



August 27, 2010

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9994-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

By Electronic Mail

**Re: Patient Protection and Affordable Care Act:
Preexisting Condition Exclusions, Lifetime and
Annual Limits, Rescissions, and Patient Protections**

Dear Sir or Madame:

Bayer Healthcare LLC ("Bayer") thanks the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury ("the Agencies") for their continued efforts to ensure that individuals have access to high quality health insurance coverage under the provisions of the Patient Protection and Affordable Care Act ("PPACA").¹ We appreciate this opportunity to comment on the Interim Final Rules regarding the PPACA: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections (hereinafter "Interim Final Rules").²

For more than 100 years, Bayer has been an active participant in the healthcare industry by innovating high-quality drugs, biologicals, and medical devices that have helped patients lead healthier lives. Our research and business activities are focused on a number of specialized areas of healthcare, many of which involve the management of chronic diseases: hematology / cardiology, oncology, diabetes, primary care, specialized therapeutics, diagnostic imaging and women's healthcare. A significant number of our patients suffer from chronic conditions. Accordingly, we present the following comments, in summary, for your consideration:

- **Support for Prohibition on Preexisting Condition Exclusions:** Bayer strongly supports the Agencies'

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¹ Patient Protection and Affordable Care Act, Pub. L. 111-148 (2010).

² 75 Fed. Reg. 37188 (June 28, 2010).

actions in implementing the PPACA's prohibitions on preexisting condition exclusions. We commend the Agencies for expanding the definition of "preexisting condition exclusion" to include denials of coverage.

- **Definition Needed of "Essential Health Benefit":** With regard to annual and lifetime dollar value coverage limits, the Agencies declined to provide a specific definition of "essential health benefit." Defining "essential health benefit" is critical in order to give substance and meaning to the annual and lifetime limits prohibitions as Congress intended. We believe the Agencies must adopt a specific definition in the final regulations and allow stakeholders to comment on that definition.
- **Restricted Annual Limits are Too Low and Based on Incomplete Data:** The restricted annual coverage limits set by the Interim Final Rules are too low to ensure that access to needed services is made available, as required by the PPACA. In addition, the data available on the number of persons whose healthcare costs are likely to exceed such annual limits are inadequate to make reliable conclusions. We believe that the Agencies must increase the restricted annual limits until more data is available.
- **Rigorous Standards Needed for Waiver of Restricted Annual Limits:** The proposed waiver program is not expressly permitted by the PPACA; however, to the extent the Agencies decide to move forward with the waiver program, rigorous standards are needed in order to prevent abuse and ensure beneficiary access to critical services.
- **Allowing Complete Exclusions of Benefits Instead of Annual or Lifetime Limits Not Permitted by Congress:** The Interim Final Rules do not prevent a plan or issuer from excluding all benefits for a particular condition. This provision will most likely lead to less coverage for individuals with the most serious chronic conditions, and therefore runs counter to the purpose of the statute and Congress' intent.

Moreover, implementing such a provision exceeds the Secretaries' authority under the PPACA.

- **Support of Reenrollment Opportunity:** Bayer commends the Agencies for providing an opportunity for individuals to reenroll for coverage that was denied due to the applicability of a lifetime limit. However, there are a number of opportunities for clarification regarding the reenrollment standards.
- **Health Reimbursement Arrangements (“HRAs”):** The Agencies specifically requested comments on the application of annual limits to stand-alone HRAs which are not retiree-only plans. Bayer suggests that the same standards apply to such plans as apply to group health plans and health insurance issuers offering group or individual health insurance coverage.
- **Support for Prohibition of Rescissions:** Bayer strongly supports the Agencies' implementation of the rescission prohibition and commends the Agencies for their efforts in this area.
- **Support for Patient Protections:** Bayer supports the provisions of the Interim Final Rules providing for patient protections and commends the Agencies for implementing these important rules.

These comments are discussed in further detail below.

I. Support for Prohibition on Preexisting Condition Exclusions

Bayer strongly supports the Agencies' actions in implementing the PPACA's prohibitions on preexisting condition exclusions. Prior to healthcare reform, patients with chronic illnesses, such as cancer and diabetes, were often excluded from insurance coverage and suffered severe financial hardship. We commend the Agencies for swiftly promulgating regulations which will help to protect America's most vulnerable patient populations.

Bayer particularly commends the Agencies for expanding the definition of “preexisting condition exclusion” to include not just a limitation or exclusion of benefits, but also a denial of coverage. This important change will help to ensure that Congress' intent to provide access to coverage for individuals with preexisting conditions will be carried out.

While Bayer understands that the 2014 effective date for the preexisting condition exclusion was set by Congress, Bayer is concerned that individuals with the most serious medical conditions will continue to be denied healthcare coverage until these provisions take effect in 2014. We understand that the federally run high-risk pool will provide access to insurance for uninsured individuals with a preexisting condition until the preexisting condition exclusion prohibition takes effect in 2014. However, we would like to note that in order to make this high-risk pool program meaningful, the benefits provided under the high-risk program, and ultimately the Interim Final Rules, must ensure that the sickest patient populations receive adequate services to cover their medical needs.

II. Definition Needed of “Essential Health Benefit”

Effective for plan years beginning on or after September 23, 2010, the PPACA prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from establishing lifetime or annual dollar value limits on coverage of “essential health benefits.”³ Section 1302(b) of the PPACA defines general categories of “essential health benefits,” but defers to the Secretary to define the specific benefits included in each category.

In the Interim Final Rules, the Agencies declined to provide a more specific definition of “essential health benefits.” Rather, the Interim Final Rules simply cross-reference the general definition provided in the PPACA. For plan years beginning before the issuance of more specific regulations defining “essential health benefits,” the Agencies propose to take into account “good faith efforts” to comply with a “reasonable interpretation” of the term.

While Bayer strongly supports the Agencies’ efforts in implementing prohibitions against annual and lifetime limits, it is critical that a more specific definition of “essential health benefits” be provided in order to make these prohibitions meaningful. Without a more specific definition of “essential health benefits,” this important part of the statute is rendered meaningless. There is a financial incentive for health insurers to define “essential health benefits” narrowly and continue to limit benefits which are critical to many Americans.

The impact of the Interim Final Rules is further compromised by the highly permissive standard provided for health insurers. Under the Interim Final Rules, plans are not even required to comply with a “reasonable interpretation” of the term “essential health benefits”; rather, they are only required to comply with the less stringent standard of making a “good faith effort” to comply with a reasonable interpretation. Such a loose standard will almost certainly result in many Americans being denied coverage. Individuals who exceed lifetime or annual limits are often those with very serious medical problems that require expensive treatment and frequently face severe financial difficulty, or lack of access to care once those limits have been exceeded. It is this population of patients who are the intended beneficiaries of the lifetime and annual limits provisions, and in order for the Agencies’ important actions to have teeth, the definition and standards regarding “essential health benefits” must be more specific and more stringent.

³ PPACA §§ 1001(5) and 10101.

Accordingly, we strongly recommend that the Agencies include the following as “essential health benefits”: chronic disease management, such as diabetes, diabetes self-management training, cancer screenings and related treatment, heart disease and hypertension treatments, treatments for multiple sclerosis, hemophilia treatments, utilization of remote monitoring devices (telehealth devices), access to reproductive health products, antibiotics, and radiological procedures (including contrast agents and radiopharmaceuticals).

III. Restricted Annual Limits are Too Low and Based on Incomplete Data

While the PPACA permits the Secretary to determine “restricted annual limits” for plan years prior to January 1, 2014, the statute requires that the Secretary ensure that access to needed services is made available with a minimal impact on premiums. The restricted annual limits set in the Interim Final Rules are too low to adequately ensure access as required by this Congressional mandate.

As discussed above, the PPACA generally prohibits group health plans and health insurance issuers offering group or individual health insurance from establishing annual lifetime dollar limits on coverage of “essential health benefits” beginning in 2014. For plan years beginning prior to January 1, 2014, however, the PPACA permits plans to impose “restricted annual limits,” as defined by the Secretary. Pursuant to this statutory provision, the Agencies have provided that for plan years beginning on or after September 23, 2010 but before September 23, 2011, plans may continue to impose annual limits as low as \$750,000; for plan years beginning on or after September 23, 2011 but before September 23, 2012, plans may impose limits of \$1,250,000; and for plan years beginning on or after September 23, 2012 but before January 1, 2014, plans may impose limits of \$2,000,000.

However, the data available on the number of persons whose healthcare costs are likely to exceed such annual limits are inadequate to make reliable conclusions. The Agencies admit that there “are scant data on annual limits on which to base this impact analysis.”⁴ The data on which the Agencies rely to estimate the number of persons whose healthcare costs are expected to exceed annual limits is based on a study of the “insured population.” As Congress has recognized through its implementation of healthcare reform laws, the “insured population” likely excludes many of the sickest Americans with the most costly health problems who are currently uninsured. As these individuals may become increasingly insured under the new laws, the data used by the Agencies underestimates the number of individuals who would be affected by these restricted annual limits. The low limits set by the Agencies will likely continue to exclude the sickest individuals with the highest drug costs, contrary to Congress’ intent.

For example, patients suffering with severe hemophilia typically incur extremely high healthcare costs associated with managing their disease, often reaching \$500,000 or more. A few hospitalizations or trips to the emergency room could bring such patients dangerously

⁴ 75 Fed. Reg. at 37203.

close to the \$750,000 limit proposed for 2011. For these patients, exceeding annual limits could compromise their access to care and have a devastating financial impact on both the patients and their families.

As such, we request that the Agencies increase the restricted annual limits to at least \$2,000,000 per year until more data is available in order to ensure that, as intended by Congress, the sickest Americans continue to have access to healthcare coverage.

IV. Rigorous Standards Needed for Waiver of Restricted Annual Limits

The Interim Final Rules permit the Secretary of Health and Human Services (“HHS”) to establish a program under which the restricted annual limits may be waived by a plan if compliance would result in a “significant decrease in access to benefits or a significant increase in premiums.”⁵ This waiver program is not expressly authorized by the PPACA. To the extent the Agencies decide to move forward with the proposed program, rigorous standards are needed in order to prevent abuse and ensure beneficiary access to critical services.

The Agencies have indicated that additional guidance will be issued regarding the scope and process for applying for a waiver under this program. We strongly urge HHS to ensure that such waivers are issued in appropriate circumstances. While Bayer applauds the Agencies for seeking to ensure access to benefits and reasonable premiums for beneficiaries, insurers will likely attempt to use this waiver program proposed by the Interim Final Rules to try to avoid compliance with the restricted annual limits imposed by the Agencies.

In issuing additional guidance on the waiver program, we urge HHS to set rigorous standards for insurers to justify any potential increase in premiums as a result of the imposition of restricted annual limits. Section 10101 of the PPACA provides that for plan years beginning prior to January 1, 2014, plans and issuers

may only establish a restricted annual limit on the dollar value of benefits for any participant or beneficiary with respect to the scope of benefits that are essential health benefits under section 1302(b) of the [PPACA], as determined by the Secretary. In defining the term ‘restricted annual limit’ for purposes of the preceding sentence, the Secretary shall ensure that access to needed services is made available with a minimal impact on premiums.⁶

Thus, we strongly urge HHS to set rigorous standards for insurers to justify any increases in premiums that may result from compliance with annual limits. It is imperative that the waiver program not be used as a mechanism for non-compliance with the Congress’ intent to ensure individual access to health insurance with appropriate annual limits in place.

⁵ 75 Fed. Reg. at 37191.

⁶ PPACA § 10101.

V. Allowing Complete Exclusion of Benefits Instead of Annual or Lifetime Limits Not Permitted by Congress

The Interim Final Rules purport to clarify that the annual and lifetime limit prohibitions enacted by Congress through the PPACA do not prevent a plan or issuer from excluding all benefits for a particular condition. This provision of the Interim Final Rules is counterintuitive to the purpose of the annual and lifetime limit provisions, contrary to Congress' intent, and exceeds the Secretaries' authority. The provisions of the PPACA dealing with annual and lifetime limits do not address the complete exclusion of benefits or in any way suggest that such complete exclusions are permitted. The Agencies cannot purport to "clarify" a provision of the PPACA which does not exist.

Further, this provision of the Interim Final Rules is counterintuitive to the purpose of the annual and lifetime limits provisions, because allowing plans to completely exclude benefits for certain conditions will lead to impaired access to coverage for certain individuals with, most likely, the most serious medical conditions. Patients who reach annual or lifetime limits are those with the most severe, often chronic and debilitating medical problems. Accordingly, if plans and issuers are required to forego annual or lifetime limits, but are permitted to entirely exclude coverage for certain conditions, they likely will choose to exclude coverage for services related to the most costly and medically complicated conditions. By permitting plans and issuers to completely exclude benefits, the Agencies are opening the door for insurers to institute policies which could make it difficult for these vulnerable patients to receive coverage for the services they require. We strongly urge the Agencies to withdraw this potentially debilitating and far-reaching provision.

VI. Support of Reenrollment Opportunity

Bayer commends the Agencies for providing an opportunity for individuals to reenroll for coverage that was denied due to the applicability of a lifetime limit. This provision will be critically important and beneficial to the sickest Americans who have experienced extreme health care costs. While Bayer particularly commends the Agencies for requiring that reenrolling individuals be offered all the benefits packages available to "similarly situated" individuals who did not lose coverage, a number of clarifications are needed regarding this standard.

First, Bayer suggests that the Agencies more clearly indicate who will be considered a "similarly situated" individual for the purposes of determining which benefits packages and prices must be offered. There will be a financial incentive for plans to adopt an interpretation of "similarly situated" that minimizes their obligation to provide coverage. We urge the Agencies to consider implementing more specific guidelines regarding the definition of "similarly situated" in order to ensure that plans provide meaningful coverage to these individuals.

Second, the Agencies do not explain why this "similarly situated" standard applies for group health plans but not for issuers of group or individual health insurance coverage. We

request that the Agencies consider providing a consistent standard for group health plans and group and individual health insurance coverage in order to benefit all enrollees. Similarly, the Agencies have provided no justification for declining to provide for a reenrollment opportunity for individuals who reached their lifetime limits on individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. We urge the Agencies to implement a similar reenrollment process for these individuals.

Finally, the Agencies have not articulated any reason why the reenrollment window is limited to 30 days. We suggest that individuals not be limited in the amount of time they have to reenroll. Many of these patients are dealing with severe illnesses and may not be physically or mentally able to complete the reenrollment process within such a short time frame.

VII. Health Reimbursement Arrangements (“HRAs”)

The Agencies have specifically requested comments regarding the application of annual limits to stand-alone HRAs which are not retiree-only plans. Bayer recommends that the standards that apply to group health plans and health insurance issuers offering group or individual health insurance coverage be consistently applied to stand-alone HRAs which are not retiree-only plans, keeping in mind, however, the deficiencies in those standards discussed above.

VIII. Support for Prohibition of Rescissions

The PPACA provides that, effective September 23, 2010, a group health plan or health insurance issuer offering group or individual health insurance coverage must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This provision also applies to all grandfathered health plans.

Bayer supports the Agencies’ implementation of this rescission prohibition, as these rules will provide important protection for individuals who do their best to honestly complete enrollment materials but have, up to now, been denied coverage based on inadvertent errors. We further commend the Agencies for providing that additional guidance will be issued to combat efforts to subvert the rules and ensure that individuals do not lose health coverage unjustly or without due process.

IX. Support for Patient Protections

Bayer supports the provisions of the Interim Final Rules providing patient protections and commends the Agencies for their efforts in implementing these rules.

X. CONCLUSION

Thank you for this opportunity to comment on the Interim Final Rules. We greatly appreciate your thoughtful consideration of the important issues discussed above.

Sincerely,

A handwritten signature in blue ink, consisting of several overlapping loops and a horizontal line at the bottom.

Sandra Oliver
Vice President, Public Policy and Government Affairs