POLICY & PRACTICE

Feds Launch Sickle Cell Campaign

The National Institute of Diabetes and Digestive and Kidney Diseases is spearheading a campaign to stress the importance of careful hemoglobin A_{1c} testing in people with diabetes who have sickle cell trait or similar blood disorders. "If you see a significant discrepancy between a patient's A_{1c} reading and the results of routine blood glucose monitoring, consider the possibility that your patient may have a hemoglobin variant and find out if your lab is using an accurate method to measure A_{1c}," Dr. Griffin P. Rodgers, NDDK director, said in a statement. In diabetes patients of African, Mediterranean, or Southeast Asian descent, several situations may raise suspicions of a hemoglobin variant, such as an HbA_{1c} test result that does not correlate with results of self-blood glucose monitoring, a result that radically differs from a previous test result after a change in lab methods, or a result higher than 15%. "In the United States, more than 3,000 labs rely on 20 different methods to measure A_{1c} in people with diabetes," Randie Little, Ph.D., who heads the National Glycohemoglobin Standardization Program, said in a statement. "However, six of these methods yield unreliable results in patients with sickle cell trait." More information for physicians and patients can be found at www.diabetes.niddk.nih.gov.

Part D Plans Not Tracking Costs

Medicare drug plans have not met all requirements for tracking out-of-pocket spending by beneficiaries in the Medicare Part D prescription drug program, according to a report from the Health and Human Services Department Office of Inspector General. Tracking out-of-pocket costs is needed to determine when each beneficiary has reached the required spending threshold at which Medicare's catastrophic drug coverage starts. "Implementing the program has been a large undertaking for [the Centers for Medicare and Medicaid Services], its contractors, and the private Part D plans," said HHS Inspector General Daniel Levinson in a statement. "[Medicare] should place more emphasis on conducting Part D oversight." The report found that 29% of Part D plans did not submit required information to the Centers for Medicare and Medicaid Services (CMS) on enrollees' additional drug coverage data. And 34% of Part D plans—covering nearly half of Part D enrollees—did not submit prescription drug event data to CMS in the required time frames. In addition, the limited oversight CMS has conducted so far on Part D plans' tracking of out-of-pocket costs relied on plans' self-reported data. And even then, about half of the plans were not in compliance with one or more of four CMS requirements in this area. The full report is available at www.oig.hhs.gov.

FDA Can't Fulfill Mission

Three members of the Food and Drug Administration's Science Board issued a damning report on the state of the agency, saying that "the agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." The authors wrote that the FDA has become weak and unable to fulfill its mission because of the increasing number of demands and an inability to respond because of a lack of resources. "FDA's inability to keep up with scientific advances means that American lives are at risk," wrote the panelists, adding that the agency can't fulfill its mission "without substantial and sustained additional appropriations." The report was written by Gail Cassell, Ph.D., vice president of scientific affairs at Eli Lilly & Co.; Dr. Allen D. Roses, Jefferson-Pilot Corp. Professor of Neurobiology and Genetics at Duke University; and Dr. Barbara J. McNeil, head of the health care policy department at Harvard Medical School. Members of the Coalition for a Stronger FDA and the FDA Alliance urged Congress to heed the report's warnings. "FDA can't improve its science, prepare for the future, or protect American consumers without significant additional resources," said coalition member Don Kennedy, Ph.D., a former FDA commissioner and editor in chief of the journal Science, in a statement.

Access Reduced by Cost

Forty million Americans can't get access to needed health care, and 20% said the main reason was because they could not afford the services, according to a report issued in December by the Centers for Disease Control and Prevention. *Health, United States, 2007*, is a compilation of pertinent data gathered by the CDC's National Center for Health Statistics. According to the report, in 2005, 1 in 10 people between the ages of 18 and 64 years reported that they had not been able to get prescription drugs in the past year because of the cost. Another 10% said they had delayed necessary medical care because of cost issues. The report also found that 30% of 18- to 24-year-olds were uninsured, and another 30% of that age group did not have a usual source of medical care. Ten percent of 45- to 64-year-olds did not have a usual source of care. The report highlighted some other age-specific data as well. For instance, about 70% of men and more than 80% of women over age 75 either had hypertension or were taking antihypertensives in 2001-2004, compared with about 35% of adults aged 45-54. And about 20% of 16- to 17-year-olds, and more than 40% of 18- to 25-year-olds reported binge alcohol use in 2005; 20% of the latter age group reported illicit drug use in the previous month.

DEA Accused of Electronic Stalling

The Drug Enforcement Administration, which investigates crimes involving illicit use of controlled substances, has been criticized for stalling implementation of a national electronic prescribing system for controlled substances. Sen. Sheldon Whitehouse (D-R.I.), speaking at a Senate Judiciary Committee hearing, faulted the DEA's tardiness in developing regulations for such a system and its reluctance to commit to a deadline for completing the regulations. Currently, doctors write prescriptions for controlled substances but can prescribe noncontrolled substances electronically. DEA official Joseph T. Rannazzisi told the committee that the agency is concerned an electronic system would be susceptible to abuse.

—Joyce Frieden

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Contact Andrea Lamonica
Elsevier-Clinical Endocrinology News
1120 Jensen Avenue
Mamaroneck, NY 10543
(800) 381-0569 • FAX: (914) 381-0573.
Email ad to: a.lamonica@elsevier.com