Prescribing frequency and doc payments often linked

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Drugmakers funnel payments to high-prescribing doctors

By Bob Herman

Nearly one-quarter of Medicare’s top-prescribing physicians received consulting fees or other financial perks from manufacturers of the drugs they prescribed in 2013, renewing nagging questions about conflicts of interest in medical decisionmaking.

More than 400 physicians prescribed at least $1 million worth of drugs in the Medicare Part D drug benefit program, and 23% of them accepted some form of a non-research payment from the corresponding drugmaker in 2013, according to a Modern Healthcare analysis of the CMS’ recent Part D data release and of the Open Payments database.

For instance, Dr. Gavin Awerbuch, a neurologist based in Saginaw, Mich., billed Medicare in 2013 for more than $6.4 million worth of Subsys, a pain reliever for cancer patients. That was the second-highest total for one doctor prescribing a single drug. Insys Therapeutics, the maker of Subsys, paid Awerbuch more than $56,000 that same year for an array of services, including $4,100 for a Subsys-related speaking engagement.

The Justice Department indicted Awerbuch last year, accusing him of fraudulent prescribing of unneeded medication. His case is pending. Calls to Awerbuch, Insys and state prosecutors were not returned.

The Modern Healthcare analysis found that some physicians and provider groups prescribe large volumes of brand-name drugs from pharmaceutical firms and accept money from those same manufacturers. About 17% of the almost 36,000 providers in the Part D database who prescribed $100,000 or more of a single drug received money from the maker of that drug. The same holds true for 20% of the 2,200 physicians who prescribed at least $500,000 of one drug.

In total, the database included more than 800,000 physicians, nurse practitioners and other providers. Actelion Pharmaceuticals, Celgene Corp. and Teva Pharmaceuticals USA were among the drugmakers that appeared often in both databases.

Some experts say these correlations suggest an unholy linkage between prescribing behavior and industry payments to doctors. But others caution that it’s hard to draw conclusions without more detailed information about the physicians’ practices and the nature of the financial relationships, such as whether the payments are for research or marketing purposes.

“It is frankly magical thinking to believe that those two things are not related,” said Eric Campbell, a Harvard Medical School sociologist who studies conflicts of interest in healthcare. “It’s just completely not in the realm of reality to deny—when you see over and over that the highest-paid speakers are among the ranks of the highest prescribers—that there isn’t a relationship there.”

“It’s an enormous problem,” said Dr. Steven Nissen, chair of cardiovascular medicine at the Cleveland Clinic. He co-published research in 2007 that found Avandia, a former blockbuster diabetes drug made by GlaxoSmithKline, was associated with increased risks for heart attacks. “I believe it is incompatible with our roles as independent decisionmakers,” he said.

The CMS cautioned that payments to providers from drugmakers and biotechnology companies don’t necessarily mean there is a conflict of interest. The agency said in a written statement that it has “a range of tools” in place to track fraudulent behavior and odd prescribing patterns. ”Information about financial relationships alone is not enough to decide whether they’re ben-

Spotlight on potential conflicts

Ten highest-prescribing Medicare physicians who took at least $5,000 in general payments from related drug companies in 2013

<table>
<thead>
<tr>
<th>Cost/drug prescribed</th>
<th>Payments received/company</th>
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<tbody>
<tr>
<td>Dr. Gavin Awerbuch, Saginaw, Mich.</td>
<td>$6.4 million worth of Subsys</td>
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<tr>
<td>Dr. David Siegel, Hackensack, N.J.</td>
<td>$5.6 million worth of Revlimid</td>
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<tr>
<td>Dr. Valerie McLaughlin, Ann Arbor, Mich.</td>
<td>$4.8 million worth of Tracleer</td>
</tr>
<tr>
<td>Dr. Ben Thrower, Atlanta</td>
<td>$3.7 million worth of Copaxone</td>
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<tr>
<td>Dr. Peter Engel, Cincinnati</td>
<td>$2.9 million worth of Tracleer</td>
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<tr>
<td>Dr. John McConnell, Louisville, Ky.</td>
<td>$2.9 million worth of Tracleer</td>
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<tr>
<td>Dr. Fernando Torres, Dallas</td>
<td>$2.6 million worth of Tracleer</td>
</tr>
<tr>
<td>Dr. Jonathan Calkwood, Golden Valley, Minn.</td>
<td>$2.5 million worth of Copaxone</td>
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<tr>
<td>Dr. Brian Steingo, Pompano Beach, Fla.</td>
<td>$2.4 million worth of Copaxone</td>
</tr>
<tr>
<td>Dr. Robert Vescio, Los Angeles</td>
<td>$2.1 million worth of Revlimid</td>
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Sources: CMS data and Modern Healthcare reporting
official or improper,” according to the CMS. “Just because there are financial ties doesn’t mean that anyone is doing anything wrong. Transparency will shed light on the nature and extent of these financial relationships and will hopefully discourage the development of inappropriate relationships.”

There are some caveats in analyzing the Part D and Open Payments data. Not all the physicians listed equate to one individual physician. In some instances, all the providers in one medical group bill Medicare under one doctor’s name. Some physicians may then appear to be prescribing higher amounts of certain drugs than is actually the case.

In addition, the data are somewhat incomplete and there are inconsistencies in provider information between the two databases. The Open Payments database, created by the Physician Payments Sunshine Act provision of the Affordable Care Act, does not provide specific provider identities for 60% of reported payments. Consequently, Modern Healthcare’s analysis covers only the $1.4 billion of identified payments. Also, the Open Payments database accounts only for the last five months of 2013, meaning that payments from drug companies to providers are potentially even higher.

The next round of Open Payments data will go live June 30.

Dr. Mark McClellan, a former CMS administrator and now a senior fellow at the Brookings Institution, said some associations between specific drug prescribing patterns and payments “will lead to further questions.” But, he added, without knowing the full details of every relationship, it may be “hard to reach definitive conclusions about whether particular providers or practices are good or bad.”

Whether there is actual bias in prescribing patterns “is potentially worthy of a bit more investigation,” said Dr. Aaron Kesselheim, a pharmacoeconomics faculty member at Brigham and Women’s Hospital in Boston. For example, do high prescribers of particular drugs attract pharmaceutical companies to them, or do drug companies seek out physicians who then become high prescribers?

Nissen said he consults with drugmakers and helps them with research but has a personal policy of rejecting any payments that constitute income, such as speaking fees or honoraria.

He appears in the Open Payments database, receiving $5,412.48 from Amarin Pharma, a cardiafocused drug firm based in Bedminster, N.J. Most of that amount was donated to the Cleveland Museum of Natural History, while the remainder covered his basic expenses for an out-of-town research meeting. Nissen appears in the Medicare Part D database twice, and neither listing involves drugs from Amarin.

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Eric Campbell
Sociologist
Harvard Medical School

The questions become more concerning when drugmakers benefit financially from the prescribing habits of doctors they are paying. But some physicians offer convincing arguments about the legitimacy and social value of drugmakers’ payments to them.

Dr. Vallerie McLaughlin, a cardiologist at the University of Michigan Health System in Ann Arbor, prescribed more than $4.8 million of Tracleer to Medicare beneficiaries in 2013—making her the sixth-highest prescribing physician of a single drug. She also received $40,491 in clinical consulting fees, meals and travel from Actelion Pharmaceuticals, the Swiss conglomerate that manufactures Tracleer. None of the payments were directed to charities or other third parties.

Tracleer treats pulmonary arterial hypertension (PAH), a rare type of high blood pressure that affects the lungs and is potentially fatal.

McLaughlin told Modern Healthcare that her prescribing patterns and her payments from Actelion “reflect the large volume of pulmonary arterial hypertension patients I see and manage in one of the country’s largest PAH programs.” Eighty of her patients use Tracleer, and she prescribes other, less-expensive therapies for PAH when appropriate, she said.

“I prescribe many and varied treatments for PAH, based on guidelines and a shared-decision model with patients, including Tracleer, which was the first oral therapy approved for PAH back in 2001,” McLaughlin said. “Many patients have done well on the drug for many years.”

She defended the payments from Actelion, saying that none were related to marketing and that physicians’ paid consulting with drugmakers is beneficial for drug development. Many of her reported payments from Actelion also were related to Opsumit, a PAH drug made by Actelion that was approved by the Food and Drug Administration in 2013.

“It’s in the best interest of clinical-care delivery for biomedical companies to be advised by the knowledgeable, experienced experts,” McLaughlin said. “I have treated PAH patients and have been involved in clinical trials in PAH for 20 years. My consulting is related to drug development and clinical trial design. All of my consulting engagements are disclosed to and approved by the University of Michigan.”

Actelion said in a written statement that payments to McLaughlin were for clinical research and scientific consulting work. “Only a portion of the payments in the CMS database went to Dr. McLaughlin personally,” according to the company. “The decision by physicians to use Tracleer, or any other drug for PAH, is based on their independent medical judgment as to what is best for their patient. Actelion does not provide incentives to physicians for prescriptions.”

Actelion made payments to other top physician prescribers as well. Eight of the 30 highest Medicare Part D prescribers in 2013 were listed for their prescribing of Tracleer, the patent for which expires this year. Five of those physicians received some type of consulting payment, speaking fee or general reimbursement from Actelion, according to Modern Healthcare’s analysis.

Worldwide sales of Tracleer totaled $1.68 billion in 2013, $445 million of which came from Medicare.

Another drugmaker that made significant payments in 2013 to top prescribers of its drug was Israel-based Teva Pharmaceutical Industries and its U.S. subsidiary. Fourteen Medicare providers billed at least $2 million for Copaxone, a costly multiple-sclerosis drug made by Teva. Half of those providers received honoraria or other
payments from Teva. “We value our ongoing collaboration and research partnerships with healthcare professionals,” Teva said in a written statement. “Industry support for medical education, clinical data and research allows for continued innovation that benefits patients.”

Copaxone’s global sales were $4.3 billion in 2013. The costs to Medicare represented about $1.1 billion of that total.

Experts say that while consumers generally view doctors and nurses as having high ethical standards, public perceptions of financial conflicts of interest have the potential to erode that trust. “Outliers can influence trust in the broader population,” said Stephanie Morain, a health policy ethicist at the Johns Hopkins Berman Institute of Bioethics.

On the other hand, a study published last year in the Journal of Law, Medicine & Ethics found that patients saw drug companies payments to doctors for consulting or speaking engagements as a sign that those doctors are recognized experts in their field.

Harvard’s Campbell said it’s “completely inappropriate” for academic physicians and department heads to do marketing work for drug companies. But he acknowledged that many consumers may see such payments as evidence of a physician’s “level of skill as a clinician and understanding what’s in the field.”

However, it’s less ethically defensible for physicians to take payments for marketing and promotional activities rather than for research because those activities generally don’t have any scientific purpose, Kesselheim said. His department has a policy that bars its members from entering personal consulting relationships with drug companies. While drug companies fund research studies, Kesselheim and his colleagues have full control over the results and their publication.

Nissen said the U.S. “desperately” needs a comparative effectiveness organization like the United Kingdom’s National Institute for Health and Care Excellence, which conducts binding national assessments of which drugs are the best and worst buys. That alone wouldn’t eliminate conflicts of interest, he said, but it could spur physicians to more closely analyze the value of the drugs they prescribe.

“I believe we need a vibrant pharmaceutical industry to develop products to save lives. It’s clearly appropriate to get a return on investment from R&D,” Nissen said. “But we are not doing a good job of balancing those competing priorities.”

Regulation

FDA overhaul bill moves ahead after funding deal

By Steven Ross Johnson

Sweeping legislation to overhaul the nation’s drug and device approval process and boost medical research funding raced ahead last week in the House of Representatives.

The House Energy and Commerce Committee voted unanimously Thursday to move the 21st Century Cures Act to the full House for consideration after lawmakers reached agreement on pay-fors for its estimated $13 billion cost over 10 years. “Every single member here on both sides of the aisle has something in this bill,” said committee chairman Fred Upton (R-Mich.).

The bill would provide more than $10 billion over five years to the National Institutes of Health, as well as $550 million in added funds to the Food and Drug Administration to help it handle the revised approval process.

Senate leaders plan to craft their own biomedical innovations bill, though they say it won’t be ready until the fall at the earliest.

Lawmakers were worried about potential cuts to Medicare and Medicaid to offset the bill’s costs. Instead, lawmakers agreed to fund the bill from the sale of crude oil from the Strategic Petroleum Reserve, as well as from limiting Medicaid rates for some durable medical equipment to Medicare rates.

The deal also would alter the timing of reinsurance payments to Medicare Part D prescription drug plans to reduce accrued interest. America’s Health Insurance Plans opposes that provision.

A congressional aide said on background that a detailed estimate of how much money each pay-for would generate will come in a few weeks.

Supporters say the Cures Act would speed life-saving innovations in drugs and devices. Critics argue that the bill would heighten the risk for patient harm by loosening approval standards and that it could increase healthcare spending for products of marginal value.

A key provision would allow the FDA to grant market approval for a drug based on early stage testing for safety and effectiveness.

Devicemakers would be able to apply for a “breakthrough designation” pathway for products that treat conditions where no alternative exists or that significantly improve on existing therapies.

The FDA also would be required to establish a process for the use of surrogate markers in clinical trials, cutting the time needed for getting results from drug trials.

A controversial proposal to lengthen market exclusivity for some new medications was significantly scaled back. In addition, language to tighten controls over the 340B program giving hospitals serving low-income and uninsured patients a discount on drugs was removed.