



1399 New York Ave, NW, Suite 300
Washington, DC 20005
Phone: (202) 296-7272
Fax: (202) 296-7290

October 11, 2011

Kathleen Sebelius
Secretary
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850
VIA ELECTRONIC DELIVERY

Re: Summary of Benefits and Coverage and the Uniform Glossary (CMS—9982—P)

Dear Secretary Sebelius:

Genentech is writing to provide comments in response to the proposed rule entitled, "Summary of Benefits and Coverage and the Uniform Glossary," published by the Departments of the Treasury, Labor, and Health and Human Services (Departments) in the *Federal Register* on August 22, 2011.¹

Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. Our products are used by Americans of all ages, ethnicities, and income levels. Access to, and costs associated with, these products is important to individuals comparing options among group health plans and health insurance in the individual market.

In the comments below, we express support for the transparency afforded by the implementation of a standardized summary of benefits and coverage (SBC) and uniform glossary, and emphasize some considerations to ensure timely access to important coverage information by individuals of different ages, ethnicities, and income levels. Finally, we acknowledge the operational challenges these proposed regulations impose on the insurance industry.

The Affordable Care Act adds Section 2715 to the Public Health Services Act (PHS Act) directing the Departments to develop standards for use by a group health plan and a health insurance issuer in compiling and providing an SBC that "accurately describes the benefits and coverage

¹ 76 Federal Register 52442–52475, published August 22, 2011, available at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-22/pdf/2011-21193.pdf>, last accessed September 22, 2011.

under the applicable plan or coverage.²” Section 2715(b)(3) further specifies that the SBC include “Uniform definitions of standard insurance terms and medical terms so that consumers may compare health coverage and understand the terms of (or exceptions to) their coverage.” Genentech supports transparency in the health insurance marketplace and efforts such as this to promote consistent, easily understood, and accessible information to inform health care choices. This is particularly important as it relates to patients’ cost sharing responsibility for services and drugs, as this is a key determinant of what plan is best suited to an individual given his or her personal characteristics and likelihood of using different volumes and/or types of health care services and products. Understanding the language and terms used in the SBC, which will be facilitated through the use of a uniform glossary, will promote informed healthcare choices by improving transparency and patient understanding.

PHS Act section 2715(b)(3) generally outlines nine content elements that must be included in the SBC, with examples such as uniform definitions of standard insurance terms (the uniform glossary); description of coverage, including cost sharing, for each category of benefits; and contact information about who to call with questions³. As described by the Departments in the proposed rule, the National Association of Insurance Commissioners (NAIC), with whom the Departments were directed to consult in the drafting of the proposed rule, went beyond those statutorily required content elements to include four additional recommended elements. One proposed additional element would require: “for plans and issuers that maintain a prescription drug formulary, an Internet address where an individual may find more information about the prescription drug coverage under the plan or coverage.⁴” Genentech fully supports the inclusion of this content element and urges the Departments to retain this additional content in the final rule. While it is not statutorily required, it is central to the concept of sharing information upon which consumers will select their health coverage plan. Information about formularies and associated cost sharing for drugs is required for individuals considering enrollment under Medicare Part D and Medicare Advantage⁵; as the Departments have proposed, it should be similarly available to enrollees or potential enrollees in group or private health insurance plans. While information about drug formularies may be readily available to plan enrollees, it can be more difficult to find prior to plan enrollment when making comparisons, particularly in the individual market. Having consistent information readily available prior to enrollment is critical to consumers' decision making process.

In addition to drug formulary information, Genentech urges the Departments to ensure that information about prior authorization requirements be made available to consumers. Potential enrollees who know they will be seeking physician services, such as infusion of cancer drugs, that may be subject to prior authorization or other utilization management requirements, should be able to compare plans based on their utilization management requirements, timelines, and appeal processes. In the individual market, there exists substantial variation across states in the disclosure of prior authorization requirements, with some limiting disclosure to current enrollees and others only requiring disclosure to the managed care segment of the market. To arm consumers with the full range of information they need to make informed decisions about their health care, Genentech urges the Departments to utilize the SBC to

² 76 Federal Register at 52443.

³ 76 Federal Register at 52446.

⁴ *Ibid.*

⁵ 42 CFR § 423.128(a)

consistently describe prior authorization requirements and the services and products to which they will apply.

In the language quoted above on access to formulary information, the SBC as proposed would provide an "Internet address" where individuals could find such information. While Genentech supports making the information about formularies and also prior authorization available on the internet, we are concerned that limiting the source of this information to an Internet address is not adequate. Seniors and low-income individuals may face challenges with Internet accessibility or capability, and access to paper copies should be available upon request and in a timely manner. A 2005 study by the Kaiser Family Foundation found that less than a third (31%) of seniors (age 65 and older) had ever gone online⁶. While they also found that the next generation of seniors (those age 50-64) were going online at a higher rate (70%), these figures show a sizeable portion of this segment of the population requiring information in formats other than the Internet. Cultural and linguistic appropriateness are also critically important for these groups, as well as minority populations, and we support the Departments' explicit consideration of these elements in the proposed rule.

Finally, Genentech acknowledges that the requirements associated with the SBC impose tremendous operational challenges on the insurance industry. We understand the wide variety of products provided by some insurers, and the imminent need to standardize and frequently update documents numbering from the hundreds to tens of thousands is daunting. We urge the Departments to consider these operational challenges and the insurance industry's suggestions for addressing them carefully; and to streamline the process to the extent possible without compromising the goal of improving access to information in the marketplace.

Genentech appreciates the opportunity to comment on the proposed rule. If you have any questions regarding our comments, please do not hesitate to contact Stephanie Dyson, Senior Director for Government Affairs, at 202-296-7272 or via email at dyson.stephanie@gene.com.

Sincerely,

A handwritten signature in black ink that reads "Evan L. Morris". The signature is written in a cursive, flowing style.

Evan L. Morris, Esq.
Vice President, Government Affairs
Genentech Inc.

⁶ Kaiser Family Foundation. eHealth and the Elderly: How Seniors Use the Internet for Health. Available online at <http://www.kff.org/entmedia/entmedia011205pkg.cfm>. Last accessed September 28, 2011.