

IMPLEMENTING HEALTH REFORM

The Physician Payments Sunshine Act

The Physician Payments Sunshine Act, a provision of the Affordable Care Act, aims to bring transparency to the practice of pharmaceutical and device companies providing meals, gifts, and payments to physicians. It requires that these companies, as well as biologic manufacturers and medical suppliers, report any “payment or other transfer of value” of \$10 or greater to physicians and teaching hospitals. The manufacturer must report all payments to a single physician if they reach \$100 in aggregate value for a year. The Centers for Medicare and Medicaid Services released a proposed rule in December 2011 outlining how the disclosures would work. Drug and device manufacturers can hold off collecting information until the CMS issues a final rule later this year. The agency predicted that



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MR. COUKELL

the first reports required under the Physician Payments Sunshine Act will be publicly available by Sept. 30, 2013.

Allan Coukell, director of medical programs at The Pew Charitable Trusts in Washington, discusses the program's likely impact on physicians and patient care.

CLINICAL ENDOCRINOLOGY NEWS: What information would be reported and where would the public see it?

Mr. Coukell: The law creates a number of categories such as speakers bureaus, consulting, research, and so on. The act is comprehensive so any transfer of value must be reported. There are exceptions for drug samples as well as a provision that the reporting of payments for research can be delayed to protect commercial confidentiality. Companies do not have to report payments to physician employees. Information for the public would be available on a website.

CEN: Do physicians need to do anything to prepare for the implementation of this provision?

Mr. Coukell: They don't have to report anything. They have the option to review the reports during a 45-day window before they go public.

CEN: Will this type of public disclosure slow industry payments to physicians?

Mr. Coukell: No one knows. We may never know because the Sunshine Act exists in the larger context of some evolving industry models. Generally, payments go down during recessions and as drugs come off patent, and while there

are fewer heavily marketed blockbuster products. Also, we've had a trend in recent years of physicians being a bit less likely to see sales reps and a bit less likely to accept the lunches and gifts. There's no reason to think that research would go down. That's beneficial and will continue. We may see some of the smaller gifts, payments, and meals trail off, possibly because there's a cost to the company to track those items. However, there's nothing in the law that changes the fundamental business model for the industry.

CEN: What will be the likely effect of this regulation on prescribing and patient care in general?

Mr. Coukell: This is part of the larger context of a reevaluation by the medical profession of what constitutes an appropriate relationship between prescribers and the industry that markets products. Groups such as the Institute of Medicine and the Association of American Medical Colleges, leaders of the journals, a lot of high-profile academics, and professional societies are all saying we need to evaluate the extent of these relationships and their potential impact on care. Additionally, lot of medical schools and medical centers are instituting new industry-relations policies. The Sunshine Act brings some transparency to those relationships, but what will happen next is part of a larger overall shift. I do think there is something of a movement within the profession to have a little bit more of an arm's length relationship with the marketing department. Research collaboration, on the other hand, is clearly beneficial and will continue.

CEN: This provision has been touted as being good for patients. Is it good for physicians, too?

Mr. Coukell: Transparency is good for everyone. When the Institute of Medicine did its report on conflict of interest in 2009, this was one of its major recommendations and it was part of restoring trust in the profession. Having these relationships out in the open and having a healthy public dialogue is helpful. It's also a chance for the drug and device companies to be able to provide context to the payments. You may hear that a doctor gets a big payment, but is that going into his pocket or is it to cover the cost of tests or procedures for a clinical trial? Bringing some real substantive information to this is going to be beneficial to everybody. ■

ALLAN COUKELL oversees the *Pew Prescription Project*, which conducts nonpartisan research related to federal oversight of drug safety. He previously practiced as a clinical pharmacist in oncology and bone marrow transplant at Victoria Hospital and London Regional Cancer Center in London, Ontario.



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Diabetes Affects Income, Jobs

Adolescents and young adults with diabetes are 6% more likely to drop out of school than are those without the disease, according to Health Affairs report. The disparity is similar to the difference in dropout rates seen between young people who have attention deficit-hyperactivity disorder and those without ADHD, the study showed. Young adults with diabetes can expect to earn \$160,000 less in wages over their working lives, compared with adults without the condition, said the researchers at Yale University, New Haven, Conn. By age 30, a person with diabetes can expect to have a 10-percentage-point reduction in the likelihood of being employed — in part because of reduced education — and to earn \$6,000 less each year, compared with peers who do not have diabetes, the researchers said.

Nutrition Therapy for More

As more baby boomers enter Medicare, the Centers for Medicare and Medicaid Services should expand coverage of medical nutrition therapy (MNT) to chronic conditions such as hypertension and obesity, the Academy of Nutrition and Dietetics (formerly the American Dietetic Association) told the agency in a letter. “Chronic conditions can be controlled or treated with medical nutrition therapy, so it just makes sense to try to expand the Medicare beneficiary's access to these important services,” Marsha Schofield said in a news release. Currently, Medicare reimburses for MNT services when provided by registered dietitians for people who have diabetes and renal disease. The letter is in the January issue of the *Journal of the Academy of Nutrition and Dietetics*.

NDEP Gets New Chair

The National Diabetes Education Program has a new chair, Dr. John Buse of the University of North Carolina at Chapel Hill. He replaces Ms. Martha Funnell of the University of Michigan, Ann Arbor. Dr. Buse will focus on strengthening the program's outreach and engagement to reduce the burden of diabetes. “Our nation is facing a diabetes crisis,” He said in a news release. “The disease is affecting more people and at younger ages. The NDEP plays a unique role in bringing together diverse stakeholders to foster cooperation and collaboration to translate research-proven approaches to

prevention and therapy into action by patients, providers, and communities.” NDEP is a joint program of the National Institutes of Health and the Centers for Disease Control and Prevention.

NFL Should Test for hGH

Sen. John McCain (R-Ariz.) has asked the Senate's Committee on Commerce, Science, and Transportation to hold a hearing on human growth hormone (hGH) testing for players in the National Football League. Citing the NFL Players Association's “continued intransigence,” Sen. McCain wrote that “ridding sports of substances like hGH is essential to the integrity of athletic competition, enhances player health and safety, and sends important messages to young athletes.” His request includes a letter from the World Anti-Doping Agency. The NFL Players Association ratified a collective bargaining agreement in August 2011 to test NFL players for hGH. Sen. McCain said the association has “refused to implement the agreement,” and has “questioned the validity of the testing.”

NSF Funds Diabetes App

The National Science Foundation has awarded \$1.2 million to researchers at Worcester Polytechnic Institute to develop a smartphone application for people with advanced diabetes and foot ulcers. The 4-year project aims to create an app that integrates wirelessly with a personal glucose meter and scale, tracks and archives weight and blood sugar levels, and captures and analyzes photos of foot ulcers. “Nearly all the management of a person's diabetes is done by the patient, away from a doctor's office or clinic,” said Bengisu Tulu, Ph.D., one of the project's leaders. Such apps are part of the growing field of mobile health, or mHealth, and their effectiveness is yet to be shown through long-term studies.

Part D Cost-Sharing Grows

Medicare patients are spending more for their prescription drugs under Part D plans, in an analysis by consulting firm Avalere Health. The number of drugs covered by different plans varies, so patients who shop for a plan only by price may find that the drugs they need are not covered. Medicare Part D plans will increase their use of prior authorization and quantity limits for 2012 slightly, according to Avalere Health.

—Naseem S. Miller

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