A VISION FOR A HEALTHIER FUTURE

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1503-P

August 24, 2010

Submitted via Internet

Dear Dr. Berwick:

The Partnership to Fight Chronic Disease (PFCD) recognizes the important opportunity that the new, annual wellness visit represents for improving the health of the Medicare population. We are pleased to see regulations moving forward that will effectuate the annual wellness visit and help ensure that beneficiaries receive the benefit of a visit dedicated to the identification and mitigation of risk factors that lead to the onset of chronic illness, reduce the quality of life, and increase health care costs. PFCD, a national coalition of patient, provider, community, business, and labor groups, advocates for comprehensive health reform that controls health care spending through measures that simultaneously reduce costs and improve health outcomes.

The new Medicare annual wellness visit represents a significant step forward to promote proactive practices that prevent the onset and progression of chronic disease. The success of the new benefit and its uptake among both providers and beneficiaries will depend largely on their initial experiences with it. Accordingly, assuring that providers have the information they need to provide personal, actionable recommendations that helps patients improve their health is essential to fulfilling the promise the new benefit offers to both improving health and lowering long-term costs.

To help assure the successful implementation and achievement of its potential to improve health, we offer the following comments to the proposed regulation on the new wellness visit.

<u>Include the Health Risk Appraisal (HRA) at Implementation</u>

We strongly support the requirement that the annual wellness visit include an HRA, and urge CMS to include an HRA as a part of the wellness visit at implementation. Data show that use of an HRA within a Medicare population can yield significant savings.[1] Linked closely with the wellness visit, the information obtained through a thorough HRA will help providers to personalize the wellness visit and

[1] R Ozminkowski, R Goetzel, et al., "The Savings Gained from Participation in Health Promotion Programs for Medicare Beneficiaries," J Occup Environ Med 2006;48:1125-32.

the follow-up recommendations to align closely with the individual patient's needs. Accordingly, it is critical that CMS issue its guidance for the HRA as soon as possible because it plays a critical role in helping to make the visit efficient and effective.

We appreciate that having some standardization for the Medicare HRA is important as it would allow for the collection and effective analysis of comparable data across populations, provide invaluable information to CMS on population health trends, and help to identify opportunities to better the health status among Medicare beneficiaries. We do not, however, agree that implementation of the HRA should occur after the wellness visit benefit is available on January 1, 2011.

If CMS cannot issue standards for the HRA in time to coincide with implementation of the new wellness visit, we encourage CMS to consider allowing the use of HRAs that are offered by organizations that are accredited for wellness by respected external quality evaluation organizations, such as NCQA and URAC, and meet the statutory parameters set out in subsection (4)(A) of Section 4103 in the Affordable Care Act:

- identify chronic diseases, injury risks, modifiable risk factors, and urgent health needs of the individual
- may be furnished through an interactive telephonic or web-based program, during an encounter with a health care professional, or through community-based prevention programs

to assure compliance with statutory intent and provide some preliminary criteria upon which to determine suitable HRA tools for providers to use. In particular, CMS recognition of accredited wellness organizations will ensure the use of HRAs that have an adequate scope of risk types, are evidence-based, utilize biometric screenings or similar screening types and provide appropriate feedback.

Inclusion of Required Elements of Personalized Prevention Plan

Rather than spell out a number of required clinical elements, the statute provides a list of elements that "may" be addressed as part of the prevention plan. The key to the personalized nature of the plan is a comprehensive risk assessment focused on modifiable behavioral factors. Such an assessment should serve as a prelude to and a basis for an office visit to avoid the administration of tests and procedures that may not be warranted and to help providers identify the highest priority concerns to address during the visit.

The regulation, in turn, sets out certain activities as required elements of the annual wellness visit, removing some of the flexibility built into the statutory language. Recognizing that the personalized prevention plan and the HRA may share certain elements as outlined in the proposed rule (e.g., family medical history), we recommend that all of the elements outlined in the proposed rule be required for the overall service – allowing flexibility for the inclusion of some elements to be captured as part of the HRA and others as part of the office visit.

We also strongly urge that implementing regulations clearly describe the linkage of the HRA to the prevention plan service. The HRA is a fundamental and statutorily mandated component of the prevention plan service; yet, the proposed regulations do not make a reference to the direct links between the two. We recommend that CMS reiterate the statutory requirement that an HRA is required as a prelude to the office visit (completed prior to or as part of the same visit), and that the visit must take into account the results of that HRA.

Definition of "Detection of Any Cognitive Impairment"

We applaud the inclusion of evaluating cognitive impairment as a required part of the annual wellness visit, but have concerns about the reliance solely on subjective means of detection. Currently, regulation defines detection of any cognitive impairment as:

> "assessment of an individual's cognitive function by direct observation, with due consideration of information obtained by way of patient report, concerns raised by family members, friends, caretakers, or others."

We suggest that CMS change the definition to include objective criteria, as well, in the form of a brief cognitive screening test that could be administered by the provider or incorporated into an HRA that would alert the provider to a potential issue with cognitive function and allow for appropriate follow up.

A broad range of instruments, such as the GPCOG, Mini-Cog and MIS, are brief, easy to administer, available with acceptable levels of sensitivity and specificity, and minimally affected by education, gender, and ethnicity.[2] We do not suggest that CMS be prescriptive about the specific instrument, except that ensuring that it has well established psychometric properties that would make it suitable for the purposes of the wellness exam.

Include Depression Screening in Annual Wellness Visit

We also support the inclusion of screening for depression as a part of the annual wellness visit and HRA. Older Americans experience high rates of depression: depression affects 6.5 million of the 35 million Americans age 65 and older.[3] Depression is not a natural part of aging, however, about 58 percent of people age 65 and older believe that it is "normal" for people to become depressed as they get older.[4]

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[2] Milne A, Culverwell A, Guss R, et al. Screening for dementia in primary care: a review of the use, efficacy and quality of measures. Int Psychogeriatr. 2008 Oct;20(5):911–26.

[3] National Alliance on Mental Illness, "Depression in Older Persons Fact Sheet."

[4] National Mental Health Association, "American Attitudes about Clinical Depression and its Treatment," (March 27, 1996).

According to the U.S. Preventive Services Task Force (USPSTF) recommendations, several groups are at risk for depression throughout their lifetime:

- Persons with other psychiatric disorders, including substance misuse
- Persons with a family history of depression
- Persons with chronic medical diseases
- Persons who are unemployed or of lower socioeconomic status.

The USPSTF also notes that significant depressive symptoms are associated with commonly occurring life events in older adults, including medical illness, cognitive decline, bereavement, and institutional placement in residential or inpatient settings. Given the incidence of depression among older Americans, the high prevalence of chronic disease among the Medicare population, and the commonality of other risk factors among seniors, we recommend that depression screening be included in each annual wellness visit, either as a part of the visit or the HRA.

Maximizing the Potential of the Annual Wellness Visit Depends on the Value Derived

Realizing the full potential of the benefit and encouraging its utilization over the long-term will depend largely on the value beneficiaries derive from it and assuring provider uptake and availability. Beneficiaries will need to see the immediate value in having and following through on a personalized prevention plan; and the greater the degree of relevance to the beneficiary, the greater the value. For providers, assuring adequate reimbursement for the intensity of the service needed to evaluate HRAs, identify and evaluate health issues identified during the wellness visit, and developing a personalized prevention plan is critical. We urge CMS to consider these critical value determinations and factor them into the final regulation.

Outreach and education on the new benefit to both beneficiaries and providers will be critical to its success, and we look forward to assisting those efforts. We strongly encourage that outreach and education efforts include information for both beneficiaries and providers about the opportunities to improve health by proactively identifying and addressing health risks, how the new, annual wellness visit differs from the existing “Welcome to Medicare physical,” and linkages to other preventive care benefits under Medicare.

We appreciate the opportunity to comment on this important new benefit for people with Medicare, and look forward to working with you in the development of guidance for the health risk appraisal and implementation of these historic new benefits.

Sincerely the 38 undersigned PFCD partners and other interested organizations:

Alzheimer's Foundation of America
Alliance for Aging Research
American Academy of Nursing
American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)
American Association for Geriatric Psychiatry
American College of Nurse Practitioners
American College of Preventive Medicine
American Dietetic Association
American Foundation for Suicide Prevention/SPAN USA
American Mental Health Counselors Association
American Osteopathic Association
American Sleep Apnea Association
Bazelon Center for Mental Health Law
Biotechnology Industry Organization
Clinical Social Work Association
The COSHAR Foundation
DMAA: The Care Continuum Alliance
Dialysis Patient Citizens
GlaxoSmithKline
Health Dialog
Healthways
International Health, Racquet and Sportsclub Association (IHRSA)
Johnson & Johnson
Medical Fitness Association
Mental Health America
Pharmaceutical Research and Manufacturers of America
Prevent Blindness America
National Association of Chronic Disease Directors
National Association of County Behavioral Health and Developmental Disability Directors
National Association of Mental Health Planning and Advisory Councils
National Association of State Mental Health Program Directors (NASMHPD)
National Coalition for Mental Health Recovery
National Council for Community Behavioral Healthcare
National Patient Advocate Foundation
National Retail Federation
URAC
U.S. Preventive Medicine
XLHealth