



December 21, 2010

The Honorable Thomas R. Frieden, M.D., M.P.H.
Director
Room 5127, Mailstop D-14, Mailstop D-28
ATTN: Health Risk Assessment Guidance
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE
Atlanta, GA 30333

Mr. Andy S. Rein
Associate Director for Policy
Office of Prevention through Healthcare
CDC
395 E Street, SW
Suite 9100
Washington, DC 20201

RE: FR Doc. 2010-28788, Request for Information (RFI), Development of Health Risk Assessment Guidance

Dear Director Frieden:

Thank you for the opportunity to submit comments and recommendations on the CDC's RFI to develop federal guidance for Health Risk Assessments (HRAs). As the RFI states, employer-based health and wellness programs have established the majority of existing HRAs and according to the 15th Annual National Business Group on Health/Towers Watson Survey Report, 78% of employers offer HRAs. Our members have a plethora of first-hand experience in this area and we look forward to sharing our experiences and knowledge with you as you develop HRA guidance for the effective implementation of the HRA for the annual Medicare wellness visit, to support the broader use of HRAs within primary care and to provide useful information on HRAs to privately insured populations and employer-sponsored health care plans.

The National Business Group on Health represents over 308 companies, including many of America's largest employers (64 of the Fortune 100) who voluntarily provide health benefits and other health programs to over 50 million American employees, retirees, and their families.

Despite the fact that the economy is in a downturn, employers still view HRAs as a good value for their money to improve employees' health and productivity. Information from HRAs can help providers know how to help their patients, help patients know which risk factors they need to manage and, in the aggregate, provide data on program and benefit needs to improve the health of their populations. Research consistently shows the importance of reducing health care risks that impact the quality of life and productivity.

Employers recognize that in tough economic times, they can show their concern and investment in their employees by helping them to improve their health. Many large employers have been utilizing HRAs for years; so it is no surprise that the CDC, the Centers for Medicare and Medicaid Services (CMS) and government agencies are starting to incorporate them into their wellness programs.

Recently, the Equal Employment and Opportunity Commission (EEOC) took a major step forward in avoiding a scaling back of the use of HRAs by clarifying that the offering of incentives for the completion of HRAs that include voluntary questions on family medical history does not run afoul of The Genetic Information Nondiscrimination Act (GINA).

The reasons for offering HRAs are multifaceted. They often are part of the benefits package, but they also serve as part of the data needed to build targeted, effective, wellness programs. HRAs give employees a valuable snapshot of their personal health profiles, help them become more involved in thinking about how their lifestyle choices affect their personal health, provide suggestions on how to improve their health risks and provide feedback on areas in which they need to improve. For employers, HRAs help their health professional partners identify individuals who are at risk and triage them into the right programs. While employers pay for these services, they do not receive risk information that identifies individuals who have completed HRAs. Rather, health professionals, who are governed by federal and state laws, including the Health Insurance Portability and Accountability Act (HIPAA) and professional ethics, collect and act upon data from HRAs. Strategically, employers can aggregate the valuable data being collected in HRAs to track the impact of existing programs, assess the needs of various populations (for example, specific office locations or the demographics of particular employees) and design future programs that address the needs of their employees and dependent populations. The data also helps employers evaluate health improvement vendors (e.g., improvement in health risks or participation rates).

As you know, the Patient Protection and Affordable Care Act (Affordable Care Act) requires the Secretary of Health and Human Services (HHS) to publish guidelines for HRAs, no later than 1 year after enactment, to determine “personalized prevention plans” under a new annual wellness benefit for Medicare beneficiaries. The Affordable Care Act also requires the HHS Secretary to develop an HRA model and make it available to the public. The Affordable Care Act requires the federal HRA to identify chronic diseases, injury risks, modifiable risk factors, and urgent health needs of individuals. The HHS Secretary must also establish standards to administer the HRAs through interactive telephonic or web-based programs; during encounters with health care professionals; through community-based prevention programs or any other means to maximize privacy, accessibility and ease of use by beneficiaries.

Specifically, in the areas where the CDC is requesting comments, we offer the following recommendations:

- **The marketplace should develop standardized, evidence-based, HRA questions for the core elements under the six domains of basic demographic information; health status; lifestyle-related risks; mental health/quality of life; chronic health risks; and productivity and engagement for adoption**

- throughout the industry to develop a consistent method to compare outcomes, provide quality programming and study the health of populations;
- The CDC and CMS should draft HRAs in English and Spanish, and other languages as needed, with a finite number of culturally appropriate and relevant questions, consider Americans' average reading levels, incorporate images and graphics with easy-to-understand terminology and instructions on how beneficiaries can follow-up with their primary care providers and other health care professionals to encourage more beneficiaries to complete the assessments;
 - CDC's guidance should include language that encourages patients to choose to share their HRA results with their providers and to integrate them into their records;
 - The CDC and CMS should give seniors as many options as possible to complete HRAs, including using the latest technology, so they can select the vehicle that best suits them;
 - CMS should allow primary care practices to choose whether or not to use HRA tools alongside their own comprehensive health assessment approach based on the needs of the patient population, but, if they do, they should include the standardized HRA questions from the core elements of the six domains (on pages 4-5 below);
 - The federal government should train primary care practice team members, such as nurse practitioners or physician assistants, to incorporate HRA results in their practices to support patients in self-management and behavior change (e.g., weight, smoking, exercise, stress, etc);
 - After seniors complete HRAs, CMS or qualified vendors should report the results immediately, after receiving seniors' permission, to seniors and their primary care providers;
 - CMS should consider utilizing positive incentives to motivate patients to take HRAs and participate in health-enhancing programs and immediately evaluate the different incentives and report their results;
 - HRA certification tools should focus on the set of six core measures (listed on pages 4-5 below) for benchmarking reasons, but they should not stifle the innovation, continued development and customization of HRAs to meet the needs of specific populations; and
 - CMS should institute periodic evaluations of Medicare beneficiaries' participation in HRAs and the annual wellness visits; validity of the information collected in the HRAs; and use of HRA results/information by patients to discuss options for lowering health risks identified by their assessments with their primary care providers and other health care professionals.

Content and Design

- Risk assessment domains—What are generic elements of any HRA(s) and what elements must be tailored to specific populations, particularly those stratified by age?

Recommendation: The marketplace should develop standardized, evidence-based, HRA questions for the core elements under the six domains of basic demographic information; health status; lifestyle-related risks; mental health/quality of life; chronic health risks; and productivity and engagement for adoption throughout the industry to develop a consistent method to compare outcomes, provide quality programming and study the health of populations.

Experts agree that it would be difficult to standardize all of the various available HRAs. However, it is possible to do so for a core set of questions in HRAs, making it easier for employers to benchmark against each other and compare their own data from year-to-year.

Employers have traditionally used HRAs as a way to better understand the health risks of their workforce, track the health of their employees over time and to build supportive environments and programs to assist in improving health status. However, they have been unable to reliably compare aggregate risks and outcomes with other employers due to the lack of standardization among HRAs. In addition, if employers change vendors, the population risk information, which is very powerful in tracking and supporting appropriate workplace programming, often is lost, causing significant re-investment in programming and data adjustments. To address this challenge, the National Business Group on Health has performed a research study over the past 2 years on more than 30 HRAs offered to large employers to identify which types of core elements consistently appear within all HRAs. Based on this research, we have found that the core elements in most HRAs fall in six domains which are essential to understanding and comparing all populations, regardless of age, race or other demographic characteristics. Accordingly, the marketplace should develop standard questions for adoption throughout the industry to develop a consistent method to compare outcomes, provide quality programming and study the health of populations, including:

1. Basic Demographic Information
 - HRAs must capture basic questions related to age, gender and sex, standardized to other CMS requirements, to establish a baseline for comparison. Plans need this information to understand individual risk factors and study the overall health of a population.
2. Health Status
 - HRAs must include questions related to biometric screening and individuals' own assessments of their health to fully understand their health status and risk factors.
 - Sample questions include:
 - Height (in inches);
 - Weight (in pounds);
 - Blood pressure (systolic and diastolic);
 - Blood glucose;
 - Cholesterol (HDL/LDL/Triglycerides);
 - Body Mass Index (BMI); and
 - Self-rating on health status.

3. Lifestyle-Related Risks
 - Employers and employees can use HRAs to identify behaviors associated with poor health status to change behaviors and predict potential public health issues.
 - Questions about health risks should focus on:
 - Tobacco habits;
 - Alcohol and drug use;
 - Driving and work safety;
 - Dietary habits, such as fruit/vegetable, fat, fiber consumption; and
 - Level of physical activity.
4. Mental Health/Quality of Life
 - An often overlooked area of health is mental/emotional health. Studies have shown that behavioral health disorders, such as depression and stress, have a significant impact on the health, productivity, effectiveness at work and quality of life of individuals and their families.
 - Sample questions include:
 - Level of stress/depression;
 - Level of anger; and
 - Personal life satisfaction.
5. Chronic Health Risks
 - Individuals' health conditions and chronic diseases impact their abilities to function and overall quality of life. Therefore, HRAs must include a series of questions focused on the health conditions and chronic diseases with proven impacts on individuals' health.
 - Questions should focus on the following major health conditions:
 - Diabetes;
 - Heart disease;
 - Cancer history (breast, colon, prostate and lung);
 - Stroke;
 - Allergies;
 - Headaches;
 - Back pain; and
 - Arthritis.
6. Productivity and Engagement
 - HRAs should focus on questions related to individuals' productivity and engagement.
 - Sample questions include:
 - Satisfaction with a job;
 - Engagement in work;
 - Engagement in non work-related activities; and
 - Ability to participate in work and personal obligations.

In addition, the National Committee for Quality Assurance (NCQA) has a "health information products" certification through which organizations can seek certification for their health assessments (see <http://www.ncqa.org/tabid/572/Default.aspx> for more information). The Utilization Review Accreditation Commission (URAC) also considers

the use of health assessments in their comprehensive wellness accreditation (see http://www.urac.org/programs/prog_accred_CW_po.aspx).

- How should literacy and other cultural appropriateness factors be factored into the design?

Recommendation: The CDC and CMS should draft HRAs in English and Spanish, and other languages as needed, with a finite number of culturally appropriate and relevant questions, consider Americans’ average reading levels, incorporate images and graphics with easy-to-understand terminology and instructions on how beneficiaries can follow-up with their primary care providers and other health care professionals to encourage more beneficiaries to complete the assessments;

Previous studies have determined that overall, 33.9% of English-speaking and 53.9% of Spanish-speaking Medicare beneficiaries had inadequate or marginal health literacy.¹ The fact that elderly patients may have limited ability to read and comprehend medical information pertinent to their health, particularly in the Spanish-speaking elderly population, supports the recommendation that HRAs should at least come in both English and Spanish and other languages as needed.

Asking about 50 to 55 questions is typical on HRAs offered for the first time. Employers have found that limiting the number of questions and their complexity is most effective for the completion of HRAs. It is also important that questions are culturally appropriate and relevant for the target populations to ensure accurate responses and effective usage of the data from HRAs.

For example, a number of studies have shown that assessments presented in Spanish have often been translated from English to Spanish without the use of culturally appropriate guidelines for adaptation for Latino populations.² It is important to develop assessment materials that are culturally appropriate, with reliability and validity established in the target population.³ Using culturally appropriate tools to develop HRAs will provide accurate data to facilitate improved interventions and evaluations of HRAs for Latinos and the entire Medicare population.

HRAs should consider culturally appropriate measures across subgroups and populations by taking into account the following:

- Shared norms: socially desirable behaviors (e.g. “the do’s and don’ts”);
- Shared beliefs: ideas or assumptions about the world; and

¹ Gazmararian, Julie. Et. al. Health Literacy Among Medicare Enrollees in a Managed Care Organization. *JAMA*. 1999.

² Warnecke RB, Johnson TP, Chavez N, et al. Improving question wording in surveys of culturally diverse populations. *Annals of Epidemiology*. 1997;7(5):334

³ Ramirez M, Ford M, Stewart A, Teresi J. Measurement issues in health disparities Research. *Health Serv Research*. Oct 2005;40(5):1640-1657.

- Shared values and expectations: moral standards perceived as desirable and esteemed.⁴

In creating culturally appropriate measures, it is also essential to consider linguistic appropriateness or to target a population's reading and comprehension levels. The majority of employer plans use HRAs drafted for audiences with reading levels anywhere between 5th and 8th grade. Accordingly, CDC and CMS should target HRAs toward Americans' average reading levels in composing the HRA questions to ensure comprehension and maximum participation of Medicare beneficiaries.

The CDC should also augment its HRAs with images and graphics—a select few HRA providers that use this approach within HRA questions found it increases the chances that users will complete the assessments.

The CDC should also define complex health terminology, where possible, so users can accurately answer the questions and learn something as well.

Finally, HRAs should provide easy-to-understand results to Medicare beneficiaries to aid them in future appointments with their primary care physicians, enhance the patient-clinician discussion and provide them with the information they need to enroll in relevant health care programs.

- How should the HRA instrument support shared decision-making by provider(s) and patient(s)?

Recommendation: CDC's guidance should include language that encourages patients to choose to share their HRA results with their providers and to integrate them into their records.

To support shared decision-making, HRA reports should include language that encourages patients to share results with their primary care providers and discuss options for lowering health risks identified by their assessments, suggested questions to aid in the clinician-patient discussion, including steps they can take on their own and options they should discuss with their physicians. Many HRAs already generate a report that patients can take to their personal physicians and some have the capability to send results directly to physicians with patients' permission.

CMS should strongly encourage patients to share their results with their providers to increase their interactions with primary care professionals and preventive care services. However, some patients prefer to keep their results private. There is very little that will decrease participation in HRAs more than suspicion from participants that they do not control the flow of HRA information or how it will be used. Therefore, CMS should clearly state to Medicare beneficiaries, in easy-to-understand language, that existing federal laws including HIPAA, the privacy rule, GINA, the American with Disabilities Act Amendments (ADAAA), the Age Discrimination in Employment Act (ADEA) and state privacy laws protect their private health information and prohibit discrimination

⁴ Van Widenfelt BM, Treffers PDA, De Beurs E, Siebelink BM, Koudijs E. Translation and cross-cultural adaptation of assessment instruments used in psychological research with children and families. *Clinical Child and Family Psychology Review*. 2005;8(2):135.

based on any information supplied in the HRAs, including genetic information that includes family history, disability or age.

Mode of Administration

- How will individuals access the HRA(s) (e.g., via kiosk or some other means in the physician(s') office(s), Internet, mail-in paper form(s), other nontraditional healthcare locations, such as, kiosk(s) in a pharmac(ies))?

Recommendation: The CDC and CMS should give seniors as many options as possible to complete HRAs, including using the latest technology, so they can select the vehicle that best suits them.

The options provided in the CDC's guidance should include all the options mentioned above with an emphasis on internet and mail-in paper forms, as these are the more common ways individuals can complete HRAs. Internet-based HRAs allow for "branching logic" where individuals receive questions relevant to them, based on how they answered previous questions.

Primary Care Office Capacity

- What primary care office capacity (personnel, Information Technology (IT), etc.) is required to utilize HRA data effectively in support of personalized prevention planning?

Recommendation: CMS should allow primary care practices to choose whether or not to use HRA tools alongside their own comprehensive health assessment approach based on the needs of the patient population, but, if they do, they should include the standardized HRA questions from the core elements of the six domains (on pages 4-5);

Information Technology (IT) is not necessary to use HRA data effectively, although IT capabilities such as electronic health records may accelerate use of these tools in primary care practices. The HRAs used in primary care practices do not *need* to follow the typical computer-based tools seen in corporate settings. In fact, many physicians see them as quite limited (most are designed for patients aged 18-64) and assume they already capture most health risks in their practices.⁵ Furthermore, primary care HRAs may go beyond the typical assessments of behaviors affecting health to include: family/social/cultural characteristics, communication needs, advance care planning, reproductive health, patient/family mental health and substance use, developmental/autism screening, etc. Physician practices can also easily incorporate biometric measures.

However, primary care physicians that do choose to use HRA tools should include the standardized HRA questions from the core elements of the six domains (on pages 4-5) to ensure that providers, employers, employees, etc. can research HRA results across

⁵ Environmental Scan: Health Risk Appraisals in Primary Care, AHRQ, <http://ahrq.hhs.gov/clinic/enviroscan/envscan3.htm>, accessed on 12/14/10.

multiple providers and multiple populations to ensure that we garner the full benefits of using HRAs to improve health and wellness.

- Are training and technical assistance necessary for effective practice utilization of HRA(s)? What entity should provide this technical assistance?

Recommendation: The federal government should train primary care practice team members, such as nurse practitioners or physician assistants, to incorporate HRA results in their practices and to use them to support their patients in self-management and behavior change (e.g., weight, smoking, exercise, stress, etc).

The federal government should train primary care physicians, nurse practitioners and physician assistants in medical home practices to incorporate HRA results in their practices and to use them to support patients in self-management and behavior change (e.g., weight, smoking, exercise, stress, etc).

In addition, the Affordable Care Act's Center for Medicare and Medicaid Innovation (CMMI), charged with testing innovative payment and service delivery models in Medicare and Medicaid at CMS, should also provide technical assistance to assist primary care practices team members, Accountable Care Organizations (ACOs) and medical home pilot programs to incorporate HRA results into their practices and to use them to support self-management and behavior change for their Medicare patients.

- What is the current practice of HRA(s) in medical practices of various sizes, particularly those with five or fewer physicians?

Twenty-three percent of large medical groups and Independent Practice Associations (IPAs) reported they routinely use HRAs.⁶

The NCQA Patient Centered Medical Home Recognition program finds smaller practices are not at a disadvantage in practicing as a medical home, which includes routine administration of comprehensive patient HRAs, the teaching of self-care techniques, and monitoring outcomes.

Consumer/Patient Perspective

- How could data (from HRAs) be shared with the patients for their feedback and follow up in the primary care practice(s)?

Recommendation: After seniors complete HRAs, CMS or qualified vendors should report the results immediately, after receiving seniors' permission, to seniors and their primary care providers.

The report should use the following techniques:

⁶ Halpin, H. A., McMenamin, S. B., Schmittiel, J., Gillies, R. R., Shortell, S. M., Randall, T., & Casalino, L. (2005). The routine use of health risk appraisals: Results from a national study of physician organizations. *American Journal of Health Promotion* 20(1):34-38.

- Display information in a graphic format and color-coding (e.g., stoplight system in green, yellow and red to correspond to good, average, or poor for all data collected);
 - List what seniors can do now with the immediate results, along with phone numbers of their physicians, health coaches or disease management programs that they can call if they would like to get started right away; and
 - Personalize relevant information with comparisons to responses from previous years.
- What role, if any, do incentives play in motivating patients to take the HRA(s) and/or participate in follow-up interventions?

Recommendation: CMS should consider utilizing positive incentives to motivate patients to take HRAs and participate in health-enhancing programs and immediately evaluate the different incentives and report their results.

Numerous studies have shown incentives increase positive participation in HRAs . Whereas completion rates for HRAs are often less than 20% in the absence of incentives, participation can approach 100% with them.⁷

As it relates to participation in follow-up interventions, a 2010 National Business Group on Health survey found that incentives would motivate employees to take part in wellness programs and try to lead healthier lifestyles.⁸ When used, frequent and more immediate incentives promote behavior change more effectively.⁹

However, some research suggests that incentives do not work as well at motivating older individuals. Less than half of employees in their 50s and only 39% of workers in their 60s stated that financial incentives would drive them to participate in wellness programs.¹⁰

Certification

- What certification tools and processes should complement the HRA guidance and how should they be made available to support primary care office(s') selection of an HRA instrument?

⁷ Anderson DR, Grossmeier J, Seaverson ELD, Snyder D. The Role of Financial Incentives in Driving Employee Engagement in Health Management. *ACSM's Health & Fitness Journal*. 2008;12(4):18-22: National Business Group on Health/Watson Wyatt. *The Keys to Success: Lessons Learned from Consistent Reporters*. January 10, 2010.: National Business Group on Health/Fidelity Investments. *Employer Investments in Improving Employee Health*. January 2010 : Martinez A, VanWormer J, Pronk N. The Role of Incentives and Communication on Health Assessment Participation. *ACSM's Health & Fitness Journal*. 2008;12(3):41-44 : Taitel MS, Haufle V, Heck D, Loeppke R, Fetterolf D. Incentives and Other Factors Associated With Employee Participation in Health Risk Assessments. *Journal of Occupational and Environmental Medicine*. 2008;50(8):863-872.

⁸ National Business Group on Health/Hewitt. *The Employee Mindset: Views, Behaviors and Solutions*. 2010.

⁹ Fuhrmans V. Training the Brain to Choose Wisely. *Wall Street Journal*. April 28, 2009.

¹⁰ Watson Wyatt. *Closing the Gap: 2008/2009 Employee Perspectives of Health Care*. 2009.

Recommendation: HRA certification tools should focus on the set of six core measures below for benchmarking reasons, but they should not stifle the innovation, continued development and customization of HRAs to meet the needs of specific populations.

Recommendation: CMS should institute periodic evaluations of Medicare beneficiaries' participation in HRAs and the annual wellness visits; validity of the information collected in the HRAs; and use of HRA results/information by patients to discuss options for lowering health risks identified by their assessments with their primary care providers and other health care professionals.

Employers have recognized that a certain level of standardization of core measures would allow individuals and their physicians to compare results year-over-year or to other patients. These core measures (listed on Pages 4-5) include:

1. Basic Demographic Information;
2. Health Status;
3. Lifestyle-Related Risks;
4. Mental Health/Quality of Life;
5. Chronic Health Risks; and
6. Productivity and Engagement.

However, HRA certification requirements may actually hinder continued development and customization of HRA tools, i.e., age, cultural and literacy appropriateness, health status, delivery setting, etc. Creating variety amongst the HRAs on the market means that stakeholders may offer an assessment that is appropriate for their population. Therefore, certification tools and processes should also be unobtrusive to the creative element of HRAs to meet the needs of specific populations.

Thank you for considering our comments and recommendations as you work to develop HRA guidance both for the effective implementation of the HRA for the annual Medicare wellness visit and to support the broader use of HRAs within primary care. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012, if you would like to discuss our comments in more detail.

Sincerely,



Helen Darling
President

cc: The Honorable Donald Berwick, M.D, Administrator, CMS
The Honorable Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services
Paula Staley, Office of Prevention through Healthcare, Office of the Associate Director for Policy (OADP), CDC
Tanja Popovic, Deputy Associate Director for Science, CDC