POLICY & PRACTICE

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FDA Drafts Transparency Rules

The Food and Drug Administration's Transparency Task Force has issued 21 draft proposals concerning public disclosure of FDA operations without compromising patents or companies' trade secrets. Part of the FDA's transparency initiative launched last summer, the proposals are aimed at helping consumers, stakeholders, and others understand how the agency makes decisions and enforces them. The FDA said that one of the draft proposals would support research into rare diseases by freeing the agency to discuss that a company has abandoned its application for an orphan drug. Once made public, this information could enable another drug manufacturer to pick up where the first one left off. The FDA will accept comments on the public disclosure policies until July 20.

Medical Home Service Expands

The American Academy of Family Physicians subsidiary TransforMED, which helps primary care physicians turn their practices into patient-centered medical homes, has launched a new product aimed at practices with four or fewer physicians. The Small Practice Package bundles the usual components of the product but streamlines the process of converting to medical home practice, the company said. The materials and individualized guidance can come strictly online for a cost of $1,250 per practice per quarter or include on-site assessments at $2,500 per practice per quarter. The TransforMED announcement said that the package will enable small practices to implement the patient-centered medical home model in 2 years.

Survey: Telehealth Improves Care

Eight of ten health care and information technology professionals believe telehealth technology will improve quality of care, especially for the aging population, according to a survey conducted for the technology company Intel, which develops telehealth devices. It surveyed top medical and IT executives at hospitals, clinics, home health organizations, disease management companies, and private payers. Challenges to the adoption of telehealth technology reside mainly in financial issues, such as reimbursement for services provided. More than two-thirds said that health care providers probably will implement telehealth technology if financial issues are resolved.

House Probes Home Gene Testing

Three key House lawmakers have launched an investigation into personal genetic testing kits being marketed directly to the public. The investigation, spearheaded by House Energy and Commerce Committee Chairman Henry A. Waxman (D-Calif.) and supported by Rep. Joe Barton (R-Tex.), Rep. Bart Stupak (D-Mich.), and Rep. Michael C. Burgess (R-Tex.), has targeted the companies 23andMe, Navigenics, and Pathway Genomics. The companies already offer their tests to consumers by phone or online, and Pathway is seeking to sell testing kits in retail locations, despite concerns from the scientific community about the accuracy of test results. In letters to the companies, the lawmakers said they want information on how the companies analyze test results and identify potential genetic risks, as well as how they collect, store, and process individual genetic samples collected from consumers.

Growth in Health Accounts

About 10 million Americans are now covered by high-deductible health insurance plans, which make them eligible to open health savings accounts. That's a 25% increase over total enrollment in early 2009, according to a report from the health insurance industry group America's Health Insurance Plans. The fastest-growing market for high-deductible health plans last year was among large groups, where such plans increased by 33%, the report said. The increase of high-deductible plans was 22% among small groups of insured people and 17% among those individually insured. States with the highest percentages of enrollment in high-deductible policies were Vermont, Minnesota, Colorado, Arkansas, Indiana, and Ohio.

Seniors Did Blow the Whistle

A program that uses volunteers to train senior citizens to identify fraud in the Medicare program recovered $76,176 in 2009 and saved Medicare, Medicaid, and individuals $214,060, but Administration on Aging grants to conduct the program totaled $9.3 million, according to a report from the Department of Health and Human Services Office of Inspector General. The 55 Senior Medicare Patrol Projects had a total of 4,444 active volunteers, who conducted more than 78,000 educational sessions and media and community outreach activities, the report said. As a result of these training sessions and events, the projects received more than 63,000 inquiries from seniors, of which nearly 1,000 were referred for further action, the report said. Since the Senior Medicare Patrol Projects program began in 1997, it has recovered nearly $4.6 million in Medicare funds, the report said, but the program may not be getting full credit for savings attributable to the volunteers' work because it can't account for savings from seniors scrutinizing their bills for fraud and abuse.

—Jane Anderson

Updated Stem Cell Policy Reflects NIH Oversight

BY DOUG BRUNK

An amended version of the National Academies' Guidelines for Human Embryonic Stem Cell Research takes into account the expanding role of the National Institutes of Health in overseeing the field.

Originally published in 2005, the amended guidelines were developed "to avoid complications, contradictions, and confusion," wrote the members of the National Academies' Human Embryonic Stem Cell Research Advisory Committee, led by R. Alta Charo, J.D., of the University of Wisconsin, Madison, and Richard O. Hynes, Ph.D., of the Howard Hughes Medical Institute and Massachusetts Institute of Technology, Cambridge, Mass.

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The updated version "recognizes the new and increased influence" of the NIH Guidelines on Human Stem Cell Research released in 2009, and "incorporates references to the NIH guidelines as appropriate."

Where there is complete overlap, the report continues, "the advisory committee recommends that the NIH guidelines supersede its own. Where there are gaps or limitations in the NIH guidelines, the advisory committee recommends continued adoption of its own guidelines."

The committee identified three areas in which non-NIH guidelines will continue to guide human embryonic stem (hES) cell research in the future. The first includes cell lines derived using nonfederal funds. "Because the continuing effect of the 'Dickey-Wicker' amendment means that derivation of hES cell lines cannot be supported by federal funds, such derivations will need continuing oversight outside the NIH guidelines," the report states.

The second area in which non-NIH guidelines will continue to guide the field includes hES cell lines derived from other sources, such as from embryos produced using in vitro fertilization for research purposes or by nuclear transfer. Currently, "only hES cell lines derived from excess IVF embryos initially produced for reproductive purposes are currently eligible for NIH funding," the report states.

A third area that will require oversight outside of the NIH, according to the report, includes experiments that mix human and animal cells not currently addressed by NIH guidelines.

The report also acknowledged certain areas of tension between NIH, the National Academies, and other guidelines on human stem cell research. For example, it noted that since the 2008 amendments to the National Academies' guidelines were issued, the ethics committee of the State of New York's Empire State Stem Cell Board adopted a resolution allowing New York State–funded stem cell researchers to compensate women who donate their oocytes directly and solely to research for the time, risk, and burden involved in donating.

"Amounts of compensation are to be comparable to those received by women in New York State for similar donations for reproductive purposes," the report notes. "Compensation may not be based upon number or quality of eggs, but should cover only time and burden. While this advisory committee acknowledges that the circumstances surrounding the issue of compensation to oocyte donors continues to evolve, it chose not to change the National Academies' Guidelines" and recognizes "that states and other entities may choose to set their own policies, as New York has done."

The committee also pointed out that its guidelines for consent of all gamete donors is not reflected in the 2009 NIH guidelines. "Further, a number of states and research institutions have declined to adopt this rule, given the lack of clear legal need for such consent from anonymous donors. The advisory committee also notes that the Food and Drug Administration's recent tissue transplant rules require screening of gamete donors except in cases involving sexually intimate partners. This suggests that stem cell lines made with donor (i.e., screened) gametes may be marginally safer for tissue transplants and may be more useable for FDA-regulated trials and therapies."

The committee, which chose to disband after completion of the current guidelines, called for an "ongoing neutral forum" in which stem cell issues can be discussed. "Perhaps most needed is a forum that could bring together key stakeholders—including federal, state, academic, patient, and industry organizations and institutions—for periodic meetings that would address topics of shared interest and concern to the broader stem cell research, regenerative medicine, and policy communities," they wrote.

The National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council are private, nonprofit organizations. They provide policy advice under a congressional charter granted to the National Academy of Sciences. Together, the four organizations are also known as the National Academies. ■

Disclosures: *Funding for the report was supported by the Ellison Medical Foundation, the Greenwall Foundation, and the Howard Hughes Medical Institute.*

A pdf of the report can be downloaded at www.nap.edu/catalog/12923.html.