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January 25, 2013

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

RE: CMS-9979-P / RIN 0938-AR48

Dear Madam Secretary,

Care Continuum Alliance (CCA) appreciates this opportunity to comment on the proposed rule regarding *Incentives for Nondiscriminatory Wellness Programs in Group Health Plans*.

CCA is an association that convenes all stakeholders in the population health management industry. Our members design and provide services, programs and tools to better coordinate care for all patients along the continuum, from the healthy to those with chronic conditions. Through advocacy, research and education, CCA advances strategies that improve quality in the health care system and achieve cost savings. Our diverse membership includes: physician groups, nurses, other health care professionals, hospital systems, wellness and prevention providers, population health management organizations, health plans, pharmaceutical manufacturers, pharmacies and pharmacy benefit managers, health information technology innovators, employers, researchers, and academics.

Overall, we are pleased with the thoughtful and balanced approach by the Department of Health and Human Services (HHS), the Department of the Treasury, and the Department of Labor in jointly drafting this proposed rule. The rule makes great strides in balancing the need for flexibility in wellness program and incentives design, with appropriate patient protections to access and participate in wellness services.

Recommendation: Maintain flexibility in the core features of a “reasonably designed” wellness program.

CCA and our members would appreciate flexibility in interpreting the language of “reasonably-designed” wellness programs. In determining “reasonable design”, we strongly agree with the notion that wellness programs cannot be ‘one size fits all’. Different patient populations require different health interventions, as clearly indicated in this proposed rule. Also, maintaining a basic framework that permits flexibility in “reasonable design” reflects HHS’s broad goal of delivering the right care, at the right time, in the right setting.

We defined core components of a wellness program in the *CCA Outcomes Guidelines Volume 5 Report*.¹ This report also provides a framework and relevant factors for evaluating the impact of wellness programs on health outcomes and cost-savings. Noting that wellness

¹ Care Continuum Alliance, *Outcomes Guidelines Report*, Vol. 5 (2010)
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programs employ many different behavior change techniques and lifestyle management strategies, core design features should include:

- Help for individuals to maintain and improve their level of health and well-being by identifying health risks and educating them about ways to mitigate these risks;
- increasing awareness of factors that can affect health and longevity;
- enabling individuals to take greater responsibility for their health behaviors;
- preventing or delaying the onset of disease; and
- promoting healthful lifestyles and general well-being ²

These guidelines establish a flexible foundation to build a variety of wellness programs tailored to the specific health needs and preferences of different patient populations. We suggest that HHS maintain the level of flexibility exemplified by these guidelines in the final rule, along with core features outlined in the consensus statement by the Health Enhancement Research Organization, the American College of Occupational and Environmental Medicine, the American Cancer Society and American Cancer Society Cancer Action Network, the American Diabetes Association, and the American Heart Association.³

Recommendation: Key considerations for both wellness program and incentives design.

While CCA supports the use of evidence-based strategies in wellness program design and implementation, the proposed rules must also allow for program innovation to create new evidence on wellness strategies for specific populations. To achieve a balance and provide guidance to fellow healthcare industry stakeholders, CCA's members assembled the Outcomes Guidelines Steering Committee. The Committee developed the following basic considerations for wellness program design in a consensus report entitled *Outcomes Guidelines Report Volume 5*.⁴

- the program is designed to address modifiable health risks;
- an evidence-based tool is used to assess health risks;
- a targeted intervention is used to support healthful behavior;
- individual patient-level information is collected to measure outcomes; and
- the outcome is measured in a scientifically rigorous manner, using appropriate comparative measures

CCA and a working group of our members also outlined key considerations for designing incentives in a 2012 report entitled *Participant Engagement and the Use of Incentives*.⁵ The considerations include:

- Incentive-related needs and expectations evolve as patient needs and interests change.

² *Id.* at 37.

³ Health Enhancement Research Organization, American College of Occupational and Environmental Medicine, American Cancer Society and American Cancer Society Cancer Action Network, American Diabetes Association, and American Heart Association, *Guidance for Reasonable Designed Employer Sponsored Wellness Programs Using Outcomes Based Incentives*, *Journal of Occupational and Environmental Medicine*, vol. 54 (July 2012).

⁴ Care Continuum Alliance, *Outcomes Guidelines Report*, Vol. 5 at 42.

⁵ Care Continuum Alliance, *Participant Engagement and the Use of Incentives* (2012): 16

www.carecontinuumalliance.org/pdf/201301/Incentives-Document.pdf.

- Organizations should have an evaluation plan to determine whether incentives are improving health outcomes and/or achieving cost savings in a given population.
- Intrinsic and extrinsic incentives can have different effects.
- It is important to encourage active engagement and participation to achieve lasting healthy behavior change, not just enrollment.

The working group distilled these overarching considerations from a current comprehensive literature review and case study analysis. In light of these broad considerations, we recommend that HHS leave ample room for program innovation in wellness program and incentives design.

CCA would be glad to offer additional case studies, share peer-reviewed literature, and field questions as HHS moves forward in the rulemaking process.

Thank you,



Frederic S. Goldstein
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Vicki Shepard
Chair of the Government Affairs Committee
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