives should be initially implemented in a targeted, patient-centered and transparent way that accounts for the unique needs of Medicare beneficiaries," the organizations said. "We are very deeply concerned, therefore, that CMS' proposed Part B Model would be applied on a nationwide basis – to all states except Maryland, due to its all-payer model – and would include the 'majority' of Part B drugs."
Under the Budget Control Act, CMS has already cut Medicare reimbursement for physician-administered drugs by 2 percent, which affects some providers' ability to administer drugs at the current reimbursement rate, according to the letter.

"We therefore request that you ask CMS to permanently withdraw the Part B Drug Payment Model from consideration," they said.

The letter was sent to Senate Majority Leader Mitch McConnell, Senate Minority Leader Harry Reid, Speaker of the House Paul Ryan, and House Minority Leader Nancy Pelosi.

**Medicare Part B proposals too broad and could hurt patients, groups say**
Fierce Health Payer

March 18, 2016

In a letter sent Thursday, 316 healthcare and patient advocacy groups urged leaders in both houses of Congress to ask the Centers for Medicare & Medicaid Services to withdraw its proposal for new Medicare Part B payment models. They argue that the payment models that CMS wants to test should have been implemented in a "targeted, patient-centered and transparent way that accounts for the unique needs of Medicare beneficiaries," instead of the agency's plan to test the models nationwide and on a majority of Part B drugs. As they are proposed, the new payment models could adversely affect patients with complex conditions such as cancer, macular degeneration, hypertension, rheumatoid arthritis, Crohn's disease and ulcerative colitis, and primary immunodeficiency diseases, the letter says. Letter

**Stakeholders: Lawmakers Should Ask CMS To Withdraw Part B Drug-Pay Demo**
Inside Health Policy

March 17, 2016

As House lawmakers consider what steps to take regarding CMS' Part B drug-pay demo, more than 300 oncologists, specialty doctors, biotechnology groups and others on Thursday (March 17) urged House and Senate leadership to ask CMS to withdraw its proposed Part B drug-pay demonstration.

“"A Center for Medicare & Medicaid Innovation (CMMI) initiative that focuses on costs rather than patients and health care quality, implemented based on primary care service areas, rather than the unique challenges of patients, is misguided and ill-considered," the stakeholders say.
“Medicare beneficiaries with life-threatening and/or disabling conditions would be forced to navigate a CMS initiative that could potentially lead to an abrupt halt in their treatment. That is not the right way to manage the Medicare program for its beneficiaries."

CMS recently released the highly anticipated Part B drug demonstration after inadvertently posting a notice to Medicare Administrative Contractors last month about plans to test changes to Part B drug payments. In the first phase, the demo would restructure the Part B physician add-on payment to a combination of a flat fee and a lower percentage rate based on drug prices.

Medicare Part B currently pays providers the average sales price of a drug, plus 6 percent. That policy has been criticized as encouraging providers to use expensive products because a portion of providers' reimbursement is based on the percentage of drug prices.

CMS officials also ask for input on five other drug-spending policies they are considering testing for outpatients in the second phase of the pilot, which would begin in January 2017. Those policies include paying the same amount for therapeutically similar drugs; discounting or eliminating patient cost-sharing; adjusting payment for drugs based on how well they work; adjusting payment based on the diseases they're prescribed for; and creating prescribing guidelines.

The stakeholders, including the Alliance of Specialty Medicine, the Biotechnology Innovation Organization, Community Oncology Alliance, Healthcare Leadership Council and others, say that CMMI is statutorily required to make sure its initiatives target “deficits in care” and can only expand after an analysis of the model. But the Part B drug-pay demo would be applied on a nationwide basis, with the exception of Maryland, and will include the majority of Part B drugs, the stakeholders note, and that is concerning.

The stakeholders’ letter also says that “given the success of the current Part B reimbursement methodology in ensuring patient access to the most appropriate treatments, it is unclear what 'deficits in care' CMS is attempting to address in this incredibly wide-ranging initiative.”

Along with House and Senate leaders, the letter was also sent to the chairs and ranking members of the Senate Finance Committee, House Energy & Commerce Committee and House Ways & Means Committee. Senate Finance Chair Orrin Hatch (R-UT), House Ways & Means Chair Kevin Brady (R-TX) and Energy & Commerce Chair Fred Upton (R-MI) slammed CMS' Part B drug payment demo shortly after it was announced, calling it an “experiment on seniors.” The committee chairs also said they would pursue aggressive oversight of CMMI.

A Ways & Means spokesperson said members and staff are continuing to review the proposal and discuss an oversight strategy to make sure CMMI doesn't jeopardize beneficiaries' quality of care. That effort may include letters, briefings or hearings, the spokesperson said. A congressional aide told Inside Health Policy that Energy & Commerce staff recently met about possible action as well. An Energy & Commerce spokesperson said the committee is still
discussing next steps. -- Michelle M. Stein (mstein@iwpnews.com)

**Cancer groups line up against Medicare cost-cutting plan**

The Hill  

By Sarah Ferris - 03/17/16 03:04 PM EDT

More than 300 chronic care groups are pushing back against the Obama administration’s plan for reforming payments under Medicare Part B.

The coalition, including more than 50 cancer-focused groups, are urging GOP leaders in Congress to halt those plans, warning that the proposed Medicare reform “would wreak havoc on healthcare delivery, provider stability and patient access.”

The American College of Rheumatology, which represents patients suffering from diseases like rheumatoid arthritis and lupus, warned it would "disproportionately hit the hardest" by the plan.

The administration announced last week that it plans to pilot a new payment structure later this year intended to incentivize doctors to prescribe “higher-value” drugs rather than simply the most expensive drugs available.

Currently, doctors are paid by the Medicare Part B program based on a drug’s average sales price, plus 6 percent. That rate will drop to 2.5 percent under the model, with a flat payment of about $16.

The proposal has sparked swift backlash across healthcare groups, prompting the top Medicare official, Andy Slavitt, to **defend the plan** during a panel with PhRMA last week.

“There is nothing that we propose to do, or should do, in any way, that prevents a patient from getting a prescription medicine that they need,” Slavitt said.

The pilot for the controversial Part B payments would begin sometime this fall, pending the new federal regulations. The coalition of chronic care groups stressed in its letter that Congress could also step in to block the program.

“We urge you to ensure that our nation’s oldest and sickest patients continue to be able to access their most appropriate drugs and services,” the coalition wrote in its letter.

**Hundreds of Medical Groups Ask Congress to Step In on CMS’ Medicare Drug Payment Plan**
More than 300 medical advocacy groups have asked congressional leaders from both parties to step in and urge the Centers for Medicare and Medicaid Services to withdraw a proposal that would test new ways for Medicare to pay for prescription drugs.

In a letter to Senate Majority Leader Mitch McConnell, Senate Minority Leader Harry Reid, House Speaker Paul Ryan and House Minority Leader Nancy Pelosi, 316 groups said there was not sufficient time for the agency to receive stakeholder input on the initiative and that the test program would “adversely affect the care and treatment of Medicare patients with complex conditions.”

The signatories include many statewide groups advocating for specific diseases, the National Alliance on Mental Illness and the National Medical Association.

“These patients need immediate access to the right medication, which is already complicated by the fact that treatment decisions may change on a frequent basis,” they wrote. “These vulnerable Medicare patients and the providers who care for them already face significant complexities in their care and treatment options, and they should not face mandatory participation in an initiative that may force them to switch from their most appropriate treatment.”

Obama Proposal to Revamp Medicare Part B Faces More Opposition

By ED SILVERMAN @Pharmalot

Just days after the Obama administration unveiled an experiment to revamp the Medicare Part B program, more than 300 hundred groups representing physicians, drug makers, and patients are urging the government to withdraw its proposal.

Although some details must still be worked out, the administration wants to encourage greater use of lower-cost, but equally effective treatments. The Part B program covers injectable and infused medications for the elderly. The government also maintains its plan will be budget-
neutral, or will not cost additional money.

The move reflects growing concern over the rising cost of medications, a hot-button topic that is straining payer budgets and angering Americans. The administration hopes to lower its drug spending by reducing reimbursement fees for physicians.

But the groups, some of which tried to persuade the administration not to proceed with its plan and complained the process was not transparent, argued that patients will be harmed.

The initiative is “misguided and ill-considered” and will “adversely affect the care and treatment of Medicare patients with complex conditions,” such as cancer, macular degeneration, and rheumatoid arthritis, the groups wrote in a letter today to US Senate and House leaders.

“These vulnerable Medicare patients and the providers who care for them already face significant complexities in their care and treatment options, and they should not face mandatory participation in an initiative that may force them to switch from their most appropriate treatment,” they added.

Under the Part B program, doctors, and hospitals buy a medicine, and the government reimburses the average sales price plus 6 percent. But the experiment, which would run five years starting this fall, would pay physicians the average sales price, as well as another 2.5 percent and a flat fee of $16.80.

A lot of dollars are at stake. Not surprisingly, many physicians are upset and argue that the experiment will unfairly hurt their practices while doing nothing to lower drug costs. And drug makers oppose the effort over concerns that their revenue will take a hit.

Among the organizations that signed the letter are the National Cancer Care Alliance, the Prevent Cancer Foundation, and Rush to Live. Several drug industry trade groups and numerous medical societies also signed on. We should note that some patient groups listed receive industry funding.

But the proposal has won praise from consumer advocates that argue the current reimbursement system provides an incentive for doctors to prescribe more expensive treatments. The math differ depending upon drugs being compared, but physician behavior is expected to change.

“We don’t like to think reimbursement plays a role in prescribing decisions, but there’s research out there that says it does,” said Maura Calsyn, director of health policy at the Center for American Progress. “If you change those incentives, you might change the decisions.” Not everyone is convinced, however, that the experiment will work. One reason is that the government plans to focus on certain zip codes, but large oncology practices that operate multiple locations may be able to shift some patient to other offices and escape the lower
reimbursement rate.

The government has not “accounted for behavioral and treatment changes that could occur,” wrote Adam Fein of Pembroke Consulting, who tracks drug distribution, on his blog. “These marketplace realities will undermine the ... ability to draw accurate conclusions” from the experiment.

Whether the opposition will derail or alter the effort remains to be seen. At the time the experiment was announced last week, a 60-day window opened for submitting comments. Already, though, some lawmakers are objecting.

In a brief statement last week, Kevin Brady (R-Texas), who chairs the House Ways and Means Committee; Fred Upton (R-Mich.), who heads the House Energy and Commerce Committee; and Orrin Hatch (R-Utah), the Senate Finance Committee chairman, expressed anger over the proposal.

“This decision was made with a complete lack of transparency and clear disregard for the people and stakeholders who will be impacted the most,” they said. “The model could ultimately result in seniors receiving different standards of care based solely on where they live in the country.”

**Health Orgs Say Proposed Medicare Reform Will Harm Patients**

Law 360


Law360, New York (March 17, 2016, 8:58 PM ET) -- More than 300 health organizations from across the country on Thursday asked congressional leaders to urge the Centers for Medicare & Medicaid Services not to go through with a proposed five-year test of new drug payment policies for Medicare Part B.

In a letter to Senate Majority Leader Mitch McConnell, R-Ky., Senate Minority Leader Harry Reid, D-Nev., House Speaker Paul Ryan, R-Wis., House Minority Leader Nancy Pelosi, D-Calif., and several committee chairmen, the 316 groups said the reform puts money over patient care and would likely make patients lose access to the drugs that are most helpful to them.

“A Center for Medicare & Medicaid Innovation initiative that focuses on costs rather than patients and health care quality, implemented based on primary care service areas rather than the unique challenges of patients, is misguided and ill-considered,” the letter states. “Medicare beneficiaries with life-threatening and/or disabling conditions would be forced to navigate a CMS initiative that could potentially lead to an abrupt halt in their treatment. This is not the right way to manage the Medicare program for its beneficiaries.”
The groups, which include the Pharmaceutical Research and Manufacturers of America, the National Medical Association, the National Alliance on Mental Illness and other nonprofits, professional organizations and industry groups, had sent a nearly-identical letter to CMS Acting Administrator Andy Slavitt and U.S. Department of Health and Human Services Secretary Sylvia Burwell four days before CMS’ March 8 announcement.

The proposal would affect most health care providers that bill for Part B drugs, which tend to be injectables or infusion products administered in professional settings. Under the plan, providers would be placed randomly into one of four groups: three that use new payment models, and one that uses the existing model and serves as a control group.

Of the three new models to be tested, one would use a 2.5 percent add-on payment instead of the current 6 percent and then guarantee a $16.80 daily fee regardless of drug price. A second model would preserve the 6 percent payment but incorporate value-based elements, such as reduced cost-sharing for patients and reimbursement based on a drug’s clinical effectiveness in hopes of altering prescribing practices. A third model would use the 2.5 percent payment, the $16.80 fee and the value-based elements.

The 316 groups faulted CMS for not receiving enough stakeholder input before introducing the proposed rule, claiming it will hurt patients who have “complex conditions” including cancer, macular degeneration, hypertension, rheumatoid arthritis, Crohn’s disease and ulcerative colitis.

Medicare Part B, as it currently stands, is cost-effective and successful in making sure patients have access to the drugs they need most, the groups said.

“It is unclear what 'deficits in care' CMS is attempting to address in this incredibly wide-ranging initiative,” the letter states.

While CMS said the 6 percent add-on encourages the prescription of more expensive drugs, the agency didn’t take into account the other factors physicians use when prescribing drugs, such as patient need, according to the organizations.

Providers’ ability to give patients essential drugs at the current rate was already harmed by the Budget Control Act’s 2 percent reimbursement cut, so any further cuts would only further harm patients, the letter states.

The models could start being rolled out late this year and largely take effect in January. CMS is accepting public comment until May 9.

--Additional reporting by Jeff Overley.Editing by Philip Shea.

ASCO: Medicare Rx Payment Model Worsens Bad Situation
WASHINGTON -- The proposal by the Centers for Medicare and Medicaid Services (CMS) to change the way Medicare pays for drugs under the Part B program could really hurt oncologists, according to the American Society of Clinical Oncology (ASCO).

"Many [cancer] drugs in the Medicare program are already 'under water' -- that is, the price oncologists are putting out [to acquire them] is already above the reimbursement from Medicare," Blase Polite, MD, MPP, past chair of ASCO's government relations committee, said at a briefing here Tuesday on the state of cancer care. "We do not believe that the answer is to put a burden on the back of the providers. This is a misguided attempt to [control] the high cost of drugs."

The model, which CMS announced last week, would replace the current Medicare reimbursement -- the average sales price (ASP) of the drug plus a 6% add-on fee to cover costs -- with the ASP plus 2.5%, plus a flat fee of $16.80 per drug per day. The flat fee would be adjusted at the beginning of each year.

Since Medicare Part B pays for drugs that are administered in a physician's office or hospital outpatient department, oncologists -- who administer many cancer drugs in their offices -- would be greatly affected by the new payment scheme, which CMS officials hope will encourage physicians to chose more cost-effective drugs rather than more expensive drugs, which provide higher reimbursements under the current system.

- Cisplatin
- Vinblastine
- Capecitabine
- Azacitidine
- Decitabine
- Doxil (liposomal doxorubicin)
- Ixempra (ixabepilone)
- Ativan (lorazepam)
- Benadryl (diphenhydramine)
- Potassium
- Magnesium Sulfate
- Mannitol
- Lasix (furosemide)
- Venofer (iron sucrose)
ASCO is currently running the numbers to see what effect the new payment model would have on oncology practices. "At the first pass, it is a bad idea and I think we have to back up that sense with some real numbers," Stephen Grubbs, MD, vice president of the clinical affairs department at ASCO, said in a phone interview. "To get where we want to get -- high-quality, lower-cost medical care for all who need it -- we have to make sure practices are appropriately reimbursed to make this transformation."

At the briefing, Polite noted that the reimbursement is actually lower than it seems -- by 1.7 percentage points -- due to budget sequestration (across-the-board federal budget cuts mandated by Congress). So ASP plus 6% -- the current reimbursement -- is actually ASP plus 4.3%, and the 2.5% add-on in the new model is really just 0.8%.

For patients, another problem with Medicare's cancer drug reimbursement is inconsistency between copays for oral cancer therapies and intravenous cancer therapies. Intravenous cancer drugs "are covered under the Part B program -- where patients often have gap insurance which helps pay for copays and deductibles -- whereas oral therapies are covered under the Part D program and subject to escalating tiered formulary copayments," Polite explained. "As oncologists, we don't choose therapies based on whether they are intravenous or oral; we look for the drug that makes the most sense, the one that has the best evidence, yet our patients are facing different cost burdens depending on the drugs we choose. This simply makes no sense in the way medicine is practiced in the year 2016."

In June 2015, Rep. Leonard Lance (R-N.J.) and Sen. Mark Kirk (R-Ill.) introduced the Cancer Drug Coverage Parity Act, which would prohibit differential pricing for oral treatments. In the meantime, without a federal law, 40 states and the District of Columbia have passed their own oral parity legislation, although a federal law is still needed to impact large interstate employers who are not covered by individual state laws, according to Polite.

Polite added that CMS did not consult outside organizations before releasing its new payment model. "Lack of stakeholder engagement will not be solved by a 60-day comment period," he said.

ASCO is not the only group unhappy with the proposed payment model. On Thursday, a letter signed by 316 medical organizations was sent to congressional leaders; the letter warned that the groups believe that "this type of initiative, implemented without sufficient stakeholder input, will adversely affect the care and treatment of Medicare patients with complex conditions, such as cancer, macular degeneration, hypertension, rheumatoid arthritis, Crohn's disease and ulcerative colitis, and primary immunodeficiency diseases.

"We previously sent a letter to Department of Health and Human Services Secretary Sylvia Burwell asking her not to move forward with this type of initiative, and we now respectfully request that you ask CMS to withdraw the proposed rule."
Get ready for big changes in Medicare drug pricing
PBS

BY PHILIP MOELLER
March 16, 2016 at 2:39 PM EDT

In place of our normal dive into the reader mailbag today, I wanted to give you a heads up on a significant announcement the Centers for Medicare and Medicaid Services made last week. It is likely to set in motion far-reaching changes in the way you pay for some and perhaps eventually all of the drugs you buy through Medicare. I say “likely” because the proposal has scads of influential opponents in the medical community and Congress, so its final form and timing are anything but certain. Also, the changes wouldn’t begin until late this year. For these reasons, I’m not going to get too deeply into details today. Rest assured, I will do so when the time is right.

As I’ve complained repeatedly, Medicare is prohibited from directly negotiating drug prices with pharmaceutical companies. This was one of the “free enterprise” provisions that Republicans insisted upon when Medicare’s Part D prescription drug program was enacted in 2003 (the actual Part D plans did not begin until 2006). Preventing Medicare from directly using its powerful leverage to influence drug prices has been a major (but hardly the only) cause of what is now a runaway epidemic of higher drug prices. A government report estimates that prescription drug spending totaled about $424 billion in 2014, up 12.6 percent from 2013, and increased another 8 percent last year to an estimated $457 billion.

While no one would accuse the drug industry of taking it easy on consumers when it comes to pricing, the reasons for the increases are not all in the greed department — just mostly.

The report noted that 10 percent of the increase is due to population growth and another 30 percent caused by a rise in the numbers of prescription drugs we take. A goodly amount of this is undoubtedly due to the industry’s enormous $5 billion annual spending on consumer drug ads. Another 30 percent of the increase was attributed to “economy-wide” inflation, although this is a bit of a head-scratcher, as general inflation has been modest if not nonexistent. The final 30 percent segment was caused by drug prices that increased by more than economy-wide inflation rates and by drug prescribers moving consumers into higher priced medications. This last factor is also one that has been heavily influenced by drug companies’ marketing efforts.

Preventing Medicare from directly using its powerful leverage to influence drug prices has been a major (but hardly the only) cause of what is now a runaway epidemic of higher drug prices. To help combat this trend and influence pricing within its limited powers to do so, Medicare announced a test program last week that would change the way some providers are paid for the drugs they prescribe in Part B of Medicare. This is NOT the part of Medicare that covers
most drugs. That would be Part D. Part B covers drugs — many expensive ones — that are administered in doctors’ offices or by caregivers in an outpatient setting.

Annual Part B expenses are less than $20 billion, compared with $140 billion for Part D. But it’s hardly unreasonable to think that changing Part B payments would lead to “tests” of new Part D pricing approaches as well and then perhaps to broader prescription plans for all consumers. Calling this a test is, by the way, disingenuous. The Centers for Medicare and Medicaid Services proposes that the test will last for five years and be mandatory and that providers (and Medicare beneficiaries) in 75 percent of the country will face pricing changes.

“The proposed model would test whether changing the add-on payment to 2.5 percent plus a flat fee payment of $16.80 per drug per day changes prescribing incentives and leads to improved quality and value.”

The Centers for Medicare and Medicaid Services thinks the current flat 6 percent add-on tilts doctors and other drug prescribers toward using more expensive drugs. The logic is that 6 percent of an expensive drug puts more money in a doctor’s wallet than 6 percent of an inexpensive medication. Including a smaller percentage and a flat payment per drug, the agency says, will encourage doctors to use less expensive drugs that might be equally or even more effective.

In addition to the pricing shift, the agency also would test a number of other pricing tools, including eliminating consumer cost sharing for Part B drugs, to support the goal of so-called “value based pricing.” This objective is part of a recent law that included provisions to move Medicare away from being a fee-based insurer to one that pays providers for the quality of their care and the improved health of Medicare beneficiaries.

Later this year, the agency would begin testing the 2.5 percent, $16.80 daily flat-payment approach for some Part B prescribers, while keeping the current 6 percent add-on for others. In 2017, it would split these two groups into four by testing value-based purchasing tools for some providers in each group.

Many medical groups, particularly those treating cancer patients and others who take expensive drugs, have issued unusually strong statements of opposition to these changes, saying they will hurt and not help patients by forcing doctors to prescribe less expensive and less useful drugs. The notion that doctors would sacrifice patient welfare for financial gains doesn’t go over so well either.

In a letter to the Centers for Medicare and Medicaid Services officials, one of those medical groups, the Community Oncology Alliance, said, “we are actively pursuing every legal, legislative, and related option to stop the CMS [Centers for Medicare and Medicaid Services] Medicare Part B Drug Payment Model, which is nothing more than a perverse experiment on
cancer care provided to seniors.”

Many medical groups have issued unusually strong statements of opposition to these changes, saying they will hurt and not help patients by forcing doctors to prescribe less expensive and less useful drugs.

An earlier letter, signed by more than 100 medical groups, said, “Medicare beneficiaries — representing some of the nation’s oldest and sickest patients — must often try multiple prescription drugs and/or biologics before finding the appropriate treatment for their complex conditions. These patients need immediate access to the right medication, which is already complicated by the fact that treatment decisions may change on a frequent basis. These vulnerable Medicare patients and the providers who care for them already face significant complexities in their care and treatment options, and they should not face mandatory participation in an initiative that may force them to switch from their most appropriate treatment.”

“There is no evidence,” it added, “that the payment changes contemplated by the model will improve quality of care, and may adversely impact those patients that lose access to their most appropriate treatments. In fact, data suggests that the current Part B drug payment system has been both cost effective and successful in ensuring patient access to their most appropriate treatment, as Part B expenditures remain relatively stable and Part B drugs account for just 3 percent of total program costs.”

This is a big deal for many reasons. While not doubting the Centers for Medicare and Medicaid Services’ goal to improve quality and reduce costs, these and other test programs are likely to create very unsettling transition periods.

Stay tuned and strapped in!

**Medicare To Experiment With Tying Drug Costs to Effectiveness**

NPR


March 16, 20169:39 AM ET

Aetna and Cigna inked deals last month with drug maker Novartis that offer the insurers rebates tied to how well a pricey new heart failure drug works to cut hospitalizations and deaths. If the $4,500-a-year drug meets targets, the rebate goes down. Doesn't work so well? The insurers get a bigger payment.

In another approach, pharmacy benefit firm Express Scripts this year began paying drug makers a special negotiated rate for some cancer drugs. The goal is to reward the use of medicines that
are most effective for certain cancers.

Dubbed "value-based pricing," these are the kind of private-sector efforts the Obama administration hopes to borrow to rein in drug prices for Medicare.

The results could lead to a profound shift in how the Centers for Medicare & Medicaid Services spends $20 billion a year for drugs under Part B, which are those given through doctors' offices and hospital outpatient centers. Many cancer treatments are provided that way, as are some treatments for rheumatoid arthritis, macular degeneration and other medical conditions.

Under a proposed rule, different methods would be tried in selected geographic areas over a five-year test period. Some of these experiments would begin this year, with others added in 2017. The proposal faces two months of public comment.

"The goal is to test whether alternative approaches will lead to better value," said Patrick Conway, chief medical officer for CMS, in announcing the proposal March 8.

"There is no perfect payment system, they all have upsides and downsides," said Dan Mendelson of consulting firm Avalere Health, who lauded Medicare for considering new ways to pay even as he cautioned that it must be done carefully. "What we don't want to do is create a world where doctors only prescribe the cheapest stuff even if not in the interest of the patient."

Here are four concepts the government is investigating:

Cut add-on fees for doctors and outpatient centers.

Many drugs covered under Medicare Part B are first purchased by a physician office or outpatient center, then dispensed to patients. Once billed, Medicare pays the health care provider the average sales price plus 6 percent for costs associated with the purchase and storage of the medications. For example, a doctor or clinic would receive an add-on fee of $6 when a $100 drug is purchased, or $300 for a $5,000 treatment.

In the private sector, that practice – called "buy and bill" – is being reduced.

Instead, specialty pharmacies, often connected with pharmacy benefit management companies, purchase the drugs and deliver them to doctors' offices. The management companies, paid by insurers for their services, negotiate prices with drug makers.

But the buy-and-bill approach still dominates Medicare Part B.

Oncology specialists and other proponents say add-on fees are an important revenue source needed to keep such centers open. But critics fear they encourage use of higher-cost drugs when equally effective products could be had for less. They also say the fees reward larger
practices and centers that buy drugs at advantageous prices.

To counter that possibility, CMS would change the current reimbursement formula, cutting the add-on portion to 2.5 percent of the average sales price.

Recent industry surveys show that larger practices have resisted moving away from buy and bill. Smaller ones with less bargaining clout favor that. Drug makers and some physician specialty groups oppose this part of Medicare’s proposal, but patient advocacy groups express mild support mixed with caution.

Level payments.

In the private sector, insurers sometimes set caps on payments for services patients generally can shop around for, such as a hip or knee replacement or colonoscopies. The California Public Employees Retirement System insurance plans, for example, saw that the cost of joint replacements varied widely among hospitals, then set a cap of $30,000 for a joint replacement. If patients chose hospitals that charged more, they had to pay the difference. The move was credited with saving millions in its first two years. Most of it came from the more-expensive hospitals lowering prices.

Medicare plans to apply this model to its payments to doctors and outpatient centers for some categories of medicines. For example, it might select one price for all injectable treatments for knee pain caused by osteoarthritis. The same rate would be paid, even when centers use higher-cost products.

The question is how to set that price. While asking for comments, Medicare suggested a variety of options, including the average price for drugs in a category, the price of the most clinically effective drug or a rate developed some other way.

Medicare’s proposal would apply to some prescription medications, but not procedures. And unlike most private-sector models, Medicare patients who get drugs above a benchmark cost could not be billed for the difference. The goal is not to encourage patients to change drugs. Instead, Medicare said it will test whether grouping similar drugs into a single payment rate will give physicians incentives to use "products that provide the most value for the patient."

Tie payments to effectiveness.

Under Medicare’s proposal, drug makers would agree to offer rebates that link the final price of their products results in patients. Just what those results would be – improved health, fewer hospitalizations or some other measure – would be spelled out up front. There are more than 300 such "risk-sharing" agreements currently in place in the private sector, according to a University of Washington School of Pharmacy database.

In a related test, Medicare would adopt an approach similar to that used by Express Scripts,
varying the amount of payment based on a patient’s condition. Drugs are often approved for more than one condition – say, two different types of cancers – but may be more effective at treating one than the other. Under the proposal, Medicare would pay a physician less when a drug is less effective on that cancer.

Skeptics say the process can be complex, and savings might be eaten up by administrative costs or disagreements over whether drugs have met effectiveness targets. Moreover, these private sector efforts are so new that detailed results are not yet available.

Meanwhile, a report out Tuesday from the Institute for Clinical and Economic Review looked at similar efforts internationally. It found that such "indication-specific" pricing holds some promise, but cautioned that administrative complexity and other challenges are significant.

Cut patients' out-of-pocket costs.

To get people to take essential medications such as statins after a heart attack, some insurers, including Aetna, have reduced or eliminated patient copayments. Other insurers have experimented with similar incentives for other conditions, such as asthma or diabetes. They generally found that reduced payments make patients more likely to continue taking their medications.

In Medicare Part B, patients are responsible for 20 percent of the cost of their drugs unless they have a supplemental insurance policy that covers such copayments. Medicare proposes to cut or eliminate those payments for certain drugs considered most effective or valuable.

Lower copayments might affect what doctors prescribe and could encourage patients to stay on needed treatments. Medicare itself would make up the difference, picking up the tab for the reduced or eliminated patient payment.

Medicare is soliciting suggestions in its public comment phase as to which drugs might be the best candidates for the test.

**Why CMS’s Crazy Plan to Remake Medicare Part B Won’t Work**

Drug Channels


March 16, 2016

In an amazing display of bureaucratic hubris, the Centers for Medicare & Medicaid Services (CMS) has proposed a mandatory, real-world experiment with provider reimbursement under the Medicare Part B program. Click here to read the summary. You can read the details in this Federal Register notice.
As I explain in more detail below, CMS wants to reduce reimbursement for buy-and-bill drugs—but for only half of the country's providers. The other half will retain current reimbursement levels. After five years, CMS will see what happened.

Some potentially good ideas are buried in this mess. But the proposal so overreaches that it will face enormous opposition and has little chance of being implemented.

Even if CMS can get the first part of its proposal off the ground, I doubt that CMS will be able to draw any meaningful conclusions from it. Marketplace realities will undermine the integrity of this massive and unprecedented experiment on patients and providers.

Read on for my summary of CMS’s proposed Part B Drug Payment Model and the glaring methodological flaw that could end up raising drug costs. There will be no gold at the end of this rainbow.

POTS O’ GOLD?

Before examining CMS’s proposal, let’s briefly review buy-and-bill under the Medicare Part B program. The following material has been adapted from Chapter 3 of our magically delicious 2015-16 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors.

For physician offices and outpatient clinics, the provider purchases and administers the product before submitting a claim to Medicare. After purchasing a drug from a wholesaler or specialty distributor, the provider will store the product at its location. The provider then administers the drug to a patient. After the patient receives the drug and any other medical care, the provider submits a claim for reimbursement. The process is called buy-and-bill, because the medical claim is submitted after the provider has purchased and administered the drug.

Thus, in the buy-and-bill system for drug payment, the provider is responsible for:
- Ordering and purchasing the drug from a specialty distributor
- Managing drug inventory at the practice
- Prescribing and administering the drug to a patient
- Submitting reimbursement claims for a drug and related professional services
- Collecting a patient’s coinsurance or copayment for all services

Medicare is the largest payer of provider-administered drugs. Its Part B program covers provider-administered injectables and certain other drugs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates that Medicare use a drug’s Average Sales Price (ASP) for reimbursing provider-administered injectable drugs. ASP is based on the manufacturer’s actual selling price, i.e., a drug’s list price minus all price concessions. Commercial payers now use ASP as a key reimbursement method for physician offices (but not hospital outpatient sites), as shown in this chart from our Drug Channels post How Hospitals Inflate Specialty Drug Prices: The Latest Medical Benefit Reimbursement Data.
CMS IS ALWAYS AFTER ME LUCKY CHARMS!

CMS wants to go after the buy-and-bill system’s theoretically perverse incentive for physicians to prescribe more-expensive drugs. For pricey specialty drugs, even a low single-digit markup over ASP can generate substantial dollar profits for a provider.

Under the guise of its Center for Medicare and Medicaid Innovation (CMMI), CMS now proposes a massive, nationwide, two-phase experiment with providers’ drug payment. Here’s the CMS summary:

In other words, half of the providers will continue to receive ASP+6%. The other half will receive the lower ASP+2.5% rate plus a fixed $16.80 payment. To illustrate the impact, CMS provides the following numerical example of markups (not profits) under the current system and under the proposed Part B payment approach.

In CMS’s example, a $1,000 drug generates 20 times as much markup as a $5.00 drug. In the proposed model, the more expensive drug generates only 2.5 times as much mark-up as the lower-priced drug. A provider that administers a lower-priced drug will benefit, but one administering a higher-cost drug will lose.

Here is my summary of CMS’s projected financial impact on hospitals and five medical specialties. In calendar year 2014, these six groups accounted for 86% of total Part B drug payments. Note that the financial impact estimates exclude any behavioral offsets—an important issue that I consider below.

Oddly, CMS seems to have ignored what it recently mandated for retail pharmacies: acquisition cost reimbursement plus a professional dispensing fee. See Seven Pharmacy and Channel Implications of the New AMP Final Rule.

FOOL’S GOLD

Obviously, this is not a double-blind trial. Providers and perhaps patients will know their “treatment” arm. And therein lies the problem. CMS has not accounted for behavioral and treatment changes that could occur during its model evaluation period. Consequently, CMS will be unable to draw any meaningful conclusions about its proposed model.

Here’s why. CMS proposes assigning providers using Primary Care Service Areas (PCSAs), which are defined by aggregating ZIP areas to reflect Medicare patient travel to primary care providers. According to CMS, there are 7,144 PCSAs in the 50 states and 7,048 in the model.

Consider cancer drugs, which accounted for 42.1% of Part B spending in 2014 (per the ASPE brief, page 8). Anyone with even a passing familiarity with cancer care knows that the largest multi-location oncology practices appear to operate across dozens of PCSAs. Examples include Florida Cancer Specialists, which operates more than 90 locations throughout Florida,
and Texas Oncology, which operates more than 165 locations throughout Texas and southeastern Oklahoma. Florida, for example, has hundreds of PCSAs. (View map.)

These practices are for-profit private businesses. They will surely attempt to optimize against the CMS Phase I proposal by, for example, strategically directing patients to certain locations based on the cost of therapy and expected reimbursement.

There are big dollars at stake. We estimate that drug reimbursement accounts for more than 70% of a typical oncology practice’s revenues. On average, a practice generates about $4.5 million in gross drug revenue per full-time equivalent oncology or hematology physician. (See Section 3.1. of our wholesaler report.)

CMS briefly acknowledges reality, stating: “It is possible, however, that large practices may have practice locations in more than one PCSA. As a result, there could be situations during the model test in which those large practices are exposed to multiple arms, and thus to different payment methods simultaneously” (page 13238).

I disagree. Instead, multi-location practices will be frequently and consistently exposed to multiple study arms, especially in the southeastern and southwestern United States. These marketplace realities will undermine the integrity of the Phase I results and CMS’s ability to draw accurate conclusions from its unprecedented experiment.

Consequently, cancer patients will undergo a giant experiment that will likely be a waste of time.

CMS even claims that its Phase I proposed model is “budget neutral.” This conclusion is based on the false assumption that there will be no behavior change in response to the study. (See CMS’s comments that it did “not attempt to predict behavioral responses to our policy changes” on page 13254 of its proposal.) I suspect that total payments could ultimately be higher due to market reactions to the proposal.

CMS also ignores the possibility that patients will be shifted to higher-cost sites of care, including hospital outpatient departments. The Office of Inspector General (OIG) has documented how 340B-eligible hospital outpatient departments earn tremendous profits from the Medicare Part B program. Gross profit margins are about 60% compared with 3% to 4% for a non-340B outpatient program. See New OIG Report Shows Hospitals’ Huge 340B Profits from Medicare-Paid Cancer Drugs.

Since CMS is unable (or unwilling) to attack hospitals’ excess 340B profits, it instead wants to monkey around with the 3% to 4% margin for non-340B outpatient programs. 340B hospitals' higher profits also mean that the financial sting from CMS’s experiment will be mild—and may further shift business away from community practices.

THE FIGHTING IRISH
A few years ago, CMS tried to blow up the Medicare Part D program. A broad and diverse coalition successfully got CMS to run away from reconsider its overhaul. Refresh your memory with Run Away: CMS Abandons Part D Preferred Pharmacy Network Changes.

We are already seeing similarly brutal opposition to CMS’s latest brainstorm. For an early preview, check out the Community Oncology Alliance’s (COA) blistering letter, which is warning: “[P]lease understand that we are actively pursuing every legal, legislative, and related option to stop the CMS Medicare Part B Drug Payment Model, which is nothing more than a perverse experiment on cancer care provided to seniors.”

Three senior senators, including Senate Finance Committee Chairman Orrin Hatch (R-UT), have issued a negative press statement illustrating the political battle ahead:

“Yesterday’s announcement marks another troubling example of unelected bureaucrats making decisions behind closed doors that impact the American people and their healthcare. This decision was made with a complete lack of transparency and clear disregard for the people and stakeholders who will be impacted the most.

CMMI’s proposed experiment on seniors stands to limit access to the critical care the sickest Medicare beneficiaries rely on, as well as disrupt how health care providers serve patients in the future.

The model could ultimately result in seniors’ receiving different standards of care based solely on where they live in the country.”

In addition, more than 100 patient groups, industry associations, and companies also sent CMS a stern letter of opposition. Click here to read it.

A final word of caution: Before you celebrate our oh-so-wise government’s focus on “value,” I hope the plan’s cheerleaders think through the real-world implications of this poorly thought-through experiment. There's much more at stake than clovers and blue moons.

**Drug pricing wars, Part B**

Político


By BRETT NORMAN 03/14/16 12:00 PM EDT

With help from Sarah Karlin-Smith and Mary Lee

WELCOME TO THE PART B WARS — Much of the Hill’s rhetoric over drug pricing has focused on
Medicare’s retail prescription drug program. But now, CMS is facing backlash over its proposal for a sweeping overhaul of how it pays doctors and hospitals for the drugs they administer to patients. Reaction to the proposed Part B demonstration drew a swift reaction from drug companies and doctors’ groups. Critics questioned the CMS Innovation Center’s authority to run such a large-scale experiment on a program that spent $18.5 billion on drugs in 2014, and they blasted the plan as an ill-conceived imposition that could threaten patients’ access to medicines.

“This proposal would apply to the vast majority of the country, violating the definition of a demonstration and the spirit of the [CMMI] authority outlined in the statute,” PhRMA CEO Steve Ubl said at the trade group’s annual meeting last week. “It would usher in a new era of government deciding what seniors can get.”

Rep. Fred Upton and Sen. Orrin Hatch called the move “another troubling example of unelected bureaucrats making decisions behind closed doors that impact the American people and their healthcare.”

The proposal was welcomed by some insurers, however. It would initially trim the add-on percentage paid for Part B drugs from 6 percent to 2.5 percent plus a flat fee, starting late this year in some parts of the country. CMS says the plan is designed to be budget neutral. Those who prescribe the most expensive drugs, like cancer doctors, would likely see pay cuts. But the more dramatic reforms are included in a second wave of experiments, not expected before 2017, which include indications-based pricing, reference pricing, and other value-based payment proposals.

CMS Acting Administrator Andy Slavitt said the proposed rule process “invites the most public input possible … Have we thought of every consequence possible? Absolutely not,” he said, also speaking at the PhRMA meeting. Our story, ICYMI. The proposed rule.

Groups Scrutinize White House Plan to Cut Drug Costs in Medicare
New York Times

WASHINGTON — The Obama administration touched off a tempest on Wednesday with its plan to test new ways of paying for prescription drugs under Medicare, widely seen as the administration’s first serious attempt to rein in drug spending.

Groups representing Medicare beneficiaries welcomed some of the proposals but expressed concern about others. Drug manufacturers and some cancer doctors criticized the initiative, saying it placed too much emphasis on saving money and too little on ensuring patients’ access to treatment.
“I deal every day with people fighting for their lives, and I am more sympathetic to them, their desire to live and to get the right treatment,” said Ellen V. Sigal, the founder and chairwoman of Friends of Cancer Research, a public education and advocacy group, even as she noted her concern about rising drug costs.

Under the proposal, announced Tuesday, Medicare would try a half-dozen new ways of paying for prescription drugs in Part B of Medicare, under which $20 billion was spent last year on medications administered in doctors’ offices and hospital outpatient departments.

The announcement is only a proposal for a test, but it has huge implications for the pharmaceutical industry, especially for the big, fast-growing category of specialty drugs known as biologics. The proposal could, for the first time, link Medicare payments to the effectiveness of a drug and the cost of comparable medications — factors not normally considered in the current reimbursement formula, which is based on the average sales price of drugs, with an additional 6 percent allowance for storage and handling costs.

For decades, Congress has legislated Medicare payment rates in minute detail. But the Affordable Care Act authorized the secretary of health and human services to test new “payment and service delivery models” and adopt them nationwide if they save money without harming the quality of care.

Sylvia Mathews Burwell, the health secretary, has shown she is willing to make aggressive use of this power, with the blessing of President Obama.

The Republican chairmen of three powerful congressional committees denounced the administration’s plan on Wednesday, describing it, in a joint statement, as “another troubling example of unelected bureaucrats making decisions behind closed doors.” The proposal could limit access to care for some of the sickest Medicare beneficiaries, said the statement, issued by Senator Orrin G. Hatch of Utah, the chairman of the Senate Finance Committee, and Representatives Fred Upton of Michigan, the chairman of the House Energy and Commerce Committee, and Kevin Brady of Texas, the chairman of the Ways and Means Committee.

The Obama administration said its proposal would not interfere in any way with the “medical judgment” of doctors or their “ability to order reasonable and necessary Part B drugs as appropriate.” It did say, “We intend to achieve savings,” though officials could not say how much. The administration said it expected to change the “prescribing behavior” of doctors by giving them financial incentives to choose less expensive drugs that are at least as effective as more costly medications.

Stacy J. Sanders, the federal policy director at the Medicare Rights Center, a consumer advocacy group, welcomed the proposal, saying it would reduce the incentive for doctors to prescribe drugs that are expensive and ultimately unaffordable for low- and middle-income people who have no supplemental insurance.
Other advocates were cautious in their initial reactions.

Leslie B. Fried, a health lawyer at the National Council on Aging, a service and advocacy group, said: “If this is a way to take account of the value of treatments and control Part B costs, that’s a good thing. But we also have to be concerned about access to care for beneficiaries. It’s a balance.”

In a notice to be published in the Federal Register on Friday, the administration says it wants to require “mandatory participation” for doctors and hospitals that provide Part B drugs to Medicare beneficiaries in geographic areas selected for the test, a large part of the country. In three-fourths of the nation’s 7,000 “primary care service areas,” Medicare would pay for Part B drugs using reimbursement formulas different from the ones in the Medicare law.

Congress has provided broad bipartisan support for Mr. Obama’s plan to collect genetic data on one million volunteers so scientists can develop drugs and treatments tailored to the characteristics of individual patients. Some of the most enthusiastic supporters of this “precision medicine initiative” expressed concern about the new Medicare drug payment model.

“We are moving into an era of personalized medicine,” said Leslie Ritter, a vice president of the Society for Women’s Health Research, a nonprofit advocacy group. “The primary focus should be on the patient, not on costs. In many cases, we don’t know what works best for patients because women and members of minority groups were not adequately represented in clinical trials.”

Two influential lobbies, the Pharmaceutical Research and Manufacturers of America and the Biotechnology Innovation Organization, strenuously opposed the administration’s plan, saying it could put Medicare patients at risk. Prices for new cancer drugs often exceed $100,000 a year, and it is not unusual to see television commercials and magazine advertisements promoting such treatments.

Dr. Allen S. Lichter, the chief executive of the American Society of Clinical Oncology, which represents cancer doctors, said the administration had identified a real problem, “the skyrocketing prices of drugs.” But he added, “Doctors did not create this problem, and it will not be solved by putting pressure on physicians.”

Oncologists Blast New Medicare Part B Drug Plan
MedPage Today
http://www.medpagetoday.com/PublicHealthPolicy/Medicare/56674

Proposed payment model called 'misguided,' 'dangerous'

by Joyce Frieden
WASHINGTON -- The reviews are in from the oncology community for the Centers for Medicare & Medicaid Services (CMS) proposal to restructure payment for drugs under Part B of the Medicare program -- and they're overwhelmingly negative.

"On both policy and process, CMS missed the mark with this proposal," the Association of Community Cancer Centers said in a statement Wednesday. "The agency sought no stakeholder input and is providing little turnaround time before implementation of such a sweeping, misguided change in Medicare reimbursement."

The proposed payment model "is an inappropriate, dangerous, and perverse mandatory experiment on the cancer care of seniors who are covered by Medicare," wrote Bruce Gould, MD, president of the Community Oncology Alliance, in a letter to CMS acting administrator Andy Slavitt and Health and Human Services Secretary Sylvia Burwell. "This experiment is a misguided government intrusion on the treatment of seniors with cancer and a very dangerous precedent in severing the sacred physician-patient bond."

The model, which CMS announced Tuesday, would replace the current Medicare reimbursement -- the average sales price of the drug plus a 6% add-on fee to cover costs -- with a rate of the average sales price plus 2.5%, plus a flat fee of $16.80 per drug per day. The flat fee would be adjusted at the beginning of each year.

Since Medicare Part B pays for drugs that are administered in a physician's office or hospital outpatient department, oncologists -- who administer many cancer drugs in their offices -- would be greatly affected by the new payment scheme, which CMS officials hope will encourage physicians to choose more cost-effective drugs rather than more expensive drugs, which provide higher reimbursements under the current system.

It wasn't just the oncology community that was unhappy. "Yesterday's announcement marks another troubling example of unelected bureaucrats making decisions behind closed doors that impact the American people and their healthcare," said representatives Fred Upton (R-Mich.), Kevin Brady (R-Texas), and Sen. Orrin Hatch (R-Utah) in a statement issued Wednesday.

"This decision was made with a complete lack of transparency and clear disregard for the people and stakeholders who will be impacted the most. [CMS's] proposed experiment on seniors stands to limit access to the critical care the sickest Medicare beneficiaries rely on, as well as disrupt how health care providers serve patients in the future. The model could ultimately result in seniors' receiving different standards of care based solely on where they live in the country."

But others had a different view. "I applaud the idea," Len Nichols, PhD, director of the Center for Health Policy Research and Ethics at George Mason University, in Fairfax, Va., said in an interview with MedPage Today. "It won't solve all our problems because it presumes that
there's a choice [of medications] and in many of the most recent cancer [drugs] there's no choice. But at the same time it is a move in the right direction."

The Department of Health and Human Services (HHS) also released positive outside comments about the CMS proposal. "Part B drug payments are generally not based on value, or on the competitive approaches that have helped bring a value focus to Part D drug payments," said Mark McClellan, MD, PhD, former CMS administrator under President George W. Bush. "While not all of these ideas will work out, testing new Part B drug payment models and finding more effective ways to encourage drug innovation while avoiding unnecessary costs is very important for Medicare beneficiaries and the Medicare program."

"The new models proposed ... by CMS are an important step in our goal to deliver the best, value-based care to patients," said Vincent Rajkumar, MD, of the Mayo Clinic in Rochester, Minn., in another statement released by HHS. "It is critical that these models are tested if we are to provide access to the most effective treatments to our patients in a manner that is affordable and value-driven."

*Contributing Writer Shannon Firth contributed to this story.*

**Critics push back against new Medicare Part B payment proposals**
Fierce Health Payer

March 10, 2016 | By Katherine Moody

When the Obama administration announced its plan to test new ways of paying for prescription drugs under Medicare Part B, a slew of criticism from industry stakeholders quickly followed--though some say they see potential in the new models.

Drug manufacturers and cancer doctors believe the government's proposals put too much focus on saving money and too little on ensuring patients' access to treatment, according to the New York Times. Indeed, groups such as the Community Oncology Alliance and the trade group Pharmaceutical Research and Manufacturers of America (PhRMA) have had sharp criticism for the new proposals, FierceHealthPayer has reported.

Leslie B. Fried, a health lawyer at the National Council on Aging, had a more measured view. "If this is a way to take account of the value of treatments and control Part B costs, that's a good thing," she tells the Times. But we also have to be concerned about access to care for beneficiaries. It's a balance."

The three Republican chairman of the Senate Finance Committee, though, say the Obama administration's decision to test the new payment methods was not at all transparent and
"could limit access to the critical care the sickest Medicare beneficiaries rely on."

Centers for Medicare & Medicaid Services Acting Administrator Andy Slavitt defended the agency's proposals, saying that it could be a way to increase patient access to potentially life-saving medication, according to an article from The Hill. Speaking at the annual PhRMA conference, Slavitt stressed that the plan was still in the early stages, and that the agency would be soliciting feedback for several months.

"There is nothing that we propose to do, or should do, in any way, that prevents a patient from getting a prescription medicine that they need," Slavitt said.

**Biopharma, Republicans and doctors dig in for fight against new CMS cancer-drug cuts**

Fierce Pharma


March 10, 2016 | By Emily Wasserman

Doctors, lawmakers and the pharma industry are rolling out the cannons against the Centers for Medicare and Medicaid Services (CMS) over a proposal that would reduce physicians' payments for pricey cancer drugs. The backlash comes a day after CMS unveiled the plan, and it could portend a messy battle as industry groups and healthcare providers fight the proposed changes.

Biotech's largest trade association, the Biotechnology Innovation Organization (BIO) says it's "gravely concerned" about the Medicare Part B proposal. Most of the pushback centers on cuts to physician and clinic reimbursements, which CMS says are designed to quash incentives to use pricier meds.

Normally, doctors get reimbursed the average sale price of a drug plus a 6% premium, which some say encourages them to choose expensive therapies. The new plan would lower the premium to 2.5% and add a $16.80 fee. The proposal is now in a 60-day comment period.

Cancer doctors and lawmakers are staging a vocal opposition. Some physicians said the proposal should be withdrawn because independent oncology practices will fold. And cancer centers and oncologists said curbing rising drug costs shouldn't be handled by reducing their payments.

"It is an understatement to say that this latest CMS initiative is misguided and a perilous cancer care policy," Ted Okon, executive director of the nonprofit Community Oncology Alliance (COA), said in a statement.

"It will only serve to accelerate the consolidation of cancer care into the more expensive hospital setting and undermine the physician-patient collaboration on the treatment of cancer.
I thought we were at war on cancer, not cancer care," he said.

Republican lawmakers are lodging their complaints, too. "Yesterday's announcement marks another troubling example of unelected bureaucrats making decisions behind closed doors that impact the American people and their healthcare," Sen. Orrin Hatch (R-UT) and Reps. Kevin Brady (R-TX) and Fred Upton (R-MI) said in a statement.

The CMS is standing by its proposal. The changes would pay doctors for the cost of every drug, unlike the current system which penalizes doctors if the right drug is cheaper, administration officials said. Patients will not have any trouble accessing the meds and might actually get better care under the new system, the agency says.

But the changes would likely affect drugmakers making pricey meds, SunTrust analyst Yatin Suneja said in a note to clients. The CMS' move "could reduce incentives for physicians to prescribe expensive medications such as oncology drugs and biologic therapeutics," Suneja said, especially when similar, cheaper meds are available.

Case in point? Regeneron's ($REGN) retinal disease drug Eylea. The med "is likely to be most at risk from this proposed rule change" as it faces competition from Roche's ($RHHBY) cheaper alternative Avastin, Suneja said.

**Medicare Tries an Experiment to Fight Perverse Incentives**

New York Times


Suppose you’re an eye doctor and you’re treating a patient with macular degeneration, a disease that can cause blindness. You have the choice of giving one of two drugs — one that costs $2,000 per treatment and another, very similar one, which costs $50 per treatment.

Do you think it would influence your decision if you were paid $117 more if you chose the more expensive drug?

That, essentially, is the system we have now. For doctors who give drugs in their offices, mostly cancer, eye and arthritis specialists, Medicare asks them to buy the drugs themselves and then pays them back when they give the drugs to patients. Currently, Medicare pays doctors the average sales price of the drug, and then tacks on a 6 percent bonus to cover their administrative costs. Obviously, 6 percent of $2,000 is a lot more than 6 percent of $50.

Doctors argue that they choose drugs based on what’s most medically appropriate for their patients — and most probably do. (There are some good reasons a doctor might choose the $2,000 drug over the $50 drug for some patients.) But several analysts have looked at this
policy and determined that it creates the wrong kind of incentives for doctors — encouraging them to choose pricier treatments even if they are no better than cheap ones.

Some studies have found evidence that the system has actually shifted doctors toward the more expensive drugs. President Obama has repeatedly proposed changing this policy in his annual budget, and the Medicare Payment Advisory Commission, which studies the program for Congress, has also suggested an end to the 6 percent premium.

On Tuesday, his administration took action on its own authority through the Affordable Care Act. Medicare announced that it would use those broad new powers to test out a new system, to see if reducing the financial incentives for prescribing expensive drugs might change the choices that doctors make. The agency is setting up a sort of randomized experiment, keeping the system intact for doctors in some parts of the country, while introducing a new payment method for doctors in a set of communities.

Doctors in the experimental places will no longer get paid 6 percent of the cost of the drug to cover their overhead. Instead they will get 2.5 percent of that cost, plus a flat fee, regardless of the price of the drug. Under the new system, the difference in payment for the expensive eye drug, Lucentis, will be less than $50 more than the cheaper alternative, Avastin.

Medicare isn’t changing the direction of the incentive — there’s no bonus for picking a cheaper choice — but it’s narrowing the payment gap between different drugs. Dr. Peter Bach, the director of the center for health policy and outcomes at Memorial Sloan Kettering Cancer Center, compares the new system to U.P.S.: We pay the company a fee for moving the box, but we don’t pay different prices based on the value of the box’s contents.

The Centers for Medicare and Medicaid Services, the government agency that runs Medicare, devised the new payments to be budget neutral. That means that it expects, over all, that Medicare will pay doctors the same amount through the lower percentage fees and the new flat administrative fees. But the change will clearly have effects for some individual physician offices. Doctors who prescribe a lot of newer, more expensive drugs will earn less than they used to. Doctors who already prescribe a lot of cheaper, older drugs may get a raise. Doctors who tend to pay above-average prices for drugs — like small, independent practices — may have more trouble covering the cost of certain drugs, and could run into financial trouble. Most community doctors and large hospitals, who treat a range of cancer types and thus prescribe both cheap and expensive drugs, should not see a huge change, the government estimates.

The proposal, which was accidentally published in draft form in February, has infuriated several groups of cancer doctors. They argue that there’s not enough evidence of malfeasance in the current system to be worth the possible harms to doctors and drugmakers — and theoretically to patients.

The government is “proposing a mandatory experiment on seniors’ cancer care,” Ted Okon, the executive director of the Community Oncology Alliance, a trade group for small oncology
practices, said in an email. “The policy regulators, without any supporting data, are, in effect, saying that seniors under Medicare are receiving inappropriate cancer treatment.”

The pharmaceutical industry is also worried. Any policy that steers doctors away from newer drugs could cut into their sales. The lower margin on drugs will also make it harder for drugmakers to raise prices without hurting doctors. There’s a time lag between when prices in the market shift and when the government starts paying those new prices. That means that, with a smaller percentage bonus, price increases could cause doctors to lose money on drugs while they wait for the Medicare price to catch up.

A later phase of the experiment is still in development, but it may give those parties more to worry about. Medicare officials suggested that they want to test other methods that might punish doctors who use more expensive drugs if doctors can’t prove they work better.

Before Obamacare, a payment change this large would have required new legislation. But the health law allows Medicare to introduce pilot programs and experiments, and expand them nationwide if they measure up. Earlier, such experiments were voluntary, but the drug pilot is one of a small number of tests that are now mandatory for doctors and hospitals who practice in certain parts of the country.

In abstract terms, the mandatory, regional design of the program makes it a great way to test whether new payment incentives can lead to more rational, and perhaps less expensive, prescribing behavior. Over time, the government will be able to compare the spending and health outcomes for Medicare patients in the places testing the new policy with those who continue to use the old one. In the early years of the health law, critics were frustrated that the government was mostly using voluntary pilot programs in place of real experiments like this.

But the reality is that the change may have some negative consequences for certain doctors and hospitals whose payments will be cut.

“Does it make a ton of sense in theory? Yes. Is it a more rational payment system? Yes,” said Caroline Pearson, a senior vice president at the health consulting firm Avalere Health. “But in the meantime, it causes a lot of disruption.”

**GOP Lawmakers Blast Part B Drug-Pay Demo As 'Experiment On Seniors'**

Inside Health Policy


March 09, 2016

Senate Finance Chair Orrin Hatch (R-UT), House Ways & Means Chair Kevin Brady (R-TX) and Energy & Commerce Chair Fred Upton (R-MI) slammed CMS' newly announced Part B drug payment demonstration, calling the proposed demo an “experiment on seniors” that could lead
Changes to Medicare should be “done in the light of day,” the lawmakers say, adding their committees will pursue aggressive oversight of CMS' innovation center.

“Yesterday's announcement marks another troubling example of unelected bureaucrats making decisions behind closed doors that impact the American people and their healthcare. This decision was made with a complete lack of transparency and clear disregard for the people and stakeholders who will be impacted the most,” Hatch, Upton and Brady said in a statement Wednesday (March 9).

The lawmakers' concerns echo those of oncologist, pharmaceutical and biological drug lobby groups, as well as dozens of other stakeholders that had tried to get CMS to scrap the plan before it was proposed. CMS, however, says the agency has support for the demo from doctors and experts.

CMS unveiled the highly anticipated Part B drug demonstration Tuesday after inadvertently posting a notice to Medicare Administrative Contractors last month about its plans to test changes to Part B drug payments. In the first phase, the demo would restructure the Part B physician add-on payment to a combination of a flat fee and a lower percentage rate that is still based on drug prices.

Medicare Part B currently pays providers the average sales price of a drug, plus 6 percent. That policy has been criticized as encouraging providers to use expensive products because a portion of provider reimbursement is based on the percentage of drug prices.

CMS officials also ask for input on five additional drug-spending containment policies they are considering testing for outpatients in the second phase of the pilot, which would begin in January 2017. Those policies include paying the same amount for therapeutically similar drugs; discounting or eliminating patient cost-sharing; adjusting payment for drugs based on how well they work; adjusting payment based on the diseases they're prescribed for; and creating prescribing guidelines.

A fact sheet says that all providers and suppliers dispensing Part B drugs would be required to participate in the demonstration model, though not all would be a part of each test. Providers would be placed in control or study groups based on clusters of zip codes that are built on patterns of Part B primary care services. Maryland would be excluded because hospital outpatient departments operate under an all-payer model, the fact sheet says.

CMS also requests advice on value-based drug purchasing arrangements in fee-for-service Medicare, the defunct Competitive Acquisition Program, and bundled or episode-based approach that moves beyond a fee-for-service payment structure.

“[Center for Medicare and Medicaid Innovation's] proposed experiment on seniors stands to limit access to the critical care the sickest Medicare beneficiaries rely on, as well as disrupt how
health care providers serve patients in the future,” the lawmakers say. “The model could ultimately result in seniors' receiving different standards of care based solely on where they live in the country.” -- Michelle M. Stein (mstein@iwpnews.com)

Medicare official defends controversial drug plan
The Hill

The top Medicare official defended the administration’s controversial new plan to overhaul payments for prescription drugs on Wednesday, which he pitched as a way to increase access to potentially life-saving medicine.

“There is nothing that we propose to do, or should do, in any way, that prevents a patient from getting a prescription medicine that they need,” Andy Slavitt, the acting administrator of the Centers for Medicare and Medicaid Services, said Wednesday.

Slavitt spoke for the first time about the Medicare proposal in front of more than 100 pharmaceutical executives at the annual Pharmaceutical Research and Manufacturers of America (PhRMA) conference.

In a question-and-answer session with Slavitt, PhRMA board member and Merck CEO Kenneth Frazier deadpanned that he was going to ask about “the elephant in the room.”

The proposal had been unveiled just one day earlier.

“As you can imagine, people have a great deal of concern about the proposal,” Frazier said.

Under the pilot model, the reimbursement rate in Medicare Part B would be slashed by more than half, but with a new flat rate per prescription. Currently, doctors are paid by the Medicare Part B program based on a drug’s average sales price, plus 6 percent. That rate will drop to 2.5 percent under the model, with a flat payment of about $16

The proposal, which was officially unveiled Tuesday after it was leaked weeks earlier, is intended to rein in government spending on drugs and promote more effective treatments.

New Medicare Drug Payment Scheme Will Need Help From Doctors
Morning Consult
http://morningconsult.com/2016/03/medicare-prescription-payment-system-depends-on-doctors/

CAITLIN OWENS  |  MARCH 9, 2016
The Obama administration’s latest proposal to rein in prescription drug costs relies on doctors
and their price savvy. It is, in essence, a gamble that they will be more thrifty in their treatment of patients.

A proposed rule, unveiled Tuesday, aims to change the way the federal government pays for prescriptions administered by Medicare doctors. Although it comes after months of railing against the cost of drugs, it would most directly impact doctors and outpatient facilities if it isn't changed before it is finalized.

Prescription drug costs top the list of voters’ health care concerns, and the concern has been reflected both on the presidential campaign trail and in congressional hearings. The Obama administration held a forum on the issue in the fall.

The new payment proposal fits into the Center for Medicare and Medicaid Services’ broader goal of tying health care payments to value. It marks a major change to the way Medicare now pays doctors, but it’s unclear whether it will be effective in lowering costs. Already, there is a lot of complaining about it.

“There are a lot of very dramatic changes proposed here, many of which are likely to be strongly opposed by the pharmaceutical industry as well as, potentially, providers,” said Caroline Pearson, a vice president at Avalere Health, an independent consulting firm.

On Wednesday, for example, the Community Oncology Alliance sent a scathing letter to CMS calling its proposal “inappropriate, potentially dangerous, and [a] perverse experiment.”

The proposed rule has two major pieces. The first piece would change the structure of drug reimbursement payments under Medicare Part B, which covers drugs administered in a doctor’s office or in a hospital outpatient department.

Currently, Medicare pays doctors and hospitals the average sales price of a drug prescribed to a patient, plus an additional 6 percent. The model the government wants to test would lower the add-on payment to 2.5 percent and offer a flat fee payment of $16.80 per drug per day. This would be a test program at first, including a study group and a control group. It would begin no earlier than 60 days after the final rule is released.

The second piece would test “value-based purchasing tools” and would go into effect no earlier than January 2017. The administration would tinker with different models like varying the payment for a drug based on its clinical effectiveness, setting a benchmark rate for a group of therapeutically similar drug products, and allowing CMS to enter into voluntary agreements with drug makers to link patient outcomes with price adjustments.

CMS said the payment restructuring fits into its larger effort to tie health care payments to value.

“First and foremost, our job is to get beneficiaries the medications they need. These proposals
would allow us to test different ways to help Medicare beneficiaries get the right medications and right care while supporting physicians in the process,” said Andy Slavitt, acting administrator for CMS.

Pharmaceutical Research and Manufacturers of America immediately cried foul. “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,” said Allyson Funk, a spokeswoman for PhRMA.

PhRMA argues that the current Medicare drug payment methodology is already effective at controlling costs. The price growth for drugs prescribed under Medicare is below that “overall medical inflation,” Funk said.

The oncologists, for their part, said the thinking behind the rule is “based on an insulting assumption that community oncologists practice medicine solely by financial incentives, not by what is in the best interests of their patients.”

The logic behind CMS’ proposal is that the current system offers doctors an incentive to prescribe and administer more expensive drugs because CMS reimburses more for them. For example, say Drug A and Drug B do the exact same thing, but Drug A costs $5 and Drug B costs $100. Under the current system, a doctor will get paid $.30 for giving Drug A and $6 for Drug B. Under the test model, a doctor would receive $16.93 for Drug A and $19.30 for Drug B.

CMS hopes the flat fee will produce savings through changes in prescribers’ behavior, but for now, officials are considering it a budget neutral change.

“The idea behind the proposal is to test whether the current payment system now gives physicians a disincentive to administer lower-cost Part B drugs, and how alternative approaches might affect prescribing practices, quality and costs,” said Tricia Neuman, a senior vice president at the Kaiser Family Foundation.

If reimbursement moves away from being tied to the cost of the drug prescribed, doctors have less financial incentive to prescribe the more expensive drug. If doctors are prescribing cheaper drugs, the Medicare program saves money overall.

But none of those predictions could come to pass, depending on how doctors and clinics respond to the changes. “Right now, how expensive a drug is influences how much a physician earns for administering the drug,” Pearson said. “This will be a big change. ... You’ve sort of restructured the whole reimbursement model, and everyone’s going to have to figure out what it means for them specifically.”

This change in provider behavior would, in theory, impact drugmakers by giving them incentive to make cheaper drugs. It’s a secondary effect, however. Medicare payments are tied to the average price of a drug, meaning the price would have to lower throughout the healthcare
system, outside of Medicare as well, to reduce costs.

The changes could leave some doctors in trouble financially, one Republican health care expert said.

“I expect to hear very quickly that [2.5 percent] plus flat fee will leave [doctors] underwater on certain drugs no matter what,” the expert said. The current model allows doctors to be paid for expensive drugs that might cost more to administer. The test payment system would significantly reduce the amount paid for high-cost drugs.

Congressional Republicans were also quick to rail against the proposal. On Wednesday, several top GOP healthcare leaders in the House and the Senate issued a joint statement condemning it.

“[CMS’] proposed experiment on seniors stands to limit access to the critical care the sickest Medicare beneficiaries rely on, as well as disrupt how health care providers serve patients in the future. The model could ultimately result in seniors’ receiving different standards of care based solely on where they live in the country,” said House Ways and Means Committee Chairman Kevin Brady (R-Texas), House Energy and Commerce Committee Chairman Fred Upton (R-Mich.) and Senate Finance Committee Chairman Orrin Hatch (R-Utah).

The effectiveness of the plan is highly dependent on prescribers’ behavior. If doctors start prescribing lower-priced drugs, this could have a ripple effect on the market, reducing the cost of drugs overall. That’s exactly what the administration is hoping for.

“It provides incentives for drug manufacturers to price appropriately based on value. And rising drug costs are driving growth in overall health care costs,” said Topher Spiro, vice president for health policy at the Center for American Progress.

**Battle Lines Drawn Over Medicare Pricing Proposal**

U.S. News

Cancer specialists clashed Wednesday over a Medicare proposal to test new ways to pays for drugs given in doctor’s offices and hospital outpatient clinics.

The proposal by the Center for Medicare and Medicaid Services applies to Part B drugs, a class that covers certain cancer drugs, antibiotics and eye-care medications. Some cancer drugs are among the costliest on the market, ranging from $9,000 to $100,000 a month, according to America’s Health Insurance Plans. Last year, Medicare paid doctors and outpatient clinics $20 billion for Part B drugs.
Medicare patients also pay whopping out-of-pocket costs for these drugs, through coinsurance that totals 20 percent of the drug's price. Unlike employer-based health plans, "Medicare doesn't have a limit on out-of-pocket spending," says Tricia Neuman, director of the Kaiser Family Foundation's program on Medicare policy, noting that cancer therapy can drive patients into bankruptcy.

The controversy arises out of a long history of heated debate about how best to pay for medications that must be administered by doctors. The system was set up at a time when these medicines were cheap, "like Band-Aids and bags of saline," says Dr. Peter B. Bach, director of the Center for Health Policy at Memorial Sloan Kettering Cancer Center, and formerly a senior adviser on Medicare to the Bush administration.

Over time, he says, prices soared, driven by incentives that prompted doctors to prescribe higher-priced drugs and pharmaceutical companies to charge more for them. The goal now is to change those incentives and reward physicians for providing higher quality care at lower cost.

When the proposal was unveiled Tuesday, Patrick Conway, the agency's chief medical officer, said as much, noting that the purpose of the trial is to reform a payment structure that now pays doctors more for prescribing higher-priced drugs.

"The current perverse incentive system doesn't benefit patients or the system," he said.

Some cancer specialists lashed out at the plan. "This proposal is a misguided, destructive, and potentially dangerous government experiment on the cancer care that elderly patients receive," says Nick Ferreyros, a spokesman for the Community Oncology Alliance, which represents community-based oncologists. "It is wholly focused on dollars and cents without considering quality or physician judgment."

Others say the experiment is overdue. "Remember the government isn't saying you can't prescribe these drugs," says Dr. Ezekiel Emanuel, chairman of medical ethics and health policy at the Perelman School of Medicine at the University of Pennsylvania. "Instead, the government is saying let's take money out of the decision."

Under the current system, doctors are paid 6 percent over the drug's average sale price, to cover handling and administration. The more expensive the drug, the more a doctor is paid for prescribing and administering it. "You have a drug that costs $20,000 or $30,000 and even a percent of that is gets to be a serious amount of money," Bach says. "There's lots of data showing it's an incentive to use one kind of drug over another."

Under the new proposal, in a trial to begin later this year, the add-on would be cut to 2.5 percent; Medicare would pay an additional flat fee of $16.80. Payments to doctors would shrink from approximately 106 percent to 102 percent, says Kaiser's Neuman. "This is an ambitious and creative proposal. It aims to address a longstanding concern about the way in which Medicare pays for Part B drugs."
Researchers note that the approach also has implications for drug companies, because it could prompt doctors to prescribe fewer high-priced drugs. "If you have a marketplace where you can sell more of your cancer drugs by charging more for them – because the person prescribing the drugs will make more money – that's a reason to raise your prices," Bach says.

The Pharmaceutical Research and Manufacturers of America, which represents the drug industry, was quick to criticize the proposal. "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," the group said in a statement.

Medicare's proposal is designed to test alternative payment methods designed to reward doctors and hospital outpatient clinics for providing better care, not more expensive care. These changes would be rolled out in certain geographic areas, where they could be measured against the status quo. "It's just a proposal now. Stakeholders will have an opportunity to comment, and that's the normal process," says Topher Spiro, vice-president of health policy at the Center for American Progress, a non-partisan policy institute.

Proposed Payment Change for Part B Drugs Draws Fiery Response
Bloomberg BNA
https://www.bgov.com/core/news/#!/articles/O3SABK3H65TS?ni_name=NewsAlert&ni_source=AlertEmail

By Mindy Yochelson | March 9, 2016 1:06PM ET

March 9 (BNA) - The leaders of the three congressional committees that oversee the Medicare agency said today they plan to “pursue aggressive oversight,” following yesterday's announcement that the Centers for Medicare & Medicaid Services would test alternative approaches to Part B drug payments.

The “proposed experiment on seniors stands to limit access to the critical care the sickest Medicare beneficiaries rely on, as well as disrupt how health care providers serve patients in the future,” Senate Finance Committee Chairman Orrin Hatch (R-Utah), House Energy and Commerce Committee Chairman Fred Upton (R-Mich.), and House Ways and Means Committee Chairman Kevin Brady (R-Texas) said in a statement.

In addition, the Community Oncology Alliance today wrote to HHS Secretary Sylvia Mathews Burwell expressing “vehement opposition” to the new payment model, which it called “inappropriate, dangerous and perverse.”

CMS wants to overhaul Part B drug payments. Oncologists call the plan 'absurd.'
The Obama administration unveiled a five-year Medicare initiative Tuesday that would test new ways of paying for outpatient drugs. The pharmaceutical industry and some provider groups quickly attacked it as an irresponsible experiment.

The mandatory program, proposed by the CMS Innovation Center would explore whether alternative models for covering drugs under Medicare Part B would curb costs and reward better patient outcomes.

Ted Okon, executive director of the Community Cancer Alliance, tweeted soon after the announcement that the pilot “is the most contrived, absurd experiment on cancer care I have seen.”

Under the current Part B reimbursement model for drugs administered by infusion or injection in doctors offices and hospital outpatient departments, Medicare pays 6% on top of the average sales price of the medication. That means providers are paid more when they choose more expensive medications—a drug with a $100 ASP yields an additional $10 while one with $1,000 ASP yields $100. Critics say the model provides a clear incentive for physicians to go with a pricier drug even when there’s no real benefit over cheaper alternatives.

The new Innovation Center initiative was inspired by a Medicare Payment Advisory Commission (MedPAC) report to Congress last summer that outlined a troubling trend in Part B drug spending, according to Dr. Patrick Conway, the CMS’ deputy administrator for innovation and quality.

“The choice of medications for beneficiaries should be driven by the best available evidence, the unique needs of the patient, and what best promotes high quality care,” Conway said in a news release.

The first phase of the program, beginning in late 2016, would test how prescribing patterns are affected by knocking down the add-on to 2.5% and substituting a flat payment of $16.80 per drug per day.

Later—no sooner than the start of 2017—the agency intends to test a “menu of value-based purchasing options” culled from a review of strategies used by private health plans, hospitals and pharmacy benefit managers.

Not all providers and suppliers would be subject to each strategy the government is testing. Beginning at least 60 days after the proposal is finalized, the CMS would divvy them up by primary-care service areas to create control groups and study groups.
The value-based strategies that would be tested are:

- Decreasing or eliminating cost-sharing under Part B to improve beneficiaries' access to and appropriate use of effective drugs.
- Creating evidence-based, clinical-decision support tools as a resource for providers and suppliers focused on safe and appropriate use for selected drugs and indications.
- Varying payment for a drug based on its clinical effectiveness for different indications.
- Testing the practice of setting a standard payment rate—a benchmark—for a group of therapeutically similar drugs.
- Entering into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.

Prescription drug spending in the U.S. totaled about $457 billion in 2015, or 16.7% of overall health spending, according to the CMS (PDF). In 2015, Medicare Part B spent $20 billion on outpatient drugs administered by physicians and hospital outpatient departments.

The Pharmaceutical Research and Manufacturers Association said in a statement Tuesday that Medicare's aggressive moves toward value-based payments under accountable care and other models are already giving providers incentives to hold down Part B drug costs. “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,” PhRMA spokeswoman Allyson Funk said in the statement.

The American Society of Clinical Oncology lashed out at the Innovation Center's intent to “modify drug reimbursement based on Zip codes,” calling it “inappropriate for CMS to manipulate choice of treatment for cancer patients using heavy-handed reimbursement techniques.” ASCO added that physicians “did not create the problem of drug pricing and its solution should not be on their backs.”

The deadline for comments on the proposed rule is May 9.

Medicare considers overhaul of doctors’ payments for drugs
The Washington Post
https://www.washingtonpost.com/national/health-science/medicare-considers-overhaul-of-doctors-payments-for-drugs/2016/03/08/90af35e2-e56c-11e5-a6f3-21ccdbc5f74e_story.html

By Laurie McGinley March 8 at 6:31 PM

Medicare officials proposed Tuesday to test new ways of reimbursing doctors who administer drugs in their offices and hospital outpatient clinics, with a long-term goal of encouraging greater use of treatments that are high quality but less costly.

The proposal by the Centers for Medicare and Medicaid Services would apply to Medicare Part
B, which covers drugs such as infused cancer medications and injectable antibiotics. Last year, Medicare spent about $20 billion on Part B drugs.

Patrick Conway, chief medical officer for CMS, said in a telebriefing that the plan isn’t designed to save money. But he left little doubt that the ultimate aim is to eliminate incentives that may encourage doctors to select higher-priced medications that benefit their bottom lines but not their patients.

Conway called the current system — in which doctors are paid the average sales price plus 6 percent for handling and administration costs — a “perverse incentive structure that doesn’t benefit patients or the system.” He said oncologists have told CMS they sometimes feel pressure from their health-care systems to pick more expensive drugs to bolster profits.

[Americans are wasting $3 billion a year on discarded cancer drugs.]

The agency intends to try different approaches in different parts of the country. Under one approach, doctors would be paid a drug’s average sales price plus 2.5 percent and a flat daily payment of $16.80. Another would peg reimbursements to a drug’s effectiveness for different uses.

The Pharmaceutical Research and Manufacturers of America, which represents the drug industry, immediately criticized the proposal. “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,” the group said in a statement.

Peter Bach, director of the Center for Health Policy & Outcomes at Memorial Sloan Kettering Cancer Center, said that he hadn’t reviewed the proposal but that it’s important to clearly separate treatment decisions by doctors from potential profits. Data shows doctors’ prescribing patterns are affected by the way they are reimbursed, he said, adding, “We need a system that pays for drugs based on value.”

Medicare Seeks New Ways to Pay for Part B Drugs
Bloomberg Goverment
https://www.bgov.com/core/news/#!/articles/O3QW1 IS3H0JK0?ni_name=NewsAlert&ni_source=AlertEmail

By Steve Teske | March 8, 2016 7:10PM ET

Medicare Part B Drug Demonstration

Development: CMS demonstration will attempt to test new incentives for prescribing Part B medications.
Next Steps: The first stage of the demo is expected to be implemented later this year. Comments on proposal due May 9.

What Big Pharma Says: PhRMA says that proposing “sweeping changes to Medicare Part B drug reimbursement without thoughtful consideration and stakeholder input is not the right approach.”

March 8 (BNA) -- The Centers for Medicare & Medicaid Services (CMS) wants to experiment with new ways of paying for Medicare drugs administered to beneficiaries in physicians' offices and hospital outpatient departments.

The agency released a proposed rule (CMS-1670-P; RIN: 0938-AS85) March 8 seeking comments on testing six different alternative approaches for Part B drugs. One alternative is changing reimbursement from the average sales price of a drug plus a 6 percent add-on, to a 2.5 percent add-on plus a flat $16.80 per drug per day. The agency said it expects the new add-on payment and flat fee will cover the cost of any drug paid under Medicare Part B.

The CMS in a fact sheet said it would update the flat fee at the beginning of each year by the percentage increase in the consumer price index for medical care for the most recent 12-month period. This test would begin in late 2016, the agency said.

The CMS also is proposing eliminating patient cost-sharing; creating evidence-based clinical decision support tools; varying the payment for a drug based on its clinical effectiveness for different indications; testing the practice of setting a standard payment rate—a benchmark—for a group of therapeutically similar drug products; and allowing the Medicare agency to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.

The rule is scheduled to be published in the March 11 Federal Register and comments are due by May 9.

Patrick Conway, acting principal deputy administrator and chief medical officer at the CMS, told reporters during a telephone conference call that the demonstration wouldn't interfere with physicians' choice of prescribing the best available medications for their patients.

“Nothing (in the demonstration) will prevent doctors from prescribing exactly what their patients need,” he said.

Pushback From Drugmakers

The drug industry expressed dismay with the proposal. “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,” the
Pharmaceutical Research and Manufacturers of America (PhRMA) said in a statement.

Medicare Part B covers prescription drugs that are administered in a physician's office or hospital outpatient department, such as cancer medications, injectables like antibiotics, or eye care treatments. Drugs paid under Medicare Part B generally fall into three categories:

- medications furnished in connection with a physician's service in the office or hospital outpatient settings;
- drugs administered via a covered item of durable medical equipment; and
- categories of drugs explicitly identified in law.

The agency in its fact sheet said the proposal is designed to test different physician and patient incentives to drive the prescribing of the most effective drugs, and test new payment approaches to reward positive patient outcomes. The plan will begin to be implemented in late 2016 and run for five years, the agency said. The demonstration will be budget neutral, although the fact sheet said “CMS intends for the test to result in savings through changes in prescribers’ behavior.”

Providers and suppliers would be placed in a control or study group based on Primary Care Service Areas, which are clusters of ZIP codes based upon patterns of Medicare Part B primary care services, the agency said. However, not all providers would be part of each test, it added. All providers and suppliers furnishing and billing for Part B drugs would be required to participate in the model, although not all would be part of each test and, with some exceptions, the agency is proposing to include all Part B drugs and biologicals in the model.

Value-Based Purchasing

The agency said its value-based purchasing strategies would be introduced early in 2017 and would include discounting or eliminating patient cost-sharing, which would decrease or eliminate cost sharing to improve beneficiaries’ access and appropriate use of effective drugs. The plan also would create evidence-based clinical decision support tools as a resource for providers and suppliers focused on safe and appropriate use for selected drugs and indications. Examples of this approach could include best practices in prescribing or information on a clinician’s prescribing patterns relative to geographic and national trends, the agency said.

The CMS also is proposing to vary drug payments based on clinical effectiveness for different indications. For example, the agency said a medication might be used to treat one condition with high levels of success but an unrelated condition with less effectiveness, or for a longer duration of time.

The proposal would introduce reference pricing, or the practice of setting a standard payment rate—a benchmark—for a group of therapeutically similar drug products, as well as risk-sharing agreements based on outcomes. The latter would allow the CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.
Also on March 8, the Department of Health and Human Services released issue briefs on drug spending and on the Part B program. In the latter document, the HHS said the Part B payment method “provides weak incentives for physicians to consider value” when choosing an effective therapy to treat a patient (see related story in this issue).

CMS Proposes Revamping ASP Formula At First, Followed By More Aggressive Policies
Inside Health Policy

March 08, 2016

CMS unveiled a highly anticipated Part B drug demonstration Tuesday (March 8) that in the first phase would restructure the Part B physician add-on payment to a combination of a flat fee and a lower percentage rate that is still based on drug prices. The agency seeks advice on five policies for the second phase that would move Part B toward the system used in the commercial market and in Part D retail drug benefit.

Medicare Part B pays providers the average sales price of a drug, plus 6 percent. CMS proposed changing the add-on payment to 2.5 percent, plus a flat fee of $16.80 per drug per day. CMS would update the flat fee each year by the percentage increase in the consumer price index for medical care for the most recent 12-month period. This first phase would take effect late this year and is not intended to reduce or increase overall spending on Part B drugs.

The first phase is similar to the approach that the Medicare Payment Advisory Commission described last year.

CMS officials seek input on five additional drug-spending containment policies they are considering testing for outpatients in the second phase of the pilot, which would begin Jan. 1, 2017. Those policies include paying the same amount for therapeutically similar drugs; discounting or eliminating patient cost-sharing; adjusting payment for drugs based on how well they work; adjusting payment based on the diseases they’re prescribed for; and creating prescribing guidelines.

The policy of paying the same amount for therapeutically similar drugs is called reference pricing. The reference price is the average of prices for drugs that are therapeutically similar, which is the amount that CMS would pay. When drugs that are more expensive than the reference price are chosen, private plans sometimes make beneficiaries pay the difference. However, CMS emphasizes that it would not allow such “balance billing” practices.

In fact, the agency proposes to reduce or eliminate the 20 percent coinsurance that patients pay for high-value drugs. Many Medicare beneficiaries have supplemental insurance that covers
their coinsurance, but the policy likely would be a relief for those without supplemental coverage. Also, CMS officials don't expect the policy to change the overall payment amount for drugs.

“In other words, we are proposing to increase Medicare’s payment percentage while maintaining the total allowed charges for the drug using this tool,” the proposal states. This proposal is in line with the drug industry's stance. Drug makers that have been clamoring for commercial plans to lower drug cost-sharing to levels paid for medical services, and plans say they keep cost sharing high to attract attention to rising drug prices.

However, the Pharmaceutical Research and Manufacturers of America does not support the other proposals, and the trade group came out against the demonstration before CMS even proposed it. Reimbursement for Part B drugs accounts for a small portion of Medicare spending, PhRMA states. The group adds that HHS recently announced that it has met its goal of tying 30 percent of Medicare payments to alternative payment models, and these models increasingly provide incentives for value in Medicare Part B.

“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,” PhRMA states.

Adjusting reimbursement based on how well drugs work for different indications is called indication-based pricing. Commercial payers have been employing this policy more frequently, but it is still uncommon. Drugs often are indicated for multiple conditions but they aren't equally effective for those conditions so CMS proposes paying according to how well they work.

“We propose to use indications-based pricing where appropriately supported by published studies and reviews or evidenced-based clinical practice guidelines, such as the ICER reports, to more closely align drug payment with outcomes for a particular clinical indication,” the proposal states.

Similarly, CMS proposes to link health care outcomes to payment. This method is sometimes used in the private sector when there is little real-world evidence demonstrating drugs' long-term value. Typically, commercial payers pay full price when drugs deliver outcomes equal to those observed in clinical trials.

The proposal states that outcomes-based risk-sharing agreements would require clearly defined outcomes, and CMS seeks advice on the methods for measuring outcomes.

“At a minimum, and in addition to sources such as evidence-based literature and best practices, we propose manufacturers provide all competent and reliable scientific evidence to create an accurate picture regarding clinical value for a specific drug; and we also propose that manufacturers provide outcome measures for any outcome-based risk-sharing pricing agreement,” the proposal states.
CMS also proposes clinical decision support tools. The proposal states that clinical decision-making should be based on up-to-date evidence on drug safety and practice guidelines. “Clinical decision support (CDS) can assist physicians and other health professionals with clinical decision-making tasks, including prescribing,” the proposal states.

In addition to the proposals associated with phases one and two, CMS requests advice on value-based drug purchasing arrangements in fee-for-service Medicare, the defunct Competitive Acquisition Program, and bundled or episode-based approach that moves beyond an FFS payment structure.

The Medicare Payment Advisory Commission also revisited the Competitive Acquisition Program last week. -- John Wilkerson (jwilkerson@iwpnews.com)

**Medicare Officials Propose Drug Payment Change**
CQ Roll Call

By Kerry Young, CQ Roll Call

Medicare officials on Tuesday unveiled a plan to test new approaches to paying for often costly prescriptions drugs administered in doctors’ offices, which include cancer treatments and medicines used to combat rheumatoid arthritis.

The Centers for Medicare and Medicaid Services on Tuesday released a proposed rule for the purchases made through its Part B program that pays for treatments given in doctors’ offices and hospital outpatient departments. Part B drugs cost a total of about $20 billion in 2015, according to CMS. The Medicare Payment Advisory Commission has suggested that there’s a need for changes in the Part B model, noted CMS Chief Medical Officer Patrick Conway on a conference call with reporters.

Medicare’s approach to Part B drugs has been to pay a premium to the reported average sales price of a medicine. The premium, originally set at 6 percent of the price, currently runs at about 4.3 percent due to the budget sequester. Among the changes that CMS is proposing through the test would be a switch to an add-on payment of 2.5 percent of the reported average sales price plus a flat fee payment of $16.80 per drug per day. Officials want to test whether this approach will eliminate an incentive that now exists to prescribe more costly medicines in cases where similar less costly alternatives may serve a patient as well.

CMS is planning to try to change the approaches in different regions of the country, Conway said.

The proposal is certain to be met with industry complaints. The Pharmaceutical Research and
Manufacturers of America, the Biotechnology Innovation Organization and other groups already have sought to dissuade CMS from moving ahead with this proposal.

"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," said PhRMA spokesperson Allyson Funk.

**CMS to overhaul Part B drug payments**  
Politico Pro  

By BRETT NORMAN 03/08/16 04:43 PM EST

The Obama administration rolled out a controversial proposal Tuesday to change the way it pays for billions of dollars in Medicare drugs.

The new project through CMS' Innovation Center would let the government vary what it spends on drugs given in the hospital or doctor’s office to test whether the existing payment model is encouraging doctors to use more expensive medicines that aren't necessarily the most effective.

It's the latest move by the Obama administration to tamp down drug costs, which spiked 12.6 percent in 2014 and have become a major political issue for Democrats in a presidential election year.

"Nothing in this proposed payment model would limit doctors from prescribing exactly the treatment they think their patients need," Patrick Conway, chief medical officer at CMS, said on a conference call with reporters. He said the initial changes are designed to be budget neutral but that over time the model may result in "smarter spending or savings" by incentivizing higher-value drugs with better patient outcomes.

More than 100 groups representing doctors, cancer advocates and drug makers have called on CMS to abandon the experiment since some details of the proposed rule released Tuesday were first accidentally published online in February. A Monday protest letter from the American Society of Clinical Oncologists, the Community Oncology Alliance and dozens of advocacy organizations said the HHS effort would hurt patients.

“Any CMMI experiment that forces these vulnerable Medicare patients to abandon treatments that are working and improving their quality of life is misguided and ill-conceived,” the groups wrote, noting their strong opposition to "any effort to rush through a cost-cutting program.”
The pricing experiment only applies to Medicare Part B, which pays for drugs administered to patients by care providers. Program spending grew to about $18.5 billion in 2014, up from $9.4 billion in 2005.

Part B currently pays the so-called average sales price plus 6 percent for such drugs, which is meant to cover doctors’ costs of buying the medicines and provide a profit after the storage and administration of them. But it has raised concerns, including from the Medicare Payment Advisory Commission, that the formula gives doctors a perverse incentive to use more expensive drugs. That’s because 6 percent is worth more for an expensive drug compared to a cheaper one.

The CMMI program, which would require participation by all Medicare providers, would let Part B instead pay 2.5 percent and a flat fee of $16.80 per day. The agency could then study whether it has an impact on doctors’ prescribing patterns. CMS plans to implement the new payment model in late 2016 in certain geographic regions that will be spelled out in the final rule, Conway said.

Next year, the agency plans to role out additional "value-based" pricing models. Those include reducing or eliminating patient co-pays for effective drugs; reference pricing, which is paying a benchmark rate for a group of equally effective drugs; and indications-based pricing, which would vary the payment for the same drug when it's used for different clinical reasons, depending on how well it works to treat a certain condition.

Conway said that nothing in the proposal "would tell doctors what to prescribe and when," and said the goal was to maintain access to drugs and improve patient outcomes.

PhRMA was quick to criticize the experiment.

“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,” the trade group said in a statement.

HHS on Tuesday also released a report finding the Part B payment model may push providers to use the more expensive alternative of equally effective drugs. It also notes that Part B does not have tools widely used by private plans to limit use of expensive medications, such as tiered cost sharing and step therapy. “[I]t is likely that implementing a variety of pricing and formulary policies could produce substantial savings for both the program and its beneficiaries without impairing quality of care,” the report concluded.

**Medicare Proposes Change in Part B Drug Payments**

Medpage Today

[http://www.medpagetoday.com/PublicHealthPolicy/Medicare/56636](http://www.medpagetoday.com/PublicHealthPolicy/Medicare/56636)
WASHINGTON -- Medicare is proposing to experiment with the way it pays for drugs that are covered by its Part B program, the Centers for Medicare & Medicaid Services (CMS) announced Tuesday.

"[We want to] test how we can improve quality and value through the way Medicare Part B pays for prescription drugs," said Patrick Conway, MD, CMS chief medical officer, in a conference call with reporters. "Our goal is to support physicians and other clinicians in delivering high-quality care to their patients."

Medicare Part B pays for drugs that are administered in a physician's office or hospital outpatient department. Generally, Medicare pays the physician the drug's average sales price (ASP) plus a 6% add-on payment. As a result of that payment structure, physicians may be incentivized to choose a higher-priced drug because their reimbursement will be higher, Conway explained.

Such a result is contrary to Medicare's current push to pay for value and outcomes across the healthcare system, he continued. Therefore, CMS issued a proposed rule Tuesday, which would test a payment model that would reduce the add-on payment to 2.5%, but would add a flat fee of $16.80 per drug per day. The flat fee would be updated at the beginning of each year. This payment scheme would be tested starting in late 2016, according to CMS.

In a fact sheet on the proposed rule, the agency gave examples of how the new model would play out. For a Part B drug that has an ASP of $5, physicians are currently paid $5.30 (the ASP plus 6%). Under the new model, they would be paid $21.93 (the ASP itself, plus 2.5% of the ASP plus $16.80).

For a drug with an ASP of $10, physicians are currently paid $10.60 but would receive $27.05 under the new model.

But the situation is reversed as the drug cost rises: for a $1,000 drug, physicians are currently paid $1,060 but would receive only $1,041.80 under the new model.

CMS is also planning to test several other Part B drug value-based purchasing ideas beginning in 2017, including:

- Discounting or eliminating patient cost-sharing. This model would test whether decreasing or eliminating cost sharing improves beneficiaries' access and appropriate use of effective drugs.
- Feedback on prescribing patterns and online decision support tools. These would be a resource for providers and suppliers focused on safe and appropriate uses of selected drugs. Examples might include best practices in prescribing or information on a clinician's prescribing patterns compared with geographic and national trends.
- Indications-based pricing. This model would vary the payment for a drug based on its effectiveness for different indications, so that a drug that's more effective for Indication A would be reimbursed at a higher price than it would if given for Indication B, for which it was less effective.
- Reference pricing. This model would test the practice of setting a standard payment rate for a
group of therapeutically similar drug products.

• Risk-sharing agreements based on outcomes. Under this model, CMS would enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.

Conway did not give specifics about where the payment models would be tested, saying only that the testing would be done "in different geographic areas across the country -- so there will be areas where there are no changes, other areas where they just may have ASP changes, and other areas where they may have the ASP changes plus value-based payment arrangements."

"This proposed rule is designed to align incentives with what's best for patients and doctors," Conway said. "Doctors want to prescribe medications without worrying about finances or what administrators think ... The current perverse incentive structure doesn't benefit patients or the system."

Conway emphasized that "Nothing in this proposed payment model will prevent doctors from prescribing exactly the treatment they think their patients need. The model will encourage doctors to choose the drug that is right for their patients."

In addition to CMS's announcement of the proposed rule, the Department of Health and Human Services (HHS) also released two drug pricing reports on Tuesday.

One of the reports was about the same issue Conway was concerned with: Part B drug spending. That report found that -- similar to what Conway told reporters -- the current payment method "provides weak incentives for physicians to consider value -- that is choose the lowest cost therapy to effectively treat a patient," and that the Medicare program has not implemented various value-based practices typically used by commercial insurers and Part D sponsors for self-administered drugs.

The second report, on overall drug spending trends, found that drug spending increased by a "remarkable" 12.6% in 2014, and that "drug spending growth is estimated to have remained elevated in 2015," the agency said.

**MedPAC Considers Alternatives To Part B Drug-Reimbursement Formula**

Inside Health Policy


March 08, 2016

The Medicare Payment Advisory Commission at its recent meeting discussed several policies to get doctors out of the drug-vendor business by moving away from the current approach that
pays doctors a percentage of average drug prices to cover the cost of administering drugs. Last Thursday's meeting drew a standing-room-only crowd; CMS is expected to unveil this week a demonstration to test new approaches to paying for outpatient drugs. Despite public opposition to the sharp rise in drug prices, the drug industry and other stakeholders are demanding the demo never see the light of day.

The commission put forward a single draft recommendation that commissioners widely supported, chiefly reducing the Medicare Part B dispensing and supplying fees to rates similar to other payers.

But commissioners disagreed on other policies they discussed for potential recommendations. These included capping the inflation rate of the average sales price, consolidating billing codes for drugs and biopharmaceuticals with similar health effects and bringing back the competitive acquisition program in a new form.

They also considered options for revamping the add-on payment for doctors, which they discussed at a previous meeting. Commissioners heard that when the reimbursement was lowered by sequestration, drug companies responded by lowering drug prices. However, the add-on payment is far smaller than the average sales price portion of reimbursement, so commissioners were told that if they want to do more to tamp down drug prices, they'll need to consider other policies.

For example, to cap rising outpatient drug prices, drug makers could be required to pay Medicare rebates when the average sales price grows quickly, similar to the inflation portion of the Medicaid rebate. Commissioner Craig Samitt, an executive at Anthem, said drug makers should be subject to the same scrutiny as providers in Medicare, so he is fine with the cap. Jack Hoadley, a research professor at the Health Policy Institute of Georgetown University, also said he likes the cap policy.

However, others said they are uneasy with the idea. Commissioner Kathy Buto, a former vice president at Johnson & Johnson, said she dislikes both the idea of a cap on drug price inflation and consolidated billing codes. Capping billing codes would cause rebates to go to the government instead of beneficiaries, Buto said. She compared the billing codes policy to the least costly alternative policy that the courts stopped CMS from using years ago.

“Oddly enough, this is even potentially more difficult for the beneficiary than LCA because under LCA I think we imagined that if they needed a higher-cost drug, they could at least appeal it,” she said, referring to the least costly alternative.

Commissioners Katherine Baicker, a professor at Harvard School of Public Health, and Willis Gradison, a former U.S. lawmaker, also said they are not fans of the capped inflation policy. Gradison said capping inflation would lead drug makers to launch drugs at even higher prices, and at that point Congress would need to consider how to keep launch prices down. He said it also could become a problem if FDA forces companies to fix manufacturing problems, then
companies aren't allowed to raise prices to account for the capital investment required to make those improvements.

“Then they have to decide whether they really want to stay in that market with that particular product,” he said.

Although Baicker also is uncomfortable with the inflation cap because it sounds to her like price controls, she is open to the billing codes policy.

Revisiting the Competitive Acquisition Program that ran from 2006 to 2008 received mixed reviews. Many commissioners said they are hesitant to bring a failed program back. The program was supposed to work by letting drug vendors bid to supply drugs to doctors, who would enroll to obtain drugs through the winning vendor. However, few physicians took part, only one vendor participated, and that vendor didn’t renew the contract.

A MedPAC researcher said the primary complaint from the vendor is that the average sale prices for drugs were not updated, and that led to them losing money on some drugs. Commissioners are considering whether the program would work better if it were restructured. It could remain voluntary but physician enrollment would be encouraged by offering shared savings, reducing or eliminating the average sales price add-on for those who don’t participate or changing it to a stock replacement model, instead of making physicians pre-order drugs for individual patients. -- John Wilkerson (jwilkerson@iwptnews.com)

DOCS, DRUG COs SEEK TO STRANGLE PART B EXPERIMENT

Prescription Pulse

More than 100 groups are urging HHS to hold off on a demonstration project in Part B that’s expected to be announced any day now. A CMMI proposal accidentally posted online earlier this year would experimentally adjust the percentage of the cost it pays to doctors, to determine whether that leads them to prescribe less expensive drugs. A letter sent to HHS and CMS on Friday argues that “that this type of initiative ... will adversely affect the care and treatment of Medicare patients with complex conditions, such as cancer, macular degeneration, hypertension, rheumatoid arthritis, and primary immunodeficiency diseases.” The letter was signed by PhRMA, BIO and a host of physician specialty societies and disease groups. A Part B proposal is currently awaiting final review at OMB. The letter: http://bit.ly/24Giz41