

What Obama's Precision Medicine Initiative May Mean for Risk Management

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Precision medicine is no longer on the fringe of the medical community. To the contrary, it is quickly becoming one of the fastest growing areas in medicine and is touted by many as the future of medical treatment. President Obama recently held a White House Precision Medicine Initiative (PMI) Summit, during which the process for implementing the large-scale initiative was unveiled. The PMI will begin gathering data from one million individuals nationwide, an effort that will span the next three to four years. Study participants will provide as much health information as they like and data-sharing will be open to both scientists and participants.

The National Institute of Health (NIH) is charged with the challenging task of building this database as part of the PMI Cohort Program. In a press release, the Director of the NIH, Francis S. Collins, M.D., Ph.D., stated that this "will be a bold initiative unlike any other." A central institutional review board has been established and both a data coordinating center and biobank, for the storage of tissue samples, are expected to be established this summer. The institutional review board is comprised of medical experts from several fields, including mHealth, bioinformatics, health disparities, epidemiology, genomics, and environmental health. The board will be responsible for overseeing and reviewing the Cohort Program. The National Cancer Institute, a recipient of \$70 million in PMI funding, is expanding its research into precision oncology. This means an increase in precision medicine clinical trials and the establishment of a national database for genomic information derived from tumors, including clinical response data and outcome information for scientists, healthcare providers, and patients.

So what does this all mean for risk managers in healthcare institutions throughout the country, especially those who plan on participating in the PMI? First, precision medicine is moving into every facet of medicine, including not only medical illness treatment, but preventative medicine. The Cohort database is expected to be used not only to identify tailored treatments for specific diseases, but also to provide environmental and lifestyle data to be used in the early identification and prevention of dormant or developing illnesses. Thus, as data becomes more accessible to medical providers, the standard of care with respect to routine examinations may very well evolve over time and require a review of the latest pertinent data.

A second risk management issue to consider is data security. Hospitals and research facilities will be storing vast amounts of highly sensitive data, including clinical and insurance claims data, survey and demographic data, genomic and other biospecimen-derived data, and mobile, implantable, or other equipment or device data, for hundreds of thousands of individuals who are likely not patients of those particular facilities. The White House issued a draft PMI Data Security Policy Principles and Framework for comment, which includes a recommendation that each participating organization identify a "governance body" that will carry out a data security plan. While some institutions may already have such a body in place, participating in the PMI may mean revisions to existing internal policies and additional resources expended on data security.

A third consideration is staffing. Any large health care facility planning on employing precision medicine should consider retaining physicians with biomedical informatics degrees. It will likely be important for hospitals and medical facilities to have such physicians on staff to assist in interpreting and transforming large quantities of data into practical clinical solutions.

The development of new personalized treatments, especially in the field of oncology, is exciting and showcases amazing achievements in both the medical and technological fields. It is important for all participants involved to keep abreast of new developments in

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precision medicine and to make sure all facets of this new treatment paradigm, including risk management, are considered as this bold initiative proceeds.

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