Feds Issue Rules for Use of Genetic Information by Insurers

BY MARY ELLEN SCHNEIDER

The federal government has issued rules spelling out how it intends to police the use of genetic information by health plans. The regulations bar health insurers from increasing premiums or denying enrollment based on genetic information. The regulations implement certain provisions of the Genetic Information Nondiscrimination Act (GINA), which was signed into law by President Bush in May 2008.

Beefing up consumer protections for genetic information should help accelerate progress in genetic testing and research, said Health and Human Services secretary Kathleen Sebelius. “Consumer confidence in genetic testing can now grow and help researchers get a better handle on the genetic basis of diseases,” Ms. Sebelius said in a statement. “Genetic testing will encourage the early diagnosis and treatment of certain diseases while allowing scientists to develop new medicines, treatments, and therapies.”

In an important rule, federal officials should provide details on how health plans can obtain and use genetic information. The regulation generally bars health plans from increasing premiums based on genetic information. They also cannot request, or even request, that individuals of family members undergo genetic testing. And health plans cannot request, require, or purchase genetic information at any time for underwriting purposes, or prior to or in connection with enrollment.

Although the rule bars insurers from charging its members more based on genetic information, it doesn’t limit them from doing so because of the manifestation of a disease. However, a health plan can’t use the manifestation of a disease in one of its members as genetic information for a family member and raise their premiums, according to the interim final rule.

The rule does allow plans to request limited genetic information if it’s necessary to determine the “medical appropriateness” of a certain treatment.

Plans also can request that individuals participate in research in which genetic testing will be conducted. However, none of the genetic information collected during that research can be used for underwriting purposes.

The interim final rule goes into effect 60 days after publication in the Federal Register. HHS officials also issued a proposed rule that would modify the Health Insurance Portability and Accountability Act (HIPAA) to comply with the provisions of GINA.

Like the GINA rule, the HIPAA rule bars health plans from using and disclosing genetic information for underwriting purposes. However, because HIPAA applies more broadly, the prohibition in the proposed rule also affects employee welfare benefit plans and long-term care policies. It would exclude nursing home fixed indemnity policies.

If the proposed rule is finalized, then plans would have 180 days to comply with the provisions.