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The Genomics And Personalized Medicine Act Of 2010

Law360, New York (August 02, 2010) -- In the wake of massive health care reform that included an emphasis on preventive care and treatment outcomes, recent legislation introduced in Congress revisits the promise of personalized medicine. Personalized health care offers the possibility of better treatment, better outcomes and ultimately reduced costs as the individual receives the treatment (or preventive strategy) that is most likely to be effective for him or her.

The emergence and importance of the initiative can be gleaned from the U.S. Department of Health and Human Services, which has a long-standing Personalized Health Care Initiative. A section on the HHS website is solely devoted to the topic:

"Personalized health care describes medical practices that are targeted to individuals based on their specific genetic code in order to provide a tailored approach. These practices use preventive, diagnostic, and therapeutic interventions that are based on genetic tests and family history information. The goal of personalized health care is to improve health outcomes and the health care delivery system, as well as the quality of life of patients everywhere."

While the concept of personalized health care has had long-standing government support, institutional barriers (e.g., limitations on product reimbursement, unclear regulatory requirements and occasional government redundancies) have resulted in relatively slow progress toward what seems like a natural pathway to better health care and ultimately lower costs.

On May 28, Reps. Patrick J. Kennedy, D-R.I., and Anna Eshoo, D-Calif., introduced H.R. 5440, the Genomics and Personalized Medicine Act of 2010. A similar bill was previously introduced by then-Sen. Barack Obama, D-Ill., during the 110th Congress. The overall goal of the act is to realize the promise of personalized medicine by expanding and accelerating genomics research, improving the accuracy of disease diagnosis, increasing the safety of drugs and identifying novel treatments.

The bill sets forth several initiatives, discussed below.

Office of Personalized Healthcare

The bill would establish an Office of Personalized Healthcare within the Office of the HHS Secretary to coordinate the activities related to genomics and personalized medicine of HHS and other relevant federal agencies, as well as private and other public entities. The office would oversee selected initiatives to realize the overall goals of the act, such as the development of a long-term strategic plan to advance personalized medicine.

Among other things, the office would be expected to coordinate efforts and prepare recommendations for a clear delineation between the roles and responsibilities of the U.S. Food and Drug Administration and the Centers for Medicare & Medicaid Services in the regulation and enforcement of products used for personalized medicine, including laboratory-developed tests, and the resolution of any conflicts or redundancies between the two agencies

Expansion and Acceleration of Research for Genomics and Personalized Medicine

If enacted, the secretary will be able to award grants to entities to increase and accelerate research and programs to collect, evaluate and disseminate genetic and genomic data. In addition, the director of the National Institutes of Health, in consultation with the director of the Centers for Disease Control and Prevention, would establish and maintain a national biobank to advance the field of personalized medicine.

Committee on the Evaluation of Genomic Applications in Practice and Prevention

The act would create an advisory committee to analyze current literature to expand and accelerate knowledge related to the clinical validity and utility of genomics and personalized medicine. The committee will, for example, develop or adapt processes for recognizing promising new products for the use of personalized medicine.

Realizing the Potential of Personalized Medicine

The act calls for the study of barriers to the implementation of personalized medicine through various avenues. For example, the secretary would:

— Establish a committee to carry out a comparative analysis of laboratory requirements to the end of reducing redundancy.

— Establish a committee including representatives of the private sector to examine barriers in research, regulation and reimbursement for medical product development for personalized medicine.

— Enter into an agreement with the Institute of Medicine to provide an independent, external review of the current billing, coverage and reimbursement methods for products and services used for personalized medicine.

The act also encourages the development of companion diagnostic tests and products in connection with the submission of investigational new drug products. Additionally, the act would implement a review and analysis of the public health impact of direct-to-consumer marketing and access to products used for personalized medicine.

Conclusion

Given the importance of the federal government as a leader in realizing the promise of personalized medicine, legislation such as that proposed in the act is critical to institutionalize and improve federal support. Personalized medicine offers viable options that are consistent with several themes espoused by the government as part of recent efforts to revive the health care system, including preventive care, a focus on health care outcomes, comparative effectiveness research and continuing concerns about the cost of health care.

While the act is likely to face time pressures in receiving full consideration this year from a Congress already exhausted by several major pieces of legislation, the act is important in retaining the focus on the promise of, and current barriers to, personalized health care.

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