DEPARTMENT OF HEALTH AND HUMAN SERVICES

Delegation of Authorities

Notice is hereby given that I have delegated to the Administrator, Centers for Medicare & Medicaid Services (CMS), and the Commissioner, Food and Drug Administration (FDA), with authority to re-delegate, the authorities vested in the Secretary of the Department of Health and Human Services under Section 6004 of the Patient Protection and Affordable Care Act, Public Law 111–148, which adds Section 1128H [42 U.S.C. 1320a–7i] to the Social Security Act.

I hereby delegate to CMS the authority vested in the Secretary to issue guidance and take other appropriate actions, to the extent that Section 1128H [42 U.S.C. 1320a–7i] relates to Titles XVIII (Medicare), XIX (Medicaid), or XXI (State Children’s Health Insurance Program) of the Social Security Act.

I hereby delegate to FDA all other authority vested in the Secretary under Section 1128H [42 U.S.C. 1320a–7i]. This shall include, but is not limited to, issuing guidance and taking other appropriate action to the extent that Section 1128H [42 U.S.C. 1320a–7i] relates to Section 503 of the Federal Food, Drug, and Cosmetic Act; identifying the information to be collected as allowed by Sections 1128H(a)(1)(B) [42 U.S.C. 1320a–7i(a)(1)(B)] and 1128H(a)(2)(B) [42 U.S.C. 1320a–7i(a)(2)(B)]; and generally, with respect to the information to be submitted under Section 1128H(a) [42 U.S.C. 1320a–7i(a)], issuing guidance and taking other appropriate action to identify the information to be submitted and the manner of submission, and overseeing and making arrangements for the collection, maintenance, and availability of such information.

This delegation shall be exercised in accordance with the Department’s applicable policies, procedures, and guidelines.

I hereby affirm and ratify any actions taken by the Administrator, CMS, the Commissioner, FDA, or other CMS and FDA officials, which involve the exercise of these authorities prior to the effective date of this delegation.

This delegation of authorities is effective upon date of signature.

Authority: 44 U.S.C. 3101.

Dated: September 30, 2011.

Kathleen Sebelius,
Secretary of Health and Human Services.