Proposed Amendments to Maryland HB 259

The requirements of Maryland HB 259 could jeopardize biopharmaceutical companies' ability to conduct clinical trials and biomedical research in Maryland. HB 259 would require private entities to delete all biometric identifiers within a 1 year of the entity's last interaction with an individual, or when the initial purpose for their collection has been satisfied, or within 30 days of receiving a request to delete an individual's biometric identifiers, whichever is sooner. The current definition of "biometric identifier" may include information that is used in clinical trials or other biomedical research. The requirement to delete this information—by a specific deadline or upon request—may conflict with researchers' legal obligations to maintain and report information collected for biomedical research. For this reason, we are seeking the proposed amendments that would exclude entities conducting biomedical research in accordance with recognized research standards, exclude information that is collected or used for research, in accordance with certain federally or internationally recognized research standards, from the definition of "biometric identifier," and include a definition for "research."

Research involving human subjects already applies recognized and accepted research standards that incorporate ethics and privacy principles, including an informed consent process. Providing an exemption for entities conducting biomedical research will help to avoid any unintended consequences that may impede the development of critical therapies and medicines by recognizing that biomedical research, conducted in accordance with existing ethical frameworks, already safeguards individuals' decision-making with regard to their information, including biometric data.

In addition, we are seeking to an amendment to define research, as defined under the federal Health Insurance Portability and Accountability Act (HIPAA), that would expressly clarify that research includes clinical trials, but also includes critical observational research outside of a clinical setting which can reflect diverse patients in real world practice settings. This type of research can lead to more efficient drug development programs, provide more robust information about the benefits and risks of new medicines, and can ultimately lead to quicker access to innovative, safe, and effective medicines for patients. This type of research also may help to understand how treatments work in a broader patient population – such as those who may not be able to participate in trials because of comorbidities or because they live far from a clinical trial site.

PROPOSED AMENDMENTS

Add to 14-4401(E)(2):

(V) AN ENTITY, OR AN AFFILIATE OF AN ENTITY, CONDUCTING RESEARCH IN COMPLIANCE WITH THE FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS, 45 C.F.R. PART 46, THE GOOD CLINICAL PRACTICE GUIDELINES ISSUED BY THE INTERNATIONAL COUNCIL FOR HARMONISATION, OR THE UNITED STATES FOOD AND DRUG ADMINISTRATION PROTECTION OF HUMAN SUBJECTS UNDER 21 C.F.R. PARTS 50 AND 56.

Add to 14-4401 as new (G):

"RESEARCH" MEANS A SYSTEMATIC INVESTIGATION, INCLUDING RESEARCH DEVELOPMENT, TESTING, AND EVALUATION, DESIGNED TO DEVELOP OR CONTRIBUTE TO GENERALIZABLE KNOWLEDGE.

Add to 14-4401(B)(2):

(IX) INFORMATION, HUMAN BIOLOGICAL SAMPLES, IMAGES, OR FILMS COLLECTED, USED, OR DISCLOSED IN THE CONTEXT OF RESEARCH CONDUCTED IN ACCORDANCE WITH THE FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS, 45 C.F.R. PART 46, THE GOOD CLINICAL PRACTICE GUIDELINES ISSUED BY THE INTERNATIONAL COUNCIL FOR HARMONISATION, OR THE UNITED STATES FOOD AND DRUG ADMINISTRATION PROTECTION OF HUMAN SUBJECTS UNDER 21 C.F.R. PARTS 50 AND 56.