



Archived Policy Statement

Genetic Alliance supports patient access to laboratory test results

Comments regarding CMS-2319-P

Genetic Alliance appreciates this opportunity to provide comments on the proposed changes to the CLIA and HIPAA privacy rule. Genetic Alliance is the world's leading nonprofit health advocacy organization committed to transforming health through genetics. Our network includes more than 1,000 disease-specific advocacy organizations as well as thousands of universities, private companies, government agencies and public policy organizations. Genetic Alliance is committed to enabling informed decision-making and actively supports programs and policies that improve access to information.

We support the proposed amendments to the CLIA and HIPAA privacy rule announced by the Department of Health and Human Services, providing patient access to laboratory test results. We believe that each individual has the right to results from health care and research activities in which they have participated. Allowing patients direct access to their laboratory test results will enable them to play more active roles in their healthcare decision-making. Access to this information can help patients better understand their condition, ask the right questions, and ultimately receive better care. Returning results directly to the patient may increase efficiencies and reduce the chance of patients not being informed of their test results. Patients would also have a copy of these records for future reference.

When laboratory test results are returned, it is imperative that standard laboratory privacy and authentication processes are followed. Laboratories must also have systems in place to ensure the ordering physician receives not only the test results but also information about patient receipt of results. We recognize that some test results (e.g. genetic tests) contain complex information, and counseling by an appropriate medical professional on how to interpret these results is warranted. Follow-up with a medical professional will also be necessary to develop a treatment plan.

Thank you for this opportunity to submit our comments. We would be happy to provide additional information if that would be useful to the Department.