May 12, 2011

Submitted electronically to http://www.regulations.gov

U.S. Department of the Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: HHS-ES-2011-001
HHS Plan for Retrospective Review under Executive Order 13563

Dear Sir or Madam:

I am writing on behalf of the American Benefits Council (the "Council") in response to the Department of Health and Human Services' ("Department") recent request under Executive Order 13563 for comments with respect to development of a process for reviewing existing regulations with the ultimate goal of making HHS' regulatory program more effective or less burdensome in achieving its regulatory objectives.

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council's members either sponsor directly or provide services to health and retirement plans that cover more than 100 million Americans.

The regulation of employee benefit plans has grown exponentially in recent years, and the employee benefits field is becoming an area of the law that is well known for its complexity and burdensome regulatory regime. This perception undermines the voluntary employer-maintained benefit plan system. Excessive administrative burdens also adversely affect American workers since the costs of plan administration are often borne by participants as well as plan sponsors. As a general comment, we urge the Department to include in its process a comprehensive review of regulatory guidance with an eye to simplifying and minimizing administrative burden and compliance costs.

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NOTICE AND COMMENT

In recent years, the Council has noticed the Department increasingly issues guidance in the form of interim final regulations or sub-regulatory guidance. For example, many of the regulations to date regarding the Patient Protection and Affordable Care Act ("PPACA") have been issued in the form of interim final regulations. Additionally, other key guidance, such as the regulations implementing the Mental Health Parity and Addiction Equity Act ("MHPAEA"), has also been issued in interim final form.

Under the Administrative Procedures Act ("APA"), federal agencies are generally required, prior to the promulgation of any regulation, to publish in the Federal Register a general notice of proposed rulemaking. In addition, the APA requires that such proposed rulemaking be subject to a comment period during which interested members of the public may submit their comments regarding the rulemaking. The APA provides only limited exceptions to this rule, such as where "the agency for good cause finds … that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b).

Although the APA gives the Department the authority to depart from notice-and-comment rulemaking under appropriate circumstances (such as where "good cause" exists for such a departure), the Council urges the Department to exercise such authority only when absolutely necessary. History has shown that the Department's adherence to the APA results in careful and deliberate rulemaking; rulemaking that is well-reasoned and that reflects broad public comment. Rules established per the APA provide consistency in rulemaking over time.

The Council understands that the Department is concerned about issuing prompt guidance in many of these areas. In many instances, Congress mandates that administrative guidance be issued within a short period of time following enactment of the underlying statute. The desire for prompt guidance, however, should not trump the necessity for clear, workable guidance. The interim final regulations governing the internal appeals and external review provisions of PPACA illustrate this point well.

The interim final regulations on claims and appeals were issued a mere four months after the enactment of PPACA. See 75 Fed. Reg. 43,330 (July 23, 2010). Rather than providing clear guidance to plans and issuers, however, these interim final regulations caused substantial confusion and concern. In an effort to alleviate uncertainty, the Department has now issued three separate Technical Releases (Technical Releases 2010-01, 2010-02, and 2011-01) in its attempt to explain the proper implementation of this interim final regulation and ensure that parties have sufficient time to comply. The Department has also promised an amendment to the interim final regulations. As a result of this series of guidance, a plan or issuer attempting to comply with the PPACA interim appeals and external review provisions must now trace their obligations through (1) the interim final regulations, (2) Technical Release 2010-01, (3) Technical

Release 2010-02, (4) Technical Release 2011-01, and (5) once issued, the amendment to the interim final regulations. Any benefit gained by the Department's prompt issuance of the interim final regulations has, no doubt, been vitiated by the confusing and complicated nature of the subsequent guidance.

In addition to the above, certain of the recent guidance issued as interim final regulations impose substantial new requirements on plans and issuers – requirements that go well beyond that required by the governing statute. For example, certain provisions of the interim final rules governing the internal appeals and external review provisions were not required by the underlying statute and therefore should have been issued in proposed form or preceded by a Request for Information (RFI). The interim final rules impose a "strict adherence" standard on plans and issuers regarding compliance with the new internal appeals processes. Prior law provided for a "substantial compliance" standard, which provided important protections for participants, while ensuring that that claims were resolved in a timely and efficient manner. Nowhere in PPACA does Congress mandate, or otherwise indicate the need for, the new "strict adherence" standard. Nonetheless, per the interim final rules, claims that are best suited for adjudication at the internal appeals phase may now be pushed into costly external review, notwithstanding the best efforts of plans and issuers.

The interim final rules also go beyond the statute in defining the class of claims subject to external review by an independent review organization. External review should only apply to claims involving situations where medical judgment is involved. Questions about plan coverage terms generally should remain the purview of the plan administrator. This makes sense for many reasons, including cost considerations, efficient claims resolution, and consistency of plan interpretation. A contrary rule serves merely to increase inefficiency as well as costs for both plans and their participants.

With respect to MHPAEA, the Department issued interim rules that, in part, require the use of a unified deductible (even where, as the preamble to the interim final regulations admits, the statute does not require such a result and may indeed support an opposite result) and mandate parity of "nonquantitative treatment limitations," a concept that does not appear in the statutory language of the MHPAEA. The use of a unified deductible limits plan-design options. Furthermore, the requirement to provide parity in so-called nonquantitative treatment limitations, both as-written and in practice, goes well beyond both the language and the intent of the MHPAEA, which appears to have been concerned primarily, if not entirely, with treatment limitations of a quantitative nature. The end result of these rules is to erect imposing and potentially counter-productive new requirements without the benefit of the insight of the interested parties in the regulated industries.

The Council recognizes that some extrastatutory changes may be necessary and productive as part of comprehensive rulemaking. Without the benefit of the insight provided by public comment by a wide range of interested parties, however, the Department is merely heightening the chances that it will miss the mark with such changes. For these reasons we urge the Department to continue to look for all opportunities to issue administrative rulemaking that accords with the terms of the APA and that comes with the benefit of public dialogue.

COORDINATION OF REGULATORY REGIMES

The Council's members often express concern about the extent to which different regulatory rules are consistent. Executive Order 13563 emphasizes the importance of agency coordination and avoiding "inconsistent" or "overlapping" rules. We applaud the Administration for this focus. In our experience, there are times in which greater coordination would be appropriate.

A primary example is federal regulation of wellness programs. The Department, the Department of Labor and the Internal Revenue Service have all issued guidance allowing for wellness programs under the HIPAA nondiscrimination rules. Per PPACA, which codified the HIPAA wellness rules and provided for some important expansions thereof, Congress has expressly indicated its support for wellness programs. Notwithstanding, the Equal Employment Opportunity Commission (EEOC) continues to create uncertainty for plans and issuers by questioning the validity of certain incentive or award programs that otherwise comply with HIPAA and GINA. Until all of the relevant agencies are able to come together and speak with one consistent voice regarding wellness programs, including those with incentive or reward components, employers and issuers are unlikely to embrace wellness programs to their fullest potential. The end result is that participants could lose access to important programs designed to promote better health and enhance affordability of health benefits coverage.

GOOD FAITH COMPLIANCE STANDARD

As mentioned above, the pace of legislation and regulation affecting employee benefit plans has greatly accelerated in recent years. Many of these changes have somewhat unrealistic effective dates. Legislation may, for example, have an effective date that is earlier than it is possible for the Department to issue interpretive guidance. Thus, plans are often put in the position of having to comply with unclear or ambiguous rules. Moreover, employers typically have a range of options from which to choose and therefore must analyze, price, seek approval, negotiate with the unions, communicate with employees, implement with service providers and amend plans in order to satisfy these law changes. These steps take time, particularly for large employers.

Plan sponsors are often concerned that they will have to make retroactive changes after the guidance is issued or that modest interpretive differences will have substantial effects. This was the case with issuance of Interim Final Regulations implementing Title I of the Genetic Information Nondiscrimination Act ("GINA") issued October 7, 2009. The interim final regulations' restrictions on the use of health risk assessments (HRAs) and disease management programs impacted many employers just as they were conducting or preparing to conduct their annual fall open enrollment periods for their benefit plans.

There does not appear to be a consistent approach to compliance before final rules are published and effective. We suggest that a single approach should be taken, namely that the Department treat reasonable good-faith compliance prior to the effective date of final rules as compliance.

BALANCING BURDENS AND BENEFITS

As a final overarching comment, the Council urges the Department to carefully consider the administrative burdens of guidance. While we appreciate the importance of rules that are appropriately protective of participant interests, these interests are not well-served by unnecessarily broad and overly burdensome requirements. Moreover, as the pace of legislation affecting plans has accelerated, it is inevitable that new rules will have both intended and unintended consequences. Regulations should be crafted with an eye to effecting legislative intent while limiting and mitigating the unintended consequences and burdens for plan administration.

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We appreciate the opportunity to comment on the need for regulatory simplification, and we look forward to working with you on these important changes.

Sincerely,

Kathryn Wilber
Senior Counsel, Health Policy