

## Comments requested in the Federal Register for the development of guidance for Health Risk Assessments (HRAs)

We received this collection of public comments from numerous public sources and in multiple formats. We have attempted to make all of these comments Section 508 compliant, but there are sections within this document that we cannot ensure will be compliant. If you experience issues reading this document, please contact us and identify, if possible, where you encountered problems.

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Office of Prevention through Healthcare  
Office of the Associate Director for Policy  
Centers for Disease Control and Prevention

## American Academy of Family Physicians



*Recv'd 1/13/2011*

### Comments on the Development of Health Risk Assessment Guidance-

The American Cancer Society Cancer Action Network (ACS CAN), the American Diabetes Association (ADA), and the American Heart Association (AHA) are pleased to submit joint public comments to the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) regarding the development of guidance for Health Risk Assessments (HRAs) pursuant to Section 4103 of the Affordable Care Act (ACA).

#### **I. Integration of the HRA tool into the Personalized Prevention Plan**

As stipulated in Section 4103 of the Affordable Care Act, we strongly recommend that the Health Risk Assessment (HRA) and the annual wellness visit be integrated into a single entity – the personalized prevention plan service. The HRA is a statutorily mandated component of the personalized prevention plan service and is a critical first step toward helping health care practitioners to create a customized health care plan for patients that optimizes delivery of care. The HRA is not another “element” or component of the annual wellness visit that simply has to be checked off, but rather it is the mechanism that drives the content of the office visit and personalizes the prevention plan service. As part of the process for developing guidelines for the HRA, the office visit’s structure must be revisited in order to more clearly define and establish the interplay between the elements, the HRA, and the prevention plan visit.

The final rule on the new annual wellness visit issued by the Centers for Medicare and Medicaid Services (CMS) did not include or make reference to the relationship between the HRA and the office visit. Consequently, CMS is requiring all the possible elements of the prevention plan service provided for in the statute to be a mandatory part of the office visit. Such an overly proscriptive approach to the office visit is unnecessary and fails to optimize this visit’s potential for improving the health and well-being of Medicare beneficiaries. Instead of a one-size-fits all office visit with a long list of required elements, the HRA must play a role in addressing many of those elements prior to the office visit. This approach allows clinicians to spend the bulk of their time during the visit on a personalized and comprehensive conversation about the patient’s risk profile in addition to identifying the steps the patient is willing to take to modify that risk.

We recommend that CDC stipulate that required elements can be addressed, at least to some degree, as part of the HRA. This information will help clarify how the personalized prevention plan visit takes into account the results of the HRA as required by statute, which will in turn provide practitioners flexibility and discretion to determine how best to set up their

prevention plan service. The HRA should serve as the primary tool for establishing/updating medical history and screening for certain risks while the office visit should be dedicated primarily to personalized counseling and planning based on the HRA and the practitioner's own expertise and/or knowledge of the patient. This approach will help avoid services that may be unnecessary for a particular patient while ensuring that appropriate services specific to the patient's needs are not overlooked.

## **II. General Comments and Guidance on HRAs**

In general, we recommend that the HRA should be:

- The key tool for guiding the visit with the healthcare provider, thus allowing the content of the appointment to be tailored to the needs of that particular patient based on their risk profile.
- Available/completed prior to a preventive medicine visit with health care provider.
- A robust enough questionnaire to uncover both health risks and disease symptoms, as well as the patient's demographic profile, that may reveal risks, health factors, and conditions amenable to intervention and modification once identified, such as diabetes, cancer, cardiovascular disease, and stroke.
- Coupled with written, personalized information in layman's terms outlining discovered risks and suggestions for risk modifications.
- Available in multiple formats from multiple vendors (i.e., do not require a single, standardized HRA) and available in the community, such as through State Health Insurance Assistance Programs (SHIP) that provide assistance to Medicare beneficiaries.
- Adequately reimbursed, taking into account the amount of time practices will need not only to analyze and interpret the HRA results, but also to provide various options for administering the assessment (e.g., some patients will be unable to complete a web-based HRA for various reasons and may need to complete a paper-based form in the office).

## **III. HRA Content and Design**

We strongly recommend framing the standard HRA requirements in a manner consistent with the elements currently required by CMS for the annual wellness visit so as to maximize the integration of the HRA and annual wellness visit. To that end, we would request that the HRA must be capable of performing and reporting the following:

- A. Establishing or updating the individual's medical and family history; at a minimum, this includes the collection and documentation of the following:
- Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries, and treatments.
  - Use or exposure to medications and supplements, including calcium and vitamins.
  - Medical events experienced by the individual's parents, and siblings, including diseases that may be hereditary or place the individual at increased risk
- B. Establishing or updating a list of current providers and suppliers regularly involved in providing medical care to the individual;
- C. Gathering or updating of key demographic factors (marital status, level of education, socioeconomic status) that may put a person at greater risk, as well as age-, gender-, and risk-appropriate measurements, if known or available in the health record, including weight, height, body mass index (or waist circumference, if appropriate), blood pressure, cholesterol, blood glucose, tobacco use status, and any other routine measurements as deemed appropriate, based on the individual's medical and family history;
- D. Screening for risk of any cognitive impairment.
- E. Generating or updating a written screening schedule for the next 5 to 10 years such as a checklist, that is appropriate for the individual's age, gender and risk factors, based on the individual's health status, screening history, and age-appropriate preventive services covered by Medicare;
- F. Asking questions to assess risk factors for common conditions and chronic diseases, including but not limited to cancer, diabetes, cardiovascular disease, stroke, depression, cognitive impairment, and functional ability and safety. In formulating these questions, experts in chronic disease should be consulted. These questions will enable the HRA to identify urgent priority health needs and generate (or update) a list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway, and a list of treatment options and their associated risks and benefits.

In order to assess risk for diabetes, cancer, heart disease, and stroke, questions should be included that capture information based on risk assessments and clinical guidelines developed by experts in these chronic disease areas. Questions to assess risk for diabetes should capture information on: blood pressure, cholesterol, overweight/obesity, history of prediabetes or being told one has an elevated blood glucose or A1c, family history of diabetes, history of gestational diabetes or past delivery of a baby weighing over 9 pounds, physical inactivity, age and race/ethnicity.

Questions to assess risk for heart disease should include family history of heart disease, body weight, age, gender, race/ethnicity, diabetes, physical inactivity, tobacco use, diet quality, cholesterol levels, and blood pressure.

Questions to assess risk for cancers should capture information on personal history of cancer, family history of cancer on both the maternal and paternal side (3 generations), smoking history and exposure to tobacco products, history of inflammatory bowel disease, and personal and family history of adenomatous polyps. For women, a history of maternal use of DES, hysterectomy status, history of benign breast biopsy confirmed proliferative lesions or lobular neoplasia, and use of hormone therapy.

G. Screening for the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations;

H. Screening for the individual's functional ability and level of safety, based on the use of appropriate screening questions or a screening questionnaire, which the health professional may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

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## National Business Coalition on Health

### Recv'd 1/11/11

National Business Coalition on Health commends you for the outreach to obtain a broad spectrum of input regarding the design for Health Risk Assessments (HRA). The National Business Coalition on Health (NBCH) is a national, non-profit, membership organization of purchaser-led health care coalitions. NBCH and its members are dedicated to value-based purchasing of health care services through the collective action of public and private purchasers. NBCH seeks to accelerate the nation's progress towards safe, efficient, high-quality health care and the improved health status of the American population.

NBCH worked with CDC on the development of *Health Risk Appraisals at the Worksites: Basics for HRA Decision Making* [http://nbch.org/kma.net/NBCH/files/ccLibraryFiles//Filename/00000000042/HRA\\_Updated\\_080303.pdf](http://nbch.org/kma.net/NBCH/files/ccLibraryFiles//Filename/00000000042/HRA_Updated_080303.pdf). This document was distributed by NBCH and available on the NBCH website. As part of this project, NBCH with CDC conducted an expert panel meeting at CDC offices to help inform the development of the document. The expert panel included academia and research, employers, coalitions and health plans, and practitioners to provide a broad spectrum of HRA experience and expertise. A copy of that meeting report is attached for your review and use as you gather input.

NBCH, with subject matter experts from CDC, conducted a webinar for members and their employer members about HRAs. This webinar included work of member coalitions in assessment support for their members in use of HRAs. Additionally, NBCH conducts an annual assessment of health plan performance using the NBCH tool eValue8™ with its members. This assessment includes queries to health plans about their use of HRAs with members. NBCH welcomes this opportunity to use its experience with these initiatives as well as input from its members to respond to this request.

We have observed a vast number of HRAs and no way to aggregate HRA findings at a community level. With the current use of HRAs that do not have at least a core set of common elements and commonalities of administration with actionable information for the users we are missing an opportunity for a valuable source of information for all stakeholders as well as the ability to identify areas for improvement at the community level. NBCH commends this initiative that will help to guide the further development and more integrated use of this valuable tool.

The following respond to the emphasis areas noted in the Federal Register.

### **Content and Design**

The content for the HRA should result in information that is actionable and useful by the employee/patient as well as caregivers and practitioners. This suggests consideration for the following:

*Content.* Content needs to be relevant to the target user group. This means age and gender but also consideration for appropriate language and level of language as well as use of selection options –words or pictures, etc. As CMS may address not just over age 65 Medicare populations but also younger disabled persons, the questions may need to reflect those differences. Especially for CMS, the caregiver engagement as well as health practitioner will be an important application. As Medicaid or SCHIP program participants are included, the question content will again need to reflect the population being addressed. Content could be designed for use in a school health education curriculum for example. Baseline biometric information is an element of content that is critical. Content should be reviewed with other government agencies for the relevance of use and the value of inclusion to avoid legal and privacy conflicts such as potential discrimination. This especially applies to family history that might be considered potentially discriminatory by another government entity yet is a significant factor in health assessment when combined with biometric and health data.

*Design.* The design of the HRA needs to relate to the audience. An educated workforce regularly using sophisticated computer applications may find a more complex design more meaningful than an older frail elderly population. As HRA standards are developed for children, the complexity of design elements may differ with the common use of computer tools, games, and texting. There may be a need for further research in this area so the content and utility of the HRA does not get lost in the design. The design should also consider how the results will be able to be linked to a personal health record, sent to a specific physician or health practitioner, and what is provided for the participant as immediate feedback. Again, actionable information that is useful the recipient should be the focus.

*Length of the assessment.* This might suggest a core “must answer” approach with options around this core that could be varied for specific uses or conditions. The core questions should lead to the discussion with the health practitioner for more in depth questions and analysis. The ability for the participant to optionally link to more information and educational material should be considered outside of the core requirements. Having a shorter HRA that leads to the participant taking action and/or the practitioner to engage with the patient should be a goal rather than a long set of questions that may not be used or result in engagement by the participant.

Options for employers to add specific questions that are relevant for their work force is also an important factor. For example, site location may be important for an employer who plans to use aggregate HRA data as an information source for any specific worksite program. Or an employer may wish to address a health safety issue that relates to their production or services. The same “options” approach may be an important element for other HRA sponsors to help with their member, employee, or patient input.

### **Mode of Administration**

Access and flexibility with ease ability to complete the HRA all need to be considered. Internet based would appear to be the most economical and least disruptive approach (when one considers follow up to participate, linking to other information or practitioner, etc.) This suggests multiple options for access and if specific for Medicare beneficiaries, information for caregivers and family as well as practitioners about the utility of the HRA. This may mean consideration of outreach through Senior or Community Centers, public libraries, employment centers and other nontraditional approaches to access as well as from home or health care provider office or workplace.

Access also reinforces the need for culturally appropriate and translated versions of the HRA plus support for completion when necessary. A caregiver or grandchild could help a frail elderly person who is not used to electronic tools for example.

Many employers use incentives such as a reduction in health plan contributions for those who employees who participate in an HRA. This approach achieves the highest level of participation. Other approaches that have been successful are when employees are allowed time from work (production line for example) to complete the HRA and/or their supervisor or other work leader strongly supports the program. If the entrée to the physician visit involved the use of an HRA, this would be another approach that would support the completion of the HRA.

Examples from the business sector include alignment of the HRA as an entrée to the health plan enrollment, HRA completion with onsite medical clinic services for follow up and care planning or with onsite or other access to a health educator or coach.

### **Consumer/Patient Perspective**

Ownership of results, access to information, and confidentiality are issues for the employee. Employees want to be assured that the HRA results will not become part of their personnel record or accessible in some other way. This means establishing trust with the source and process as well as explaining how the individual data will be used and accessed. Updating the data should also be addressed—perhaps as a time cycle for doing the HRA annually or biannually.

#### **Data**

Utility of the data resulting from the HRA for the individual participant and caregivers/practitioners as well as security of this data is critical. Access to aggregate data components is important for population health initiatives with the ability to sort the data for planning, research, and evaluation. Question that needs to be addressed include:

***Where will the data reside? Who has access? How and at what cost? How is the data maintained? Who supports the data maintenance?***

Employers typically have a third party vendor—health plan, worksite clinic, health promotion provider or other entity—who administers and houses the data. This segmented approach, while important for confidentiality and other factors—make aggregation of the data more difficult. This issue may need to be addressed through data exchanges or other mechanisms to allow researchers, planners, and others to have access to aggregate data. The fact that CMS and CDC are looking at the significant elements for HRAs affords the potential for this integration to be possible and meaningful.

#### **Certification**

Employers look for ways to select programs and vendors. A certification would help this with all of the factors being considered that are outlined above. Employers with worksite clinics may want to administer through their clinic so consideration needs to be given to certification standards for content as well as processes.

We would encourage CDC and CMS to look at the longer term evolution of HRAs as a base component that could be part of health exchanges, accountable care organizations, government sponsored programs, and schools as well as community planning using the aggregation of this data.

We appreciate the opportunity to provide input and would welcome the opportunity to remain engaged in this discussion as appropriate.

## **The Office of Health and Human Services, Commonwealth of Massachusetts**

***Recv'd Mon 1/3/2011***

Oral health, including oral cancer and dental screenings, should be included in the Health Risk Assessment. With scientific evidence demonstrating the relationship between poor oral health and chronic diseases such as cardiovascular disease, diabetes and bacterial pneumonia, it is imperative to recognize the mouth as part of total wellness. While it is true that as an adult ages, oral and dental disease are commonly experienced; however, with advances in oral disease prevention and treatment, it is no longer the norm to “age into dentures”. In a 2009 statewide oral health assessment of high-risk seniors, the Commonwealth of Massachusetts found that 68% of seniors had some natural teeth and 26% of seniors utilizing state funded meal sites had most of their natural teeth. Seniors of today have experienced many advances in health care over the year, including advances in dentistry and community based oral health prevention strategies, such as community water fluoridation and fluoride toothpaste. Yet in spite of these advances, seniors experience unmet oral health needs. Good oral health and a healthy mouth are necessary for chewing, eating and proper nutrition, the absence of dental pain, enhanced personal relationships, communication, employability and feeling good about one’s personal appearance...each in itself an important component of wellness. Even seniors with no natural teeth require attention to oral health. Including oral health as part of the Health Risk Assessment will draw attention to the needs of seniors that are imperative for total health, and yet have been historically separate.

For a detailed report on the oral health of the Commonwealth’s seniors go to [www.mass.gov/dph/oralhealth](http://www.mass.gov/dph/oralhealth)

## **National Business Group on Health**

***Recv'd 12/21/10***

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

- o 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

- o HRAs must include questions related to biometric screening and individuals' own assessments of their health to fully understand their health status and risk factors.
- o 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

- o Employers and employees can use HRAs to identify behaviors associated with poor health status to change behaviors and predict potential public health issues.
- o 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

- o 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.
- o Sample questions include:
  - Level of stress/depression;
  - Level of anger; and
  - Personal life satisfaction.

### 5. Chronic Health Risks

- o 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.
- o 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

- o HRAs should focus on questions related to individuals' productivity and engagement.
- o 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](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.<sup>1</sup> 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.<sup>2</sup> It is important to develop assessment materials that are culturally appropriate, with reliability and validity established in the target population.<sup>3</sup> 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
- Shared values and expectations: moral standards perceived as desirable and esteemed.<sup>4</sup>

<sup>4</sup> 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.

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 5<sup>th</sup> and 8<sup>th</sup> 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 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.<sup>5</sup> 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

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.<sup>6</sup>

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:

- o 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);
- o 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
- o 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.

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.<sup>8</sup> When used, frequent and more immediate incentives promote behavior change more effectively.<sup>9</sup>

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.<sup>10</sup>

#### **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?

**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

## **Anonymous**

#### ***Recv'd 1/3/11***

Thank you for inviting input regarding the development of health risk assessment (HRA) guidance as required by Section 4103 of the Affordable Care Act for use during the annual wellness visit authorized for Medicare and in other settings. We are writing to call your attention to issues of interest to Medicare beneficiaries and other populations living with or at risk for chronic hepatitis B virus (HBV) and chronic hepatitis C virus (HCV), referred to here as "viral hepatitis".

As you may know, there are approximately 4.6 million people living with chronic viral

hepatitis in the United States, yet most of these individuals do not know they are infected. Without timely diagnosis and treatment, one in four individuals with chronic HBV will die of liver disease, liver failure, or liver cancer. HCV is the leading cause of liver transplantation in the United States. Individuals born during 1945 through 1964 have a higher prevalence of HCV than does the general population and are beginning to age into eligibility for Medicare. Without changes in current HCV diagnosis and treatment practices, total annual HCV-related Medicare costs are expected to increase six-fold over the next 20 years, from \$5 billion to \$30 billion. These costs and complications can be averted through early screening and detection.

## 1. Content and Design

### A. Risk Assessment Domains

The standardized HRA should include several key domains, which are consistent with current Medicare regulations as defined in 42 Code of Federal Regulations Section 410.16: medical, social, and family history. Within each of these domains, there are specific elements that, if included, could inform Medicare beneficiaries for chronic viral hepatitis and avert preventable complications from undetected chronic liver disease. Specifically, to enable clinicians to implement Centers for Disease Control and Prevention (CDC) [hepatitis C screening guidelines](#), we would advocate that the assessment of *“past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries, and treatments”* include the question, “Did you ever receive a blood transfusion prior to 1992?”, which would signal the need for HCV screening. Similarly, we would advocate that the assessment of *“social history”* -- *“history of alcohol, tobacco, and illicit drug use”* -- include the question, “Have you or any of your partners ever injected drugs?”, which would indicate the need for HBV and HCV screening for individuals with a history of injection drug use.

To implement [CDC hepatitis B screening guidelines](#), we would advocate that the assessment of *“family history, including a review of medical events in the beneficiary's family, including diseases that may be hereditary or place the individual at risk”* include a question as to the patient's “country of birth”, which would indicate HBV screening for patients born in countries where two percent or more of the population has chronic HBV infection.

To implement [CDC hepatitis B screening guidelines](#), we would also advocate that the *“review of the beneficiary's medical and social history with attention to modifiable risk factors for disease”* include an assessment of sexual health, which would indicate HBV screening for men who have sex with men. The [CDC 2010 STD treatment guidelines](#) provide the following guidance for assessing sexual health and risk behaviors.

### The Five P's: Partners, Prevention of Pregnancy, Protection from STDs, Practices, and Past History of STDs

#### 1. Partners

- “Do you have sex with men, women, or both?”
- “In the past 2 months, how many partners have you had sex with?”
- “In the past 12 months, how many partners have you had sex with?”
- “Is it possible that any of your sex partners in the past 12 months had sex with someone else while they were still in a sexual relationship with you?”

#### 2. Prevention of pregnancy

- “What are you doing to prevent pregnancy?”

#### 3. Protection from STDs

- “What do you do to protect yourself from STDs and HIV?”

#### 4. Practices

- “To understand your risks for STDs, I need to understand the kind of sex you have had recently.”
- “Have you had vaginal sex, meaning ‘penis in vagina sex’?” If yes, “Do you use condoms: never, sometimes, or always?”
- “Have you had anal sex, meaning ‘penis in rectum/anus sex’?” If yes, “Do you use condoms: never, sometimes, or always?”

- “Have you had oral sex, meaning ‘mouth on penis/vagina’?”

For condom answers:

- If “never:” “Why don’t you use condoms?”

- If “sometimes:” “In what situations (or with whom) do you not use condoms?”

5. Past history of STDs

- “Have you ever had an STD?”

- “Have any of your partners had an STD?”

*Additional questions to identify HIV and viral hepatitis risk include:*

- “Have you or any of your partners ever injected drugs?” (*emphasis added*)

- “Have any of your partners exchanged money or drugs for sex?”

- “Is there anything else about your sexual practices that I need to know about?”

Finally, to implement the Advisory Committee on Immunization Practices’ adult immunization guidelines, we also recommend assessing the patient’s vaccination history to identify whether vaccination against hepatitis A or HBV infection is indicated.

## **B. Literacy and Cultural Appropriateness**

In many cultures, discussing sexual health, sexual behavior, disease, and drug-using behaviors is taboo. In addition, people with a history of illicit drug use, and lesbian, gay, bisexual, and transgender individuals often experience discrimination from healthcare professionals in clinical settings. Foreign-born individuals also may fear discrimination, may not feel comfortable disclosing information as to their country of birth, and face language access barriers. In California, a task force comprising more than 40 primary care clinicians, infectious disease physicians, human immunodeficiency virus (HIV) care providers, and liver specialists, reported that primary care clinicians often do not have time to ask their patients extensive risk assessment questions.

For these reasons, one option for administering risk assessments is to organize the HRA to include statements such as “If any of the above statements apply to you, check yes”. This enables patients at risk for viral hepatitis to be flagged for screening without them having to disclose which specific risk behavior or demographic characteristic indicated the need for screening. Enclosed for your reference, you will find a sample patient-administered risk assessment developed by the California Viral Hepatitis Clinical Task Force, which was developed with these considerations in mind.

It is important that the HRA be translated into the languages most commonly spoken in the geographic area where a specific provider delivers care and be made available to patients who are members of high-risk ethnic populations (e.g., Asian and Pacific Islanders). Based upon prevalence data for HBV infection, translated languages should initially include Chinese, Korean, Vietnamese, Cambodian, Lao, and Hmong. HCV prevalence data suggest the need for translating materials into Vietnamese, Russian, and Spanish; however, this will vary by region. The HRA should also be culturally appropriate for these groups.

In order to facilitate shared decision-making between the patient and a provider, the HRA should inform a summary, delivered either in-person or by computer, of which screenings and vaccinations are recommended, based on the patient information provided. Patients can use this summary, along with information on the risks and benefits of the recommended screening and vaccination, to decide which services to utilize during their visit.

## **2. Mode of administration**

The HRA should be accessible to patients via multiple venues. This includes kiosks and paper forms completed by the patient in physician waiting rooms. Additionally, online versions can be made available through health-related non-profit websites. A simple, downloadable, paper and electronic version of the HRA needs to be accessible at venues which are frequented by high-risk individuals, including methadone clinics and other drug treatment programs, syringe services programs, STD clinics and family planning sites, prisons and jails, community-based organizations that serve high-risk

populations, primary care clinics, and federally qualified health centers. The HRA should include a section that is modifiable, so that organizations using the form can add their logos and other administrative information to the form for internal use.

Whether the HRA is completed electronically or on paper, healthcare organizations that use an electronic health record (EHR) should enter information from the HRA into the EHR as soon as the assessment is completed. Where possible, information from the

HRA can inform automated prompts for appropriate screenings for patients with risk factors identified through the HRA.

### **3. Primary care office capacity**

Training on cultural, linguistic, and logistical considerations for administering HRAs and using information collected through these assessments in clinical practice can be conducted online or in-person, through networks of professional and healthcare organizations. There are also a number of potential community linkages to assist with prevention planning and follow-up care. National organizations focusing on education and linkages for people living with viral hepatitis include: the Asian Liver Center at Stanford University; Caring Ambassadors; Hepatitis B Foundation; Hepatitis C Support Project; Hepatitis Treatment Research and Education Center; and the National Viral Hepatitis Roundtable; among others.

The CDC National HIV and STD Testing Resources website ([www.hivtest.org](http://www.hivtest.org)) is a potential venue for providing service referrals for hepatitis A and HBV vaccination; HBV and HCV testing; education and support groups; and linkages to care. Patients could easily be redirected to the site through a dummy URL, such as [www.heptest.org](http://www.heptest.org), to access viral hepatitis-related service referrals.

### **4. Evaluation and quality assurance**

In order to maintain the HRA up to date, CDC should periodically (every two to three years) issue an updated standard HRA, which incorporates recently released CDC screening and vaccination guidelines for various patient populations and risk groups

## **American Dietetic Association**

*Recv'd 1/3/11*

The American Dietetic Association (—ADA) provides the following comments in response to the joint request from the Centers for Disease Control and Prevention (—CDC) and Centers for Medicare and Medicaid Services (—CMS) (collectively, the —Agencies) for guidance on the development of guidance concerning Health Risk Assessments (—HRAs). The Affordable Care Act (—ACA) requires that HRAs be included in the annual wellness visit benefit authorized for Medicare beneficiaries.

ADA has over 71,000 members including Registered Dietitians (—RDs) who provide care using evidence-based practices. RDs independently provide professional services under Medicare Part B, such as medical nutrition therapy (MNT). Medicare covers outpatient MNT provided by RDs for beneficiaries with diabetes, chronic renal insufficiency/end state renal disease (non dialysis renal disease) and post kidney transplant.<sup>2</sup> As a primary preventative technique, strong evidence supports that appropriate nutrition promotes overall health and functionality. As a secondary and tertiary preventive measure, MNT is a cost-effective disease management strategy that lessens chronic disease risk, slows disease progression and reduces symptoms.

ADA is committed to improving the nation's health and strives to optimize the nation's health through food and nutrition. As such, ADA strongly supports the use of HRAs in annual wellness visits. HRAs serve to not only benefit the providers in understanding treatment and care plans for beneficiaries, but also are well positioned to engage beneficiaries to actively participate in their health care and help monitor tangible outcomes related to their health care. Such methods of engagement are critical for a sustainable health system and align well with the present adoption of health information

technology by both providers and individuals. HRAs thereby provide a dual mechanism by which the provision of health care services and the prevention of services work symbiotically to function as a quality of care and cost savings measure. In light of these functions, ADA offers the following comments on HRAs for consideration to the Agencies:

### **A. Content and Design**

ADA supports evidence-based, validated screening tools for assessing a beneficiary's health status. ADA recently reviewed eleven (11) nutrition screening tools for their validity and reliability to identify nutrition problems in acute care and hospital-based ambulatory care settings.<sup>4</sup> Tools for which there were Grade I and II evidence were ranked in terms of highest sensitivity and specificity. Many of these tools were validated against an appropriate reference standard: either the subjective global assessment or mini nutritional assessment.<sup>5</sup> These nutrition screening tools include domains by which HRAs can be structured. These tools allow beneficiaries to see from an early stage potential risk factors for chronic diseases.

In addition to identifying risk factors for certain chronic diseases as part of the HRA domains, ADA also supports including other elements in the HRA tool, such as nutrition lifestyle patterns, including macronutrient or food group intake elements, plus smoking and alcohol habits. Additionally, physical activity/exercise and family history of diseases (cardiovascular disease, obesity, diabetes, other chronic diseases, etc.) must be included as domains. Nutrition should be a key domain in the HRA since nutrition intervention as a treatment plan results in improved clinical outcomes, reduced costs related to physician time, medication use and hospital admissions for people with obesity, diabetes and disorders of lipid metabolism, as well as other chronic diseases.

ADA believes a significant consideration for HRA content and design is that the screening should include a two-pronged approach. The first HRA should provide a basic screening to broadly assess a general review of systems and health risk. For those individuals with high risk based on their factors such as disease(s), family history and social/psychological factors, further assessment through a more comprehensive screening is recommended. This bi-level approach is integral in ensuring care for disease process as well as preventive services.

A question to consider in the HRA content and design is whether there will be a universal HRA that has standard domains or whether states will have flexibility to design HRAs that comply with certain parameters provided by the Agency. In either of these cases, cultural appropriateness and literacy factors must be taken into account to promote the efficacy of HRAs. Cultural competency is becoming a central tenant of patient-centered care and effective communication, thereby becoming a component of delivering responsive and quality care to all beneficiaries.<sup>7</sup> Therefore, HRAs should be framed or providers be given flexibility to adjust for various factors, including linguistic needs, age stratification and other cultural factors. We encourage the Agencies to create and implement HRAs that decrease health disparities – that is, the gaps in the quality of health and healthcare across racial, ethnic and socioeconomic groups.

### **B. Continuity of Care**

A critical aspect of HRAs is the extent to which healthcare providers will coordinate future care for the beneficiary. With well-designed HRAs that include nutrition screening tools as a key domain, the beneficiary can be referred to a provider who specializes in the particular area of concern to achieve positive health outcomes with appropriate treatment. For example, if an HRA demonstrates a need for nutritional intervention, the beneficiary should be referred to a RD. The inclusion of nutrition interventions and counseling, when provided by a RD as part of a health care team, can result in significant improvements in weight and Body Mass Index (BMI), hemoglobin A1C, blood pressure and serum lipids.<sup>8</sup> Positive triggers on nutrition questions included in a comprehensive HRA can be an effective tool to address not only health risk, but to determine the appropriate clinical course for effective treatment. HRAs provide the ability for a continuum of care by various providers who collaboratively prioritize the beneficiary's risk levels. With treatment plans and referrals to the appropriate qualified provider, there is a measureable connect between the risks shown in HRAs and the health outcomes of the beneficiary. Compiling these evaluative measures via an online, accessible database may allow for data collection and comparison from HRAs on a national level. This compilation may demonstrate aspects of the delivery care systems that need to be adjusted in order to further quality and access to care. The continuum of care also extends to the utilization of self-assessment screening tools by beneficiaries. A simple self-assessment tool, e.g., Mini Nutritional Assessment-Short Form, allows a precursory understanding of a potential or real health risk.<sup>9</sup> With these screening tools in place, there is more of an emphasis on preventive services providing the beneficiary with responsibility over the outcomes. With this foresight, HRAs improve health outcomes and increase cost-savings. As a result, expansion of preventive services for intensive nutrition behavioral counseling and the like, as permitted under ACA, is critical.

These services will frequently be required as part of the beneficiaries' prevention plan initiated through their annual wellness visits. ADA has commented previously to Health and Human Services concerning the critical need for continuity of care. In particular, we have requested individual patient information concerning nutrition (diet order, nutritional care plan and RD referral) become a standard part of the Continuity of Care Document (—CCD) and other standards within health information technology (—HIT). In order to assure true interoperability (and thereby continuity of care), ADA is working with Health Level Seven (HL7) to create and harmonize nutrition related standards for nutrition care within HIT—in particular, electronic health records (—EHRs). ADA has conducted a series of initiatives over the past decade that support improved health care through the use of nutrition interventions, health care standards and HIT.

### **C. Data**

HIT and EHRs will be serving as a new method of health data recording and management in the future. These tools serve as a medium to help inform beneficiaries of their health risks and follow up treatment plans. ADA, in conjunction with the American Society for Parenteral and Enteral Nutrition, developed a dataset of factors that are commonly included in EHRs to evaluate nutrition in beneficiaries. As EHR adoption evolves in health care, this dataset will be further developed to assure health data interoperability across health care systems, providers and beneficiaries alike.<sup>11</sup> When beneficiaries access their own health data and information via the Internet with a password-protected page (or alternatively, if providers are granted access), beneficiaries can then share health information to their various providers, thereby creating a virtual medical home where all their risks and care are housed.

Alternatively, HRAs should be widely accessible for any beneficiary to retrieve pertinent health information without compromising any protected or confidential data about the beneficiary. HRAs should be accessible in pharmacy or retail clinic kiosks, mail-in paper forms and other healthcare locations, including but not limited to, ambulatory care centers, hospitals and qualified healthcare provider offices.

### **D. Consumer/Patient Perspective**

HRAs included in annual wellness visits are an effective instrument not only for the providers rendering care, but also to the beneficiaries themselves. Engaging beneficiaries in their risk assessments is fundamental in proving HRAs effective. The annual wellness visit provides an opportunity for the provider to evaluate risks on behalf of the beneficiary. However, follow-up with the beneficiary to ensure their comprehension of how these risks will affect their health and where to seek out additional resources is compulsory. Beneficiaries can use the HRA preliminary screening to identify health issues to discuss with their physician and healthcare team.

ADA also encourages consistent beneficiary/family engagement and participation in care plan development following HRA evaluations. The environmental integration following HRAs may increase the initiative for beneficiaries to seek out advance care and take active interest in improving their health outcomes.

In addition to educating beneficiaries about the usefulness of HRAs, incentives may be used to encourage beneficiaries to participate in HRAs. According to the National Business Group on Health (NBGH), —incentives that emphasize a culture of health, well-being, self help, and shared responsibility can have a significant effect on costs and medical outcomes. Incentives can actively engage members in their health decisions and encourage involvement in their health plans to yield improved outcomes and lower healthcare costs.<sup>12</sup> Rebates or discounts that exist in the private health insurance markets are examples of such incentives. However, it is unclear as to where the benchmarks of average risk levels would be set. Depending on the difference between the benchmark and the risk level of the beneficiary, the beneficiary would receive a rebate in proportion to the difference between the benchmark and the lower individual risk level.

### **E. Conclusion**

Screening tools, such as HRAs, need to be integrated into the standard health evaluations that providers use when evaluating a beneficiary. These screening tools should include a variety of parameters including nutrition, physical activity and other psycho/social domains.<sup>13</sup> It remains unclear as to whether there will be a national screening tool for HRAs. However, any screening tool used with HRAs should be evidence-based and be reviewed by a well-rounded group of practitioners, including RDs, physicians and other qualified health professionals.

Because of the expertise required to ensure that nutrition screening tools are appropriate, the ADA requests that decisions made regarding the HRA include the perspective of a nutrition scientists with a PhD or equivalent who is a RD with significant clinical experience. The importance of including a broad class of providers in this process is important to achieve cost-effective, quality care for beneficiaries. Any panels, groups or —think tanks formed to address the HRA should include a RD.

In addition, the nutrition-related treatment plan driven by HRA screenings should become a standard part of the EHR and data exchange components (such as the CCD) to assure widespread continuity of care. HRAs provide a way to monitor and track coordination of care and beneficiary outcomes. By linking HRA results to treatment interventions such as MNT/lifestyle behavioral nutrition counseling, there is a measurable impact on health improvements of beneficiaries. We urge the Agencies to take into account these considerations as they work to develop and implement metrics and protocols for HRAs in annual wellness visits. Please do not hesitate to contact Jeanne Blankenship (202-775-8277 or email: jblankenship@eatright.org) with any questions or requests for additional information.

Sincerely,

Jeanne Blankenship, MS, RD, CLE  
Vice President, Policy & Advocacy  
American Dietetic Association

## National Committee for Quality Assurance

**Recv'd 1/3/11**

On behalf of the National Committee for Quality Assurance (NCQA), I appreciate the opportunity to respond to your request for information on developing guidance on Health Risk Assessments (HRAs). As America's leading HRA certifier and Wellness and Health Promotion (WHP) program accreditor, we strongly support developing guidelines for effective use of HRAs.

Medicare's new coverage for physician-administered HRAs in connection with Annual Wellness Visits will also carry tremendous benefits for seniors and public health research. We encourage you to integrate HRAs with other public health programs, administering surveys at worksite, physician and plan levels.

NCQA offers three programs that relate to your efforts in connection with HRAs:

1. **Certification of Health Information Products** (of which an HRA is one product). We certify vendors offering HRAs that:

- (1) Collect a range of health characteristics and behavioral information;
- (2) Contain explicit privacy disclosures and consent requests;
- (3) Provide actionable feedback to participants;
- (4) Are administered in an accessible way;
- (5) Are administered to individuals annually; and
- (6) Are updated on a bi-annual basis as the evidence base evolves.

2. **Accreditation of Organizations Providing Wellness and Health Promotion (WHP) Programs.** To receive NCQA's WHP accreditation, organizations must administer HRAs that comply with standards similar to those under our Health Information Product certification program. However, HRAs are just one component of successful organizations' suite of WHP services, which plan sponsors generally offer within the employer-based benefit context. We accredit organizations that offer WHP programs for providing a variety of services to plans and employers supporting HRA and health improvement goals. Other WHP services include collecting and reporting performance measures, proffering incentive-based health improvement plans, targeting at-risk individuals for intervention, health coaching, and others.

3. **Patient-Centered Medical Home (PCMH) Recognition.** We have updated our Patient-Centered Medical Home Recognition program with new standards for 2011 that require HRAs. We do not prescribe how recognized practices conduct HRAs, but do require that they include medical histories, immunizations, screenings, cultural characteristics, advance care planning, behaviors affecting health, and more.

Leveraging our expertise in evaluating and certifying these programs and products over the past several years, we offer the following responses to questions posed in the request for information.

**Content and Design:** *What are generic elements of any HRA and what elements must be tailored to specific populations, particularly those stratified by age? How should literacy and other cultural appropriateness factors be factored into the design? How should the HRA instrument support shared decision-making by provider and patient?*

We certify organizations offering HRAs based on whether they include questions:

1. On demographics, including race and ethnicity;
2. On personal and family history, including chronic illness and current treatment;
3. On self-perceived health status, including functional status;
4. To identify effective behavioral change strategies; and

5. To identify any special hearing or vision impairment and language needs.

They also must be able to collect personal health characteristics: weight; height; smoking; physical activity; healthy eating; stress; productivity or absenteeism; breast cancer screening; colorectal cancer screening; cervical cancer screening; influenza vaccination; risky drinking; and depressive symptoms. All certified administrators of an HRA must present the assessment in language that is easy to understand. The organization must present information in a clear and coherent manner and use words with common and everyday meaning, to the extent practical.

**Mode of Administration:** *How will individuals access the HRA (e.g., via kiosk or some other means in the physician's office, Internet, mail-in paper form, other non-traditional healthcare locations, such as, kiosk in a pharmacy)? What are the cultural appropriateness factors in patient HRA access?*

Currently, employers commonly sponsor HRAs at worksites, and we should ensure appropriate sharing of results with primary care providers to avoid duplicate HRAs. NCQA-certified organizations must offer HRAs either online or in print and by telephone and in easy-to-understand language. We also support physician office HRAs as part of both new Medicare wellness visits and PCMH Recognition. NCQA's WHP standards require organizations to assess language needs and be transparent about their ability to support other languages. PCMH standards also require an assessment of the patient's cultural characteristics. This helps ensure that WHP programs can support employees for whom English is not their first language.

**Consumer/Patient Perspective:** *How could HRA data be shared with the patients for their feedback and follow up in the primary care practice? What role, if any, do incentives play in motivating patients to take the HRA and/or participate in follow-up interventions?*

NCQA-certified HRA organizations must share the following results with each participant:

1. An overall summary of their own individual risk or wellness profile;
2. A clinical summary describing individual risk factors;
3. Information on how to reduce risk by changing specific health behaviors;
4. Reference information that can help the participant understand the HRA results; and
5. A comparison to previous results when applicable.

With patient consent, primary care providers should routinely get HRA findings so they can help address findings. WHP accredited systems also must offer a number of supports for health improvement. These include self-management tools, opportunities to engage in employer-sponsored activities (walking clubs, smoking cessation), health coaching, etc. The WHP organization must also conduct targeted follow-up with specific at-risk participants, such as hypertension, possible addiction or depression, or other risk factors. Follow-up may include discussion of preventive health services information or supports.

Evidence suggests that incentives for completing HRAs can increase completion rates. This helps WHP programs reach more participants and gives the organization a better understanding of the population's risk profile. Without incentives, response rates are extremely low.

**Data:** *With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non-electronic form? Are there standardized and certified tools available to support this data migration from multiple data entry sources?*

Data integration and exchange to combine health data from disparate sources into a unified portrayal of an individual's health status is a core component of any comprehensive wellness program. This is why we require accredited WHP organizations to disclose data integration and exchange capabilities for the following sources:

1. Claims or encounter data;
2. Demographic data;
3. Lab or biometric data;
4. Pharmacy benefit management organizations;
5. Disease management organizations;
6. Managed behavioral health organizations;
7. Medical providers; and
8. Data aggregators.

We require data exchange and reporting standards within our evaluation products to spur integration and representation of these data. However, we believe more is needed to ensure a universal standard. We therefore support Office of the National Coordinator for Health IT work towards a universal data exchange platform for all information, including HRAs.

**Certification:** *What certification tools and processes should complement the HRA guidance and how should they be made available to support primary care office selection of an HRA instrument?*

NCQA accreditation and certification are the most widely used tools to evaluate both HRAs and WHP programs. We developed our standards in consultation with a cross-stakeholder advisory committee and our Board of Directors, which both include academics and researchers, physician leaders, health plan representatives, consumer advocates, and others. Using NCQA's standards would foster industry-wide consistency and help NCQA evaluated programs – particularly those used by small employers – to coordinate with federal initiatives.

**Evaluation and Quality Assurance:** *How should the HRA guidance be evaluated and updated with respect to individual and population-level (practice-based panel management) health outcomes?*

NCQA requires accredited organizations to have quality improvement processes in place to identify, measure and act upon improvement opportunities. This could inform your efforts.

Thanks again for the opportunity to comment. We look forward to working with you further to expand the use of effective, evidence based HRAs.

Sincerely

Margaret E. O'Kane , President

## Alere Health

### **Recv'd 1/3/11**

Alere appreciates the opportunity to submit comments to the CDC regarding development of Health Risk Assessment (HRA) Guidance. Alere is a global leader in enabling individuals to take charge of their health at home through the merger of rapid diagnostics and health management services.

Section 4103 of the Affordable Care Act (ACA) requires HRAs to be included in the annual wellness benefit authorized for Medicare beneficiaries. Importantly, the private sector will also use the CDC Guidance to evaluate the use of HRAs to better manage chronic disease in the employer setting. Alere believes HRAs, properly designed and implemented, will be a useful tool for patients to manage their own health, and for clinicians to have more meaningful interactions with patients over time.

### **Content and Design**

**Simplicity and Ease of Use.** Alere believes HRAs should be simple, with a short battery of questions that captures the minimum set of information needed to determine a patient's risk of chronic disease or exacerbation of disease. The HRA does not need to be long to be useful to patients and physicians. Instead, it should be long enough to capture those important clinical and lifestyle risk factors that are associated with the major chronic medical conditions related to premature illness and death. At the same time, it should be short enough not to discourage completion by the patient. HRA vendors are in substantial agreement on what risk factors should be measured: clinical risks include BMI and blood pressure; lifestyle risks include physical activity and tobacco use status. In addition, the patient's status on age/gender-appropriate screenings and immunizations should be included. The HRA should be easy to understand and customizable for a wide variety of patients with different literacy levels, cognitive abilities, and cultural backgrounds.

**Customization by the Vendor to Meet Specific Patient Needs.** An HRA should not contain static fields that are not customizable by the vendor to meet the needs of particular types of patients. Clearly, all HRAs will have standard information (height, weight, BMI), but HRA's should be fully customizable to allow added questions if needed to capture information from specific population subgroups. For example, additional items assessing nutritional status might be desirable when delivering an HRA to a senior population, but inappropriate for a younger population. In addition, this customization will allow vendors with a full suite of health management services and tools the ability to help patients and their doctors manage chronic disease.

**HRA as a Tool for Health Management Over Time.** An HRA should not be seen as a static battery of questions that only produces baseline data. Rather, to be truly effective, an HRA should be a tool for the patient to modify behavior over time. Therefore, the battery of HRA questions must produce, in combination with other information, suggestions for behavior modification, and opportunities for lifestyle intervention that can be actionable by the patient and reflected in an updated HRA. A fully interactive HRA will allow patients to better modify behavior and manage chronic disease.

### **Mode of Administration**

**Types of Technology and Access.** HRAs should be available using a full range of technology. Newer technologies, like secure internet sites and mobile phone applications, offer robust platforms for data transfer to electronic health records (EHR) or personalized health records (PHR). In addition, these platforms are easily customizable, and can be paired with reminders or other interventions to help patients and physicians better manage chronic disease over time. Phone based interactions with disease management companies under contract with employers or insurance firms should be encouraged, particularly for patients who are uncomfortable with new technology. Importantly, older methods, including paper and pencil

administration should be available to accommodate the needs of older populations, or those who feel less comfortable with electronic administration. Importantly, regardless of technology, for the HRA to reach its full potential, the mode of administration should encourage patients to use it as a tool to manage their own health. For example, if patients get clear guidance on behavior modification as an outcome of using an HRA, then the HRA and the guidance need to be portable enough for the patient to use away from the physician office setting. However, some technology presents logistical and privacy challenges that shouldn't be ignored. For example, kiosks in public places, like the pharmacy setting, may create confidentiality and privacy issues. In no case, should guidelines preclude newer technologies from being adopted.

### **Consumer/Patient Perspective**

**Patient Interaction with HRAs and the Physician.** Information from the HRA should be shared simultaneously with the patient and the doctor to the extent practicable. Patients will benefit if the HRA is an interactive tool that can be used over the course of their lives to make better health care decisions in real time, and access to the health care system is easier. As a tool, a patient can use the information from an HRA to keep track of their "score" on several different risk factors for chronic disease, better managing their health. New technologies would allow patients to schedule follow-up visits with the doctor at the time new information is entered into an HRA if appropriate.

**Incentives.** Incentives are an important component to maximize participation. The most effective incentive in the private marketplace is a premium or copayment reduction (even more than cash incentives). In no case, should the proposed guidance discourage incentives.

### **Data**

**Compatibility with EHRs and PHRs.** Information from an HRA should be fully compatible with EHRs and PHRs. However, it is essential that the source of the data is identified clearly if the data migrates into an EHR or other record. Self-reported data from the patient may contain errors or omissions. Both clinicians and researchers must understand how to evaluate the data in an electronic health record.

### **Certification**

**Third Party Certification and Instrument Validation.** The Secretary should deem NCQA and URAC as nationally recognized, third party, independent organizations to certify and validate HRAs in order to make sure they are an effective tool for the management of patients' health. HRAs will only be successful if they contain valid metrics and are administered in patient-appropriate ways. Results of accreditation assessments should be made public so providers can make choices that best suit their needs.

Sincerely,

Gordon D. Kaplan, PhD  
Director of Research  
Alere Health

## **Health Dialog**

***Recv'd 1/3/11***

We are pleased to offer comments in response to the request for information regarding Health Risk Assessment guidance. We support Congress and CMS' goal to provide access to beneficiaries to an initial and annual wellness visit in FFS Medicare supported by a health risk assessment and a personalized prevention plan. Since our inception, Health Dialog's mission has been to improve the health and well-being of the individuals we serve. We achieve results by providing health coaching for wellness, chronic conditions, and medical decisions, as well as population analytics and outcomes measurement<sup>1</sup>. We currently support over 20 million individuals, including over five million participants specifically in our wellness programs.

1 Wennberg DE, Marr A, Lang L, O'Malley S, Bennett G. A Randomized Trial of a Telephone Care-Management Strategy. *NEJM*, 2010; 363.

Wellness Interventions

Our wellness programs include a personal health assessment and personalized feedback in the form of a Health Action Plan, 24/7 health coaching support, a structured telephonic behavior change program, online behavior change modules to address wellness and lifestyle topics, and wellness toolkits and other materials. These interventions can:

- Provide supportive guidance for individuals in developing evidence-based strategies for action
- Help individuals recognize and minimize barriers to behavior change
- Help individuals address knowledge gaps and create action plans to make healthy behavior changes
- Monitor and help individuals resolve feelings of ambivalence while increasing motivation

## Health Risk Assessments

Health risk assessments are designed to encourage individuals to take an active role in managing their health and well-being. Health Dialog's tool, for example, employs advanced behavior change techniques that meet individuals where they are. The objectives are to provide individuals with personalized information that reinforces self-reliance and self-care driving individuals to take appropriate action; to identify high-need and highly receptive individuals in a specific population; and to provide reports that identify near-term actions and wellness initiatives. The tool, like many widely available health risk assessments, fosters participation through a highly interactive design based on engaging individuals in their health management and well-being, as well as a proven philosophy that:

- Raises awareness of health conditions, behaviors, and risk factors
- Promotes self-reliance and quality decision-making
- Helps motivate individuals to become more proactive and confident in their health management

Health risk assessments can address general health status, health and lifestyle behaviors, physical and emotional function, chronic conditions, recent symptoms, psychosocial activity, and healthcare utilization. Specific risk assessments in our tool include smoking, body mass index (calculated from height and weight), hypertension, cholesterol level, heart failure, respiratory illness, chronic pain, arthritis, backache, and emotional health. Not only do these tools collect this information and generate specific recommendations to modify these risks, but completing the health risk assessment itself is an engaging user experience that incorporates some of the same motivational interviewing techniques used by health coaches in order to identify a participant's motivations for change and to guide individuals to take the next step in managing their health and lifestyle risks. In addition, individuals can and are referred to online tools that employ video clips to create a highly interactive and positive patient experience.

## Recommendations

In order to ensure opportunity for continual innovation and updated evidence, we recommend CMS and CDC defer to accreditation bodies to promulgate guidelines for health risk assessments. Presently, the organizations that accredit health risk assessments do so annually to incorporate the latest evidence and allow organizations to be nimble and innovative in refining their tools.

If CMS and CDC proceed with setting guidelines instead of deferring to accrediting bodies, we urge CMS and CDC to consider the following factors:

### Content and Design:

- In order to maximize the usefulness of HRAs to beneficiaries and physicians, they must be user-friendly, address appropriate senior-focused issues, fit in with the physician workflow, and the data must be extracted for analysis to identify population health trends and target wellness interventions to those who can benefit.
  - o Health literacy – a balance must be struck to ensure that HRA questions adhere to clear language principles while maintaining sufficient information to avoid a disconnect between the terminology needed for very low reading levels and the medical jargon patients will hear from their physicians. NCQA and other accrediting bodies are cognizant of this issue. We recommend deferring to relevant accreditation bodies and encouraging HRA developers to work with health literacy experts to balance clear language, validated question sets, and physician terminology.
  - o Data collection – we support extracting data for analysis to target wellness and shared decision-making interventions to those who can benefit, ensuring that consideration is given to individuals' privacy concerns about perceptions of government intrusion.
  - o Physician workflow – it is most valuable if HRA and feedback reports can flag the most important issues to discuss in advance, obviating the need to spend time in the visit repeating the questions and answers.
- Shared decision-making is the process of interacting with patients in arriving at informed, values-based choices when multiple effective treatment options exist. In order for HRAs to support shared decision-making, questions must help identify individuals in treatment decision windows. The information could then be used to encourage patients and providers to engage in the shared decision-making process, which could include the use of decision aids and coaching.

### Mode of Administration:

- We support online, telephonic, and paper HRA distribution. We believe the usefulness of HRAs is greatest when the HRA is conducted and feedback is provided to patient and physician in advance of the physician office visit.

### Primary Care Office Capacity:

- We believe HRAs are optimized when conducted and feedback is provided in advance of the physician office visit. In new provider payment models that are advanced by health reform, a focus on team-based care has emerged. We support the use of nurses and other professionals inside and outside of the physician office to administer the HRA and develop personalized health action plans.

Consumer and Patient-Perspective:

- We strongly support CMS and CDC developing a process to share feedback with patients and physicians in advance of the physician office visit.
- Incentives can serve as powerful motivators. Recent studies place HRA participation with incentives in the 70-90% range, compared to HRA participation without incentives in the 20-30% range.

Thank you for taking our comments under consideration.

David Wennberg, M.D., M.P.H.

Chief Science and Products Officer

## Medivon

### **Recv'd 1/2/11**

Medivon's Response to the Department of Health and Human Services (HHS) which is seeking public comment on the development and guidance concerning the **Health Risk Assessments** Process and CMS Compliancy

Medivon, LLC is a Predictive Medicine company involved in assessing the health risk of thousands of people across the country over the past 6 years for major corporations and service organizations. We are distributors for HealthMedia, WellSource, BiolQ, PreVue and other advanced risk assessment tests and software products. Medivon through its web portal provides a comprehensive, integrated suite of webbased

digital wellness, biometric

and health coaching programs that

combine advanced and proprietary technology.

It has become widely acknowledged that our most effective strategy for lowering the crippling cost of healthcare is to prevent people from getting sick in the first place or, if they are already ill, empowering them to contribute to their own care.

Initiatives that achieve those objectives do so by optimizing the health status of a group of employees or other targeted population – minimizing pain, maximizing productivity, and increasing longevity. Medivon believes it has a uniquely powerful, comprehensive, and cost-effective

solution to accomplish this lofty and critical goal,

substantially reducing healthcare costs for any population. Medivon's experience in

this area comes from providing what we call our Wellness Solution Modules which

can be acquired individually, or they can be combined for a Total Solution.

Whichever our clients choose, their privately labeled

Health Optimization Solution is

fully integrated via Medivon's advanced *HealthOptimizer™* Portal and Health Data Management System

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At the core of our offering is HealthMedia's NCQA (HIP 1 & HIP 2) certified Health

Risk Assessment (HRA). We can clearly see the use of this product where physicians can fulfill the requirements for the new Medicare annual visit more effectively and efficiently by delivering a concise health summary that it provides. The health summary reflects where that beneficiary resides on the health continuum and assists the physician in delivering a more informed and targeted consult.

Therefore, Medivon feels highly qualified to submit its opinion on the use of HealthMedia's Health Risk Assessment and digital coaching programs because of our experience in delivering this product to varying venues of different cohorts and providing results that drive positive behavior outcomes. For over 6 years Medivon has used Health Risk programs on participation levels of a few hundred people in

supermarkets and drug stores to over 150,000 corporate employee's using both our biometric

testing and the integrated use of HealthMedia's Health Risk Assessment web based integrated digital health coaching software.

We feel the use of the internet and smart phone technology is rapidly becoming the optimal tool set for assessing and managing one's health risk along with taking the steps needed to insure people do not regress in their health scores and in fact take advantage of advanced application to improve their health status.

Bio Metric scores, access to the HRA questions, and digital health coaching can be all accessed via the web and results can be viewed and interacted on via a computer or smart phone. Documents and test results can also be printed and the information can be electronically transmitted to their medical records, therefore integrating claims and biometric data.

Health Risk Assessments (HRAs) are commonly administered through use of a health questionnaire used to provide individuals with an evaluation of their health risks and quality of life. Commonly a HRA incorporates three key elements – an extended questionnaire, a risk calculation or stratification score, and some form of feedback i.e. face-to-face with a

health advisor or an automatic online report. It's a systematic approach to collecting vital health relevant information from individuals that identifies their risk factors and provides individualized feedback. It should in its conclusion, link the person with at least one intervention to promote health, maintain their status and prevent disease.

The main objectives of a HRA are to:

- Assess health status

- Estimate the level of health risk

- Inform and provide feedback to participants to motivate behavior change to reduce health risks

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The process of administration is designed around a set of data collection tools developed specifically to identify and quantify an individual's risk of morbidity or mortality using demographic, medical and lifestyle information. This data is normally collected from the individual themselves and later electronically cataloged and put through analysis to achieve a resultant score as to relevant probability of one's medical risk. Data is normally garnered from two primary sources. The first is bio-metric scores or levels of blood lipids and other bodily measurements to include blood pressure and certain physical measurements. The second source is self reported personal health information. Once collected, the resulting data can therefore be combined in use to assess one's relative health risk.

Example and Value of the HRA and Health Data Collection.

In 1948 the Framingham Heart Study, was designed as a Health risk Assessment and collected data was later used to identify the common factors or characteristics that contribute to Coronary Vascular Disease (CVD). This health risk assessment was done by following the group participants for a long period of time in a large group of who had not yet developed overt symptoms of CVD or suffered a heart attack or stroke. It started with researchers recruiting some 5,209 men and women between the ages of 30 and 62 from the town of Framingham, Massachusetts, and began the first round of extensive physical examinations and lifestyle interviews. The data collected would later analyze for common patterns related to CVD development. Since 1948, the subjects have continued to return to the study every two years for a detailed medical history, physical examination, and laboratory tests, and in 1971, the Study enrolled a second generation - 5,124 of the original participants' adult children and their spouses - to participate in similar examinations. Over the years, careful monitoring of the Framingham Study population it has led to the identification of the major CVD risk factors - high blood pressure, high blood cholesterol, smoking, obesity, diabetes, and physical inactivity - as well as a great deal of valuable information on the effects of related factors such as blood triglyceride and HDL cholesterol levels, age, gender, and psychosocial issues. The importance of the major CVD risk factors that were identified in this group have been shown in other studies to apply almost universally among racial and ethnic groups, even though the patterns of distribution may

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vary from group to group. In the past half century, the Study has produced approximately 1,200 articles in leading medical journals. The concept of CVD risk factors has become an integral part of the modern medical curriculum and has led to the development of effective treatment and preventive strategies in clinical practice.

Now, in addition we can make use of epidemiological needs, stage of change, levels of motivation, self confidence and personal improvement barriers. We can put these tools to work in areas that go beyond just knowing what you're at risk off. We can now immediately start to act upon those identifiable risks and do something about them at the point of awareness. Medivon's continuing use of Health Risk Assessments has given us a chance to refine their use while adding certain specialized tests to elevate assessment scores in certain individuals from relative risk to absolute risk predictions.

Medivon's Health Risk Assessment process is now focused on our use of "Succeed"®. Succeed® is a primarily a web-based intuitive risk assessment questionnaire which evaluates and assesses the following areas. Gender, demographics, **personal disease history**, (see figure 1 below) quality of life, quality of health, pain, lung cancer risk, bio-metric data and immunization history, blood pressure, cholesterol, blood sugar and other health related behaviors. Also, one's Health history, nutrition, weight physical activity, stress, tobacco use, skin protection, injury protection, and alcohol use.

**Personal Disease History** includes the Following: (Figure 1)

Heart Attack Chronic bronchitis STD (Sexually Transmitted Disease)  
Angina Asthma Diabetes  
Coronary Heart Disease Colorectal Cancer Metabolic Syndrome  
CHD (Congestive Heart Disease)  
Skin Cancer Obesity  
Other Heart Conditions Cervical Cancer Osteoporosis  
Stroke Prostate Cancer Chronic Pain  
TIA High Cholesterol Back Pain  
Peripheral Vascular Disease High Blood Sugar Depression  
Emphysema Hepatitis B Insomnia

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Once completed, Succeed® will automatically, electronically stratify the summation results and then produces a 16 page individually tailored custom action plan around the patients top four health risks – just as a health coach would.

"Health Risk Assessments (HRAs) and Medicare", as noted in an evaluation report completed by RAND for CMS, reached the following conclusions.

- Effective Health Risk Assessment (HRA) plan have demonstrated beneficial effects on behavior, physiological variables and general health status
- Interventions that combine Health Risk Assessment (HRA) feedback with the provision of Health Plans are most likely to show beneficial effects
- To be effective, Health Risk Assessment (HRA) questionnaires should be accompanied by follow-up interventions (e.g., information, support and referrals)

High quality Health Risk Assessments (HRAs) should offer, a computation for individual risk from the following most common diseases and risk factors.

- Asthma
- Chronic Obstructive Pulmonary Disease (COPD)
- Diabetes
- High Blood Pressure
- Ischemic heart disease
- Depression
- Stroke
- Overweight/Obesity
- Use of Tobaccos Products
- Mental health
- Immunizations

The Health Risk Assessment (HRA) collects and reviews information to predict a member's likelihood of experiencing the most common diseases.

Health Risk Assessments (HRAs): Demographic characteristics

A person's age, gender and ethnicity are indicators of elevated risk for certain diseases. At minimum, the Health Risk Assessment (HRA) should collect information, to the extent allowed by law, information on the member's age, gender and ethnicity.

The Health Risk Assessment (HRA) should include queries addressing the individual's personal and family history of diseases or risk factors for common diseases. The Health Risk Assessment (HRA) must include queries to assess health risks related to the highly personal health characteristics and behaviors listed below.

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- Weight Management
- Nutrition
- Use of Tobaccos Products
- High Blood Pressure
- Cholesterol
- Exercise
- Alcohol consumption
- Traveling by motor vehicle
- Stress Management
- Mental health

Perceived Health Status

The Health Risk Assessment (HRA) should include queries that assess A person's selfperceived health status. The queries should allow an individual to rate their own health status on a relative scale.

Disclosure of use of Health Risk Assessment (HRA) information

The organization should disclose how the information obtained from the Health Risk Assessment (HRA) will be used and to whom it'll be disclosed. The organization may offer the disclosure and use information within the Health Risk Assessment (HRA) tool or reports or through written communications.

Ability to save and print Health Risk Assessment (HRA) results

Internet-based Health Risk Assessment (HRA) should give the member the ability to save and print his or her Health Risk Assessment (HRA) results. For paper-based Health Risk Assessments (HRAs), the organization should have a mechanism in place for the member to receive a written copy of the results.

Health Risk Assessment (HRA) Results

Companies should offer a printed or printer-friendly internet-based report for each individual participant. The report may emphasis on either individual risks for specified diseases or on Health.

Health Risk Assessment (HRA) computations may emphasis on either individual risks based upon personal risk factors or on overall risk or health. The report should offer explanatory information to help them understand the outcome. Reports should clearly identify behaviors that can lower risk for each risk factor, and recommend targets for improvement.

Reports should include resources (e.g., community plan, internet-based information and

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materials) that can help members change to a healthier lifestyle.

Health Risk Assessment (HRA) report

The Health Risk Assessment (HRA) should give internet-based print-friendly results and the ability for the user to print the results. The Health Risk Assessment (HRA) report should include a profile of individual risk level for personal conditions or diseases according to age, gender, ethnicity and risk factors that were identified in the questionnaire. The report should clearly identify behaviors that can lower the risk for each risk factor and recommend targets for improvements.

Succeed is all this and more... Succeed™ also includes several interactive tools, videos, and recipes as well as a complete medical library. Succeed is a NCQA HIP Certified and can integrate into your Electronic Medical Record (EMR) claims and bio-metric data.

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Each patient who partakes navigates through a web-based questionnaire, question sets are dynamically changed based on individual responses to previous questions – pinpointing measures of motivations and self-confidence.

Above all it's simple to administer and get started. The following page shows the design of the Health Summary page which can be viewed via the web and printed locally.

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**How should the HRA instrument support shared decision making by provider and patient?**

An HRA must be accurate in following the most up-to-date national guidelines and recommendations, such that dialogue between patient and provider begin on a common ground.

HealthMedia's HRA follows national guidelines for prevention, screenings and immunizations. We have on staff a full time Preventive Medicine physician to oversee all of our content and recommendations, tailored to age, gender, ethnicity and personal health history.

The information should be made available to the patient so they can share the data with their provider. HealthMedia's HRA is designed to be printer friendly,

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such that patients can easily print their individual guide and share the information with their provider.

As people progress from our HRA into programs related to health conditions, these programs allocate significant portions to assessing and then working with the patient to improve their communication and relationship with their health care team, including PCP, specialists and pharmacists.

**Mode of Administration**

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

We can visualize the physician providing a printed set of simple to understand instructions for his or her patient to access using the web to log in with a secure log-on and password self created. Once completed the HRA should be accessible in all the communication venues described above including nontraditional. HealthMedia's HRA can be accessed on the web through a personnel computer, on a smart phone or at a physician's office, kiosk at a pharmacy or other healthcare facility or at the public library. Additional access to HealthMedia's HRA includes (IVR) Interactive Voice Recognition as well as print.

The completed individually tailored HealthMedia HRA plan can be transmitted electronically to the patient for printing, faxed or emailed directly to their physician for review.

The HealthMedia HRA Information can be electronically presented - transmitted to their PHI or EMR for the integration of claims processing.

**What are the cultural appropriateness factors in patient HRA access?**

As described earlier, the custom tailoring technology allows the software technology design to focus on the unique aspects for each individual so it's able to tailor not only the text but also the imagery which includes ethnicity, demographic, culture, gender, race and age. Included in the tailoring is health literacy that allows the end user to consider individual, ethnic and cultural factors.

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**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?**

The office would need to have web access. The HRA would reside on the HealthMedia servers and as such there would be no maintenance required of the physician office personnel other than providing a computer with access to the internet and a printer to review the results with the patient. The data from the HRA can be integrated with EMR or PHR applications.

**Are training and technical assistance necessary for effective practice utilization of an HRA? What entity should provide this technical assistance?**

The HMI HRA will not require technical assistance or training. The four key areas PRIORITIZED BEHAVIORS, LIFESTYLE, BIOMETRICS and SCREENING are being delivered in a clear and concise format, designed for the beneficiary and the HCP. The HCP will be able to incorporate his assessment of the bio-metrics and combined these with the HRA and his own clinical evaluation of the beneficiary.

**What are potential or demonstrated community care transition linkages—followup**

**outside the office by other providers—that help patients and providers manage priority risks identified by the HRA?**

The HealthMedia HRA is only one part of a suite of integrated coaching solutions that the beneficiary can pursue. Included in the beneficiary driven HRA is a list called BEHAVIOR PRIORITIZATIONS. The beneficiary has the ability to move forward and engage a uniquely tailored program that helps them self manage the identified behavior changes they have created through the HRA. Additionally, we continue to support the participant with tools and resources to help them support and facilitate their success. We all know that good coaches do more than teach. They listen, learn, watch, and ask questions. Then, drawing on their experience and expertise, they provide each individual with the personal guidance and tools he or she needs to reach their highest level of performance. Just one exciting tool designed to support Digital Health Coaching is HealthMedia® STEP BY STEP™, a state-of-the-art, proven goal-setting and progress-tracking tool that reinforces healthy, positive behavior changes within the Digital Health Coaching sessions. The HealthMedia® STEP BY STEP™ tracker provides a compass to a healthier life! In addition to the tools and resources we continue to offer support as an important part of the ongoing success through email communications. These communications are also tailored visually to connect with the participant's unique personal characteristics and lifestyle. Links to other resources outside of HealthMedia can also be provided within the HRA and any subsequent programs.

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

The HealthMedia HRA is a scalable solution offered via the internet and therefore is available to a solo practice or virtually any size practice or practice management group. We have partners that have physician practice management offerings that have been embedded in the HealthMedia HRA and other Digital Health Coaching programs as part of their solution. (The HealthMedia solution is scalable across all communication venues, including, web, IVR & print)

**Consumer/Patient Perspective**

**How could HRA data be shared with the patients for their feedback and follow up in the primary care practice?**

HRA data is shared with patients in the form of a tailored report that outlines their personal history, goals, emotional triggers, barriers, will power, beliefs, current stage of change, overall lifestyle score, biometrics and prioritized behavior risks. The personalized plan also acknowledges and encourages healthy behaviors and social support. Additionally, communications are tailored visually to connect with the patient's unique personal characteristics and lifestyle. These reports are available in PDF and can be printed and taken to the patient's next doctors visit to be reviewed with their physician.

**What role, if any, do incentives play in motivating patients to take the HRA and/or participate in followup interventions?**

Depending on the method of delivery, HealthMedia has found the following incentive value in correlation to HRA participation: HealthMedia has launched hundreds of successful incentive strategies. We have worked with health plan and employer partners that have deployed any combination of strategies including financial and nonfinancial incentives or disincentives and other types of recruitment approaches. We offer easy to implement incentive solutions to drive participation. These tools include the ability for participants to complete multiple programs and

receive incentives that can include variable award amount configurations and congratulatory messaging that tracks the beneficiary's progression.

### **Incentive Facts**

Correlation between Incentive Value and HRA Participation

#### **Impact on Engagement**

0 20 40 60 80 100

**\$0**

**\$25**

**\$50**

**\$75**

**\$100**

**\$250**

**\$500**

### **Incentive Values**

#### **Participation %**

Source: Deloitte Center for Health Solutions, 2009

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We have the capability through our Strategic Account Managers and Connect consultants to help design and build web based incentive tracking systems

specifically to meet your needs. Our services include strategy, rules, criteria, user interface, tracking and reporting. We know what works based on our success with other health plans and employer groups from financial based incentives to a nonfinancial strategy.

#### **Data**

**With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non electronic form?**

All modes of delivery, including print, are provided electronically and are available for export through batch export or real time web services. This includes the ability to export HRA information to a Personal Health Record or Electronic Medical Record. The resulting HRA dataset can then be forwarded either real time or in batch to other systems. Our customers have integrated the Succeed HRA data with EMR systems (Kaiser Permanente), disease management and telephonic outreach programs. Other customers are using the HRA data to triage or stratify the member and then route them to telephonic coaching services if appropriate.

**Are there standardized and certified tools available to support this data migration from multiple data entry sources?**

We employ a variety of data export and data exchange options. HealthMedia provides both a standard data extract format as well as the capability to create a customized extract based on specific customer requirements. We have interfaced with diverse environments and are conversant in Web Services, XML, and HL7 environments.

#### **Certification**

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

Essential elements of an HRA include:

NCQA (HIP1,

HIP 2)

Certification (National Committee on Quality Assurance).

The ability to provide access to the beneficiary through multimodal delivery capabilities (web, IVR, print).

The ability to share output and data with the HCP through Electronic Medical Records (EMR), Patient Health Records (PHR), and other electronic patient records.

Provide an individualized tailored wellness and prevention plan specifically addressing the unique needs of the Medicare beneficiary, including the

beneficiaries need to change, want to change, and the belief that “I” can be successful in making a change.

Provide a tailored summary of individual wellness risk factors and recommendations for reducing those risks along with references and resources.

Provide tailored immunization and preventive screening recommendations to match national guidelines and individual factors, including age, gender, ethnicity, and personal health history.

Be configurable, so that custom questions can be developed specifically for the needs of Medicare beneficiaries for data gathering, and identified research purposes.

Be able to provide an individual with an annual comparison or benchmark from previous HRA results.

A natural conduit for offering recipient additional programs and services to assist with lifestyle behavior change, behavioral health and medical condition self management.

Published studies that capture clinical and financial outcomes providing the foundation and validation for an effective HRA.

Vendor must be a science driven, evidence based organization with the ability to deliver robust aggregate reporting and the capability to partner with CDC and CMS to conduct ongoing research.

Vendor must be 508 Compliant.

Vendor must be able demonstrate capability in data security, participant consent and disclosure, with the ability to verify completion of HRA for valid reimbursement.

Vendor must have capacity to quickly revise HRA program information, recommendations and guidelines as new medical evidence emerges.

#### **Evaluation and Quality Assurance**

**How should the HRA guidance be evaluated and updated with respect to individual and population level (practice based panel management) health outcomes?**

Our HRA is NCQA HIP1& HIP2 certified and follows a rigorous and regulated process for ongoing review and update. If you would like a complete description of this certification, we are happy to provide it.

All of HealthMedia Programs are reviewed on an annual basis. Specific programs are reviewed in each quarter. Our Medical Head of Content Research, Dr. Janet Greenhut is oversees reviews of the evidence based guidelines. Updates may also be made on an as needed or urgent basis, according to remarkable guideline developments. Specific processes are outlined as follows:

#### **Review Schedule**

o For one year prior, there is a continuous monitoring of the medical and behavioral science literature by the medical consultant and behavioral scientist to check for updates to the evidence base. Publications and sites monitored include but are not limited to the following:

- JAMA
- *Annals of Internal Medicine*
- *New England Journal of Medicine*
- *American Journal of Preventive Medicine*
- *Archives of Internal Medicine*
- *Diabetes Care*
- *Circulation*

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- *Medicine and Science in Sports and Exercise*
- *American Journal of Clinical Nutrition*
- *Obesity*
- *Chest*
- *Tobacco Control*
- *Health Psychology*
- *Annals of Behavioral Medicine*
- *Addiction*
- *Archives of General Psychiatry*
- National Guideline Clearinghouse
- Agency for Healthcare Research and Quality

- Centers for Disease Control and Prevention

- o Within one month prior to planned review, a targeted literature search is done by the medical consultant and behavioral scientist to check for any changes that were missed in the informal review that relate to the program up for review. Pertinent articles and guidelines are pulled from the HealthMedia library.

- o Standards and guidelines are obtained from governmental agencies and professional associations, including but not limited to the following:

- *U.S. Preventive Services Task Force*

- *Joint National Committee on Prevention, Detection, and Treatment of High Blood Pressure*

- *Adult Treatment Panel of the National Cholesterol Education Program*

- *American Diabetes Association*

- *Office of the U.S. Surgeon General*

- *USDA/USDHHS Dietary Recommendations*

- *Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention*

- *National Heart, Lung, and Blood Institute*

- *National Institute of Mental Health*

- *American Heart Association*

- *American College of Sports Medicine*

#### **Materials Review**

- o At the beginning of each quarter, over a period of four weeks, the following program materials are assessed for each program up for review. They are evaluated for accuracy, topicality, relevance, and functionality:

- Content messages

- Graphics that contain content

- Baseline questionnaire

- Evaluations

- References

- Resources

- Tools

- o Usability testing is done and results are documented.

- o The materials are reviewed by:

- Behavioral Scientist

- Medical Consultant

- Content Developer

- Graphic Designer

- o Client Services submits program feedback from customers and provides a report to the Tailored Media Group pertaining to the program up for review, including:

- Customer feedback

- User feedback

- o Issues from the Defect Tracking Tool are compiled by the content reviewers and the project manager for the program up for review.

- o Reviewers document recommended content changes based on literature reviews and customer requests and prioritize updates into three groups (high, medium, and low).

- o Issue for programs with scoring

- Review feedback from customers and end users regarding scoring and prioritization.

- Any changes are documented.

- o Recommendations are compiled into a requirements document with the input of the Product Manager.

- o The requirements document is presented to the Steering Committee for comments.

o Proposed changes to the programs are reviewed and to planned for implementation.

#### **Implementation of Changes**

o Content developer is responsible for implementing changes and preliminary testing of:

- Messages in MTDs (Master Tailoring Document)

- Questions in baseline questionnaire and evaluations

o Content developer also updates references and resources as needed.

- References are updated in MTDs

o Program bibliography is updated and placed in SourceSafe.

o Graphic designer implements design changes.

o Coders revise code where necessary.

o SQA tests changes.

o Changes are documented in a program specific report by reviewers.

o Release notes are compiled by Director of Tailored Media and Content Developer.

o Changes to Spanish versions are implemented and tested the following quarter.

Today, the majority of U.S. health care dollars are spent on chronic diseases. 1 While it is critically important to support the highest risk participants who suffer from chronic disease and represent the highest cost claims, it is equally important to help all participants stay well and remain at the low end of the risk spectrum or reverse their trend toward unhealthy behaviors. It's also critically important to recognize and address the needs of each individual which may include lifestyle behaviors, chronic conditions and mental health issues. This is what we mean by "Population Health" – the ability to provide coaching and support to every employee or member, no matter where they are on the health continuum across wellness, disease management and behavioral health.

## **Washtenaw County Public Health**

### ***Recv'd 11/16/10***

The research on the use of health risk assessments directs us to use these tools in coordination with a primary care provider and to have regular feedback/communication with the provider on prioritizing goals and follow through. I support including the use of HRA's for Medicare beneficiaries as long as the format for the HRA can be tailored to the user (computer, paper and pencil, verbal) and integrated into the time of the office visit.

Sharon P. Sheldon, MPH, Program Manager

Health Promotion / Disease Prevention Division

Washtenaw County Public Health [sheldonsp@ewashtenaw.org](mailto:sheldonsp@ewashtenaw.org)

### ***Recv'd 1/3/11***

CVS Caremark Corporation, on behalf of its subsidiaries and affiliated entities ("CVS Caremark"), appreciates the opportunity to comment on the above request for information (RFI). CVS Caremark is the leading provider of prescriptions in the nation, with over one billion prescriptions filled or managed annually. There are over 24,000 pharmacists and over 7,000 CVS/pharmacy retail stores within our company, and we are also a leading specialty and mail pharmacy services provider. CVS Caremark also operates approximately 500 MinuteClinic locations in 26 states and the District of Columbia that employ 1700 combined nurse practitioners and physicians' assistants, providing convenient access to routine health care services. Our retail, mail and specialty pharmacies and MinuteClinics combined are leading providers of prescription drugs and health care services.

CVS Caremark is pleased that the Centers for Disease Control and Prevention (CDC) has sought input from stakeholders as it prepares guidance on health risk assessments (HRAs) as required by the Affordable Care Act (ACA). We offer our comments and suggestions on the following HRA implementation issues identified by the RFI notice: content and design; mode of administration; primary care office capacity; consumer/patient perspective; and data.

## **Content and Design**

An HRA can serve as a critical tool in evaluating the health status of patients and helps open a dialogue between the patient and the provider on preventive measures. As part of a comprehensive personalized prevention plan, an HRA should focus on key health and wellness assessments for the patient. In designing HRAs, the CDC should avoid complex and unnecessarily lengthy formats. As the complexity and the length of HRAs increases, patients' appreciation for the assessment may diminish and skew the results. HRAs that utilize even commonly known medical terms could create comprehension difficulties for many patients, especially non-native English speakers and those with CVS Caremark Comments on the RFI on the Development of HRA Guidance cognitive challenges. To alleviate these concerns, HRAs should focus on key lifestyle and risk factors without overwhelming the patient with an unmanageable number of questions. In addition, HRAs should adhere to plain language guidelines to address low literacy challenges and language barriers. HRAs requiring patient responses should be drafted in layman's terms at a fifth-grade reading level and in multiple languages, including Spanish.

The CDC should also consider creating HRAs in two parts. Part I would be completed in the provider's office with the provider, and would include an assessment of key biometric measures such as body mass index, blood pressure, lipid and glucose screening and review of current and past medical and family history. Part I alone could be sufficient to begin to assess an individual's risk for disease. Part II would be completed independently by the patient, ideally before being seen by the provider. This part should include self assessment of lifestyle factors such as diet, exercise and stress management that also impact an individual's overall health. Additionally, since one of the key goals of an HRA is to assess the need for behavior and lifestyle changes for health promotion, additional questions to assess the individual's readiness to change will help tailor interventions to match the patient readiness to take action. Part II of the HRA should be made available electronically and in convenient locations, and patients should be encouraged to complete these assessments prior to a visit with the provider. Incorporating the patient completed portion of the HRA (Part II) with the portion completed by the provider (Part I) offers a complete assessment of the patient's HRA file, which could then be used for personalized prevention and care planning purposes.

In addition, standardization of core HRAs for simplification and ease of administration is critical to ensure their optimal adoption and success. Some HRA questions will vary based on gender and the interventions resulting from HRAs will vary based on age; however, to the extent possible, the format, questions (especially those related to family history and disposition for certain diseases) and assessment methodologies for HRAs should be standardized across all patient populations. Standardization of core HRAs has several benefits. First, it will help make HRAs more portable as patients move to and from different health providers and health care systems. Portable HRAs will reduce the need to have patients complete a new HRA simply because they change providers. Second, it would be easier to raise awareness about HRAs if patients were accustomed to standard HRAs, regardless of which provider they see. Third, standardized HRAs also will permit providers to track the patient's health status progression based on responses to similar sets of questions over time, and also will be more valuable for population health studies and analyses. Finally, the process toward standardization is likely to encourage robust stakeholder participation in HRA development and future refinements.

## **Mode of Administration**

We appreciate the CDC's recognition that an HRA's success and, by extension, success of the preventive action plan and the Medicare annual wellness visit depends on making the HRA widely accessible to patients. We believe that HRAs should be available at physicians' offices and other CVS Caremark Comments on the RFI on the Development of HRA Guidance convenient health care sources. We agree with the CDC that a pharmacy kiosk could be a suitable place to obtain an HRA. HRAs also should be available in retail-based health care clinics.

CVS Caremark offers patients convenient access to routine health care services through our MinuteClinic locations, in addition to our retail, mail and specialty pharmacies. Nurse practitioners and physicians' assistants in our MinuteClinic locations, as well as hundreds of similar retail clinics, are trained to diagnose, treat and write prescriptions (as appropriate and permitted by state law) for certain common and chronic illnesses based on nationally recognized protocols and conduct screenings and monitoring for chronic conditions such as diabetes, hypertension, and hyperlipidemia. In fact, some of the components of HRAs are part of our comprehensive health screening guideline and screening and monitoring guidelines for chronic diseases.

As Congress and the Administration seek to expand health care to millions of new individuals, retail-based clinics are uniquely positioned to help address the shortage of primary care providers and are ideal places for patients to obtain an HRA. More than 50 percent of our MinuteClinic patients do not have a primary care physician and are without a medical home. For these patients, retail clinics play an important role in providing access and connect patients to the traditional health care system for follow up care, as appropriate. Thus, the CDC should ensure that advanced practice clinicians across all practice settings be allowed to perform HRAs for patients and be reimbursed at parity with other providers. Restrictive policies, such as the requirement for on-site physician supervision, will not only be costly to implement for retail based clinics, they will unnecessarily make the HRAs and other health care services more difficult to obtain.

## **Primary Care Office Capacity**

The CDC requests comments on any potential or demonstrated community care transition linkages that help patients and providers manage priority risks identified by an HRA. Based on our MinuteClinic experience, we offer the following suggestions. Providers who have appropriate infrastructures in place to disseminate HRAs to primary care physicians and other community based providers should perform the HRA to ensure their integration into the overall prevention and care plan. If the patient's wellness visit or prevention plan calls for monitoring of conditions such as diabetes, hyperlipidemia, hypertension, etc. in community settings, retail-based clinics could also provide such services and keep the primary care provider apprised of the patient's health status and the need for any follow-up care.

#### **Consumer/Patient Perspective**

We believe that consumers should share in their HRA data and findings to help them be more involved in their own health care. We have found that patients who are more aware of their health status and are otherwise engaged in their health care have better outcomes. At MinuteClinic, a full summary of the patient's visit is printed and given to the patient at the end of the visit. In addition, CVS Caremark Comments on the RFI on the Development of HRA Guidance with the patient's permission, the same summary is sent to the patient's primary care provider or specialist to ensure continuity of care for the patient. The ability to share HRA findings and action plans across provider networks will further serve to meet the needs of patients in a coordinated manner. As patients find it easier to complete and review their HRAs and take control over their health care, they are more likely to adhere to their prevention and wellness plans. With this in mind, the ease of use, length of time to complete the assessment and the ability to build in incentives to complete one's HRA are key drivers of consumer engagement in completing their HRA.

#### **Data**

The CDC should ensure that providers have the ability to export or share data across entities or have HRA information travel with the patient. To avoid costly and burdensome data management issues, standardization of data elements and reporting requirements is essential to the successful deployment of HRAs. Similar to the creation of standardized coding and IT systems in health care, the CDC should support standardization of HRA data elements to allow for ease in transferring information among entities and/or providers, regardless of the differences in technology platforms used. Moreover, all MinuteClinic locations, and all retail-based clinics of which we are aware, currently utilize electronic health information technologies, are capable of communicating with other providers and could serve as a model for how HRA data integration and exchange is possible.

#### **Conclusion**

CVS Caremark appreciates the opportunity to comment on this important RFI. If you have any questions, please do not hesitate to contact me at (202) 772-3500.

## **American Geriatrics Society**

#### ***Recv'd 1/3/11***

The American Geriatrics Society (AGS) greatly appreciates the opportunity to provide the following comments to assist in the development of guidance concerning Health Risk Assessments (HRAs) pursuant to Section 4103 of the Affordable Care Act (ACA), which requires the inclusion of an HRA in the new Medicare annual wellness visit benefit that was authorized by the ACA.

The AGS is a not-for-profit organization comprised of more than 6,000 health professionals who are devoted to improving the health, independence and quality of life of all older people. The Society provides leadership to healthcare professionals, policy makers and the public by implementing and advocating for programs in patient care, research, professional and public education and public policy. As a specialty society, our mission is to promote high quality of care and quality improvement.

Our comments are divided into two parts. First, we provide overall comments and pose several questions regarding the intent of an HRA as envisioned by the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS). Second, we respond to a number of the specific areas of emphasis outlined by the CDC in its Request for Information.

#### **I. Overall Comments**

The AGS believes that it is first necessary to define the purpose of the HRA. For example, would an HRA be used as a predictive tool to identify patients who are at high risk of developing specific diseases or conditions, or of being subject to undesirable outcomes, such as hospitalization or nursing home admission? Or would the HRA be viewed as the basis for a plan of care?

An assessment of health risk should facilitate data gathering that enables physicians and other practitioners to provide the best possible care, but should not add a layer of work that could be viewed by clinicians as

burdensome because it does not facilitate or promote better care.

The statute requires the new Medicare Annual Wellness Visit to include a health risk assessment. The Annual Wellness Visit contains the following elements:

- Establishment of a beneficiary's medical/family history.
- Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the beneficiary.
- Measurement of an individual's height, weight, BMI (or waist circumference, if appropriate), blood pressure, and other routine measurements as appropriate, based on the beneficiary's medical/family history.
- Detection of any cognitive impairment that the individual may have as defined in this section.
- Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.
- Review of the individual's functional ability and level of safety based on direct observation, or the use of appropriate screening questions or a screening questionnaire, which the health professional may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.
- Establishment of a written screening schedule for the individual, such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices (ACIP), as well as the individual's health status, screening history, and age-appropriate preventive services covered by Medicare.
- Establishment of a list of risk factors and conditions for which primary, secondary, or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an IPPE, and a list of treatment options and their associated risks and benefits.
- Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving selfmanagement, or community-based lifestyle interventions to reduce health risks and promote selfmanagement and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.
- Voluntary advance care planning (as defined in this section) upon agreement with the individual.

We point out that some of these elements, which are required by statute, are clearly exam items. But many could potentially be assisted by an HRA that the patient and physician/clinician could discuss, in order to determine health risk and to help clinicians and patients work together and to contribute to shared decision-making.

The HRA would also help to identify those patients who are in need of relatively intensive interventions immediately. For geriatric patients, an HRA could help to identify individuals who need care coordination for multiple chronic conditions.

## **II. Comments on Specific Areas of Emphasis**

### **A. Content and Design**

- Risk assessment domains—what are generic elements of any HRA and what elements must be tailored to specific populations, particularly those stratified by age?
- How should literacy and other cultural appropriateness factors be factored into the design?
- How should the HRA instrument support shared decision-making by provider and patient?

#### **Response:**

A health risk assessment tool should be relatively simple and easy to administer in the physician's office. The tool should not be complex or time-consuming, but should contribute to the practical care of the primary care patient (see Section C below for a brief discussion of an HRA of which we are aware -- the VES-13 -- to assess health risk and functional capacity in the vulnerable elderly).

As discussed above, the health risk assessment should at least conform to the required elements of the Annual Wellness Visit. Certain elements of the HRA should be tailored, for example, for the older Medicare population, who are often more frail and suffer from multiple chronic conditions requiring greater coordination amongst a team of providers. In older adults, sensory alterations are often overlooked or ignored, yet such alterations can significantly influence multiple domains of function. Questions regarding sensory function should be considered for inclusion in a HRA.

Ideally, a health risk assessment should support shared decision-making by the health care provider and the patient by first helping the provider to gather important information about the patient, and then facilitating communication

between the provider and the patient as to the best approach to the patient's care, in terms of both short term needs and in planning for the future.

#### **B. Mode of Administration**

- How will individuals access the HRA (e.g., via kiosk or some other means in the physician's office, Internet, mail-in paper form, other nontraditional healthcare locations, such as, kiosk in a pharmacy)?
- What are the cultural appropriateness factors in patient HRA access?

#### **Response:**

At least initially, we would not envision the use of kiosks, or similar self-administered technology in physicians' offices. Such technology would be expensive and impractical for use by most small primary care practices, particularly with geriatric patients, who are often very sick, frail and may suffer from multiple illness or conditions, including dementia. We would envision the use of a paper format that is not overly complex, that a patient could complete in the physician's office. The form could potentially be made available online, so that the patient or the patient's family member or caregiver could access it and complete it prior to coming in to the office.

AGS Comments on Health Risk Assessment Guidance

With respect to cultural sensitivity, the assessment tool should be easily translatable into Spanish and/or other languages that are common in different parts of the country. The Department of Health and Human Services has experience with rules that promote cultural sensitivity, particularly where individuals may have limited proficiency with English, or come from diverse cultural and ethnic backgrounds.

#### **C. 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?
- Are training and technical assistance necessary for effective practice utilization of an HRA? What entity should provide this technical assistance?
- What are potential or demonstrated community care transition linkages— follow-up outside the office by other providers—that help patients and providers manage priority risks identified by the HRA?
- What is the current practice of HRA in medical practices of various sizes, particularly those with five or fewer physicians?

#### **Response:**

Utilization of a HRA in the primary care office setting in support of personalized prevention planning will involve time and training in order to effectively integrate its use into the work flow of the practice. The type of training or technical assistance may depend upon the length, content and format of the tool. Certainly the adoption of an electronic tool may require additional technical assistance. Some practices are moving ahead with the adoption of sophisticated health information technology systems and electronic medical records, which may have the capacity to include an HRA, however time and resources will still be required to administer the instrument, and to either enter or summarize the information provided by the patient, and to then review the information with the patient.

Many primary care practices do not tend to utilize an HRA at this time. Currently providers do not have great incentive to utilize an HRA, particularly in small or solo physician practices which constitute the bulk of physician practices today. Reimbursement for the initial and subsequent annual wellness visits under Medicare begins in 2011, and these visits have been valued at the same rate as an office visit, which does not currently include the additional work associated with the administration of an HRA.

We are aware of an HRA that has been validated in a number of clinical settings. The Vulnerable Elders Survey-13 (VES-13) is a self-administered survey that consists of one item for age and an additional 12 items that assess self-rated health, functional capacity, and physical performance.<sup>1</sup> This survey identifies a population subset that is at high risk for functional decline and high medical cost. Additionally, the work of ACOVE (Assessing Care of the Vulnerable Elderly) is a widely recognized quality improvement initiative that starts with the use of this instrument. Care that is more consistent with ACOVE standards has been correlated with reduced mortality.

We note, however, AGS Comments on Health Risk Assessment Guidance that any HRA is only as useful as it was intended to be. That is, if identification of being vulnerable is useful in a given practice's population, then the VES-13 is useful, but it may not be the appropriate tool for all practices or populations.

#### **D. Consumer/Patient Perspective**

- How could HRA data be shared with the patients for their feedback and follow up in the primary care practice?
- What role, if any, do incentives play in motivating patients to take the HRA and/or participate in follow-up interventions?

#### **Response:**

Initially, we view the HRA as a simple tool that patients could complete to provide information to their primary care

practitioner either in the physician's office or prior to an office visit, in order to allow the physician/clinician to identify risks and health care needs, and to generate discussion with respect to a care plan. The HRA could provide the basis for future preventive care planning.

As discussed above, many physicians are not currently incentivized to utilize an HRA in their practice as a means of improving communication with their patients and with other providers. There may be concern that the time burden associated with the use of an HRA may only add a layer of administrative burden, without actually improving communication or outcomes. Many physicians would prefer to see improved reimbursement for the annual wellness visit that captures the work involved in administering an HRA, but more importantly, physicians and other clinicians want to ensure that the work involved will actually improve patient care, and not increase the time and administrative burden that already faces most primary care physicians.

It is unclear what type of beneficiary incentives would be either adequate or appropriate to encourage beneficiaries to complete an HRA or participate in follow-up care. If the purpose of the HRA is to encourage the sharing of information in order to identify health risks and to be able to develop a personalized plan for preventing future health issues, then improved quality of care and the potential for improved health outcomes may provide the added incentive for beneficiaries to complete a HRA.

#### **E. Data**

- With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non-electronic form?
- Are there standardized and certified tools available to support this data migration from multiple data entry sources?

#### **Response:**

We are not aware of standardized tools or certified tools available to support HRA data entered in a way to populate EMRs.

#### **F. Certification**

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

AGS Comments on Health Risk Assessment Guidance

#### **Response:**

We view the HRA as a simple, paper tool, at least initially. We do not believe primary care practices should be required to select only certified HRAs. We do not support this added layer of oversight, for a tool that may or may not assist them in practice. We acknowledge that certification, if not a requirement, could guide clinicians to better HRA's. Certification could also assist CMS in evaluation of the utility of the HRA.

#### **G. Evaluation and Quality Assurance**

- How should the HRA guidance be evaluated and updated with respect to individual and population level (practice-based panel management) health outcomes?

#### **Response:**

While it is appropriate to evaluate the HRA utility and cost, it is difficult to suggest an evaluation method until such time as the goals of the HRA are better established. Whether or not the HRA helps achieve the intended goals would be the fundamental evaluation task. We would hope that evaluations and updates would be conducted in an open process with ample opportunity for comment.

The American Geriatrics Society greatly appreciates the opportunity to provide comments on the development of guidance regarding health risk assessments. We were supportive of the provision in the ACA establishing an annual wellness visit benefit for Medicare beneficiaries and we look forward to working with the CDC and with CMS as the provision is implemented in 2011, along with the appropriate and practical use of a health risk assessment.

Please feel free to contact Susie Sherman, Coordinator Public Affairs & Advocacy at 212-308-1414/ [ssherman@americangeriatrics.org](mailto:ssherman@americangeriatrics.org) if you have any questions or if you would like any additional information.

## **American Sleep Apnea Association**

*Recv'd 1/7/11*

I am writing on behalf of the American Sleep Apnea Association regarding the request for comments concerning the Development of Health Risk Assessment Guidance. (Federal Register Vol. 74, No. 220, page 70009 - 70010)

The American Sleep Apnea Association is the only national nonprofit patient interest organization dedicated to reducing injury, disability and death from sleep apnea and to enhancing the lives of those affected with this common disorder. Our membership includes apnea patients, their families and healthcare professionals who diagnose and treat those with sleep apnea.

We are writing today to comment specifically on the risk assessment domains to be included in any Health Risk Assessment (HRA) developed for use by Medicare and private insurers.

We agree that there is considerable variation in available HRA's. We believe the development of the HRA for use in connection with the Medicare wellness visit and to support broader use of HRA in the primary care setting must include questions concerning sleep and sleep quality.

There is a growing body of medical evidence to support claims of adverse health consequences, such as cardiovascular disease, metabolic syndrome and depression arising from sleep deprivation and sleep fragmentation that occurs as a result of obstructive sleep apnea.

The addition of questions concerning sleep and sleep quality in conjunction with questions likely to already exist on the HRA such as Body Mass Index, resting Blood Pressure and history of Diabetes could provide a sufficient number of health markers to warrant further examination including possibly a sleep study.

We believe that screening for sleep disorders, like Obstructive Sleep Apnea by means of an HRA will increase the number of people who need further testing and possibly treatment. In addition, this will help to accomplish the Healthy People 2020 Sleep Health topic objective SH-1 - "Increase proportion of persons with symptoms of obstructive sleep apnea who seek medical evaluation."

We are available to be a resource to the CDC as they pursue HRA development.

Sincerely,

Edward Grandi

Executive Director

## Wellsource

***Recv'd 1/3/11***

General Comments on HRAs and the CDC/CMS RFI

As the most experienced provider of HRA tools in the country, Wellsource is uniquely positioned to work with the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) in developing this health risk assessment guidance. As such, it is pleased to provide these comments in response to the CDC's Request for Information (RFI) published in the Federal Register on November 16, 2010 (75 FR 70009).

HRAs can play a critical role in improving overall health and wellness. Used effectively, HRA tools can assess one's health status, identify priority health/wellness concerns and/or potential health enhancement opportunities, target individuals for interventions and follow-up support, and measure and evaluate progress over time.

An HRA is not a panacea, however, and should not be thought of as such. Its effectiveness can be impacted by several forces, including: the type and quantity of information solicited from patients, the accuracy of the information provided by the patient, the methodology used for analyzing gathered information, the accessibility of the reports generated, the interest of the patient in making behavioral changes, the support provided by primary care physicians and relevant ancillary providers, and access to follow-up education and support mechanisms. It is critical that the CDC/CMS HRA guidance address this panoply of factors in a holistic fashion. If the HRA guidance is not nuanced and flexible enough to address these matters effectively, the HRAs provided as part of the annual wellness physical to Medicare Part B beneficiaries (per the Patient Protection and Affordable Care Act) will not provide the impetus for improved health and wellness envisioned by lawmakers.

Wellsource believes that two factors in particular stand out as critical principles for CDC/CMS to consider in developing its HRA guidance. In general, the guidance must encourage and facilitate those HRA tools that:

1. **Address wellness comprehensively and encourage optimal health rather than simply predicting morbidity.**  
While assessing a person's risk of dying is an important component of an HRA, an HRA that *only* predicts morbidity

fails categorically to impact patients in a truly meaningful manner. A comprehensive HRA must contain quality-of-life factors in order to fully impact patients.

2. **Offer questionnaires that are comprehensive but as short as possible so as not to be burdensome.** Any questionnaire that takes more than 10 to 20 minutes to complete provides diminishing returns by resulting in lower participation rates by patients. While it is natural that policymakers and stakeholder might want to encourage HRAs that solicit from patients as much information as possible in order to make a comprehensive assessment of health and wellness, it is more prudent to limit questionnaires to high priority questions that can provide more pertinent and impactful information and encourage maximum patient participation.

### Specific Response to RFI

#### Content and Design

#### Elements of an HRA – Generic and Senior-Specific

As discussed previously, a truly effective HRA will assess not only a person's risk of dying, but will include key lifestyle practices that are linked to a higher quality of life. Other critical elements include preventive care issues, a collection of health screening biometric data, and questions relating to health interest and readiness to change in order to permit health professionals to engage patients effectively and productively. It is crucial, as discussed above, that the questionnaire be as short as possible so that patients are capable of completing all questions in no more than 10 to 20 minutes.

Specific elements that must be a part of any HRA include:

1. **Risk Assessment** – Elements that identify people at high risk for serious, preventable health problems:
  - a. *Coronary* – risk factors for heart disease (CHF, MI) and stroke
  - b. *Cancer* – risk factors for major cancers, especially those with prevention opportunities (e.g., colon, prostate, cervical, breast, lung)
  - c. *Diabetes* – risk factors for developing type 2 diabetes
  - d. *Substance Abuse* – smoking, alcohol, and drug use
  - e. *Lung disease* – lifestyle risks linked to lung disease (e.g., COPD) include smoking, physical activity, chronic cough, wheezing, heavy mucous production, and shortness of breath.
2. **Wellness Assessment** – Lifestyle practices linked to a healthier, more productive life:
  - a. Nutrition and healthy eating practices
  - b. Weight status and health practices linked to obesity
  - c. Physical activity status and preference
  - d. Mental health status (especially stress, coping, depression, and anxiety issues)
  - e. Safety practices for accident prevention
3. **Preventive Medical Care** – The following issues should be assessed:
  - a. Preventive exams (are they current)
  - b. Brief health history (specifically looking for risks for the most common major health problems)
  - c. Medication use (e.g., number of medications being taken, and use of aspirin, blood pressure medications, and/or statins)
  - d. Dental care – Brushing and flossing, smoking, dental exams, etc.
4. **Health Screening Biometric Data** – The following are recommended, as appropriate and available:
  - a. Weight and height
  - b. BMI / waist circumference / percent body fat (choose one)
  - c. Cholesterol values (LDL and HDL)
  - d. Blood pressure
  - e. Grip strength (a good predictor of adequate strength for future independence)
  - f. Blood glucose or A1C levels

- g. Aerobic capacity (e.g., step test, one-mile walk, or treadmill test) – this is a stronger predictor than blood pressure or cholesterol levels for likelihood to be alive in 10 years; it is also helpful in encouraging and documenting improvements in fitness.

5. **Health Interests and Readiness to Change** – For follow-up efforts to be most effective, it is essential to determine which health or wellness topics are of high interest to a patient and to ascertain where a patient would like to begin to make a change in his or her lifestyle.

Senior populations typically have special health needs that need to be addressed by an HRA. In addition to the items listed above, it is imperative that an HRA targeted towards persons aged 65 and older (e.g., the HRA to be conducted as part of an annual wellness exam per PPACA) include the following additional elements:

- **Alzheimer’s Disease or Cognitive Impairment** – Performing appropriate cognitive assessments to determine risk for or early signs of Alzheimer’s disease or other dementias.
- **Osteoporosis** – Checking risks for falling (balance issues), diet, physical activity level, and assessing if patients are getting bone density exams as recommended for their age.
- **Immunizations** – Checking for compliance with recommended immunizations for seniors, including pneumonia, influenza, tetanus, shingles, etc.
- **Mental health** – Senior-specific issues related to depression, anxiety, loneliness, isolation, and other social issue needs such as coping with the stress of the loss of a spouse or loved one, loss of adequate income, etc.
- **Access to medical care** – Does the individual have ready access to medical care and are there transportation issues that may inhibit access?
- **Common health problems in seniors** (e.g., arthritis, constipation)
- **Hearing and eyesight problems**
- **Assessment of ADL/IADL issues** – Determining whether individuals are impaired or challenged by activities of daily living and/or instrumental activities of daily living.
- **Nutritional concerns** – Ensuring that seniors have adequate vitamin D, B-12, calcium, water, fiber, and other key nutrients for seniors, and that they are able to chew and eat healthy foods.

## Literacy & Cultural Appropriateness

Literacy and cultural appropriateness must be factored into any HRA design. This can be accomplished in a number of ways. First, the HRA should be written at an 8<sup>th</sup> grade level or below. Second, the language used must be very explanatory. Third, culturally appropriate pictures, diagrams, and illustrations should be used whenever possible to help the reader understand what is being asked. Fourth, Interactive Voice Response (IVR) via the telephone can be offered as a means of filling out the questionnaire; this would assist individuals unable to read or individuals with sight impairments. Fifth, a Spanish version of the HRA should be available. If each of these methods is utilized, the HRA design should be accessible to an array of persons with varying degrees of education, physical impairments, and cultural backgrounds.

## Support Shared Decision-Making

An HRA can best support shared decision-making between a provider and patient by generating a meaningful, accessible, and robust report. Ideally, an HRA will generate a report in real-time so that the provider and patient can review the report together. A quality report would include an easy-to-understand list of needed health improvements in priority order. The report also would include URLs for accessing additional information, suggested educational materials, and follow-up programs.

## Mode of Administration

## Access to HRAs

The question of how individuals will access HRAs should be considered in two parts: first, what modalities can be employed, and second, what physical locations can be utilized to ensure the broadest access to HRAs.

With regard to modalities, the widest coverage can be achieved by using multiple channels: i.e., the Internet, kiosks in various locations, IVR via the telephone, and paper-based systems. Using a wide array of modalities will maximize coverage and minimize accessibility issues.

The most ideal modality is the Internet since it would allow a patient to complete the HRA online, after which the report could be printed at the doctor's office prior to the patient's appointment, or the patient could print out the report at home and bring it to their doctor appointment. In general, an online system is the gold standard: the HRA is available at the doctor's office, the patient's home, or anywhere there is Internet access; a personalized report can be printed out instantaneously; and access to follow-up information is easily available and accessible. Wellsource HRAs all are available online via the Internet.

The next most efficient modality would be a kiosk-style system. The most effective kiosks would utilize touch-screen technology; they should be turnkey systems that require only Internet access (wired or wireless) and the ability to print, so that any required IT support would be minimal. Kiosks have the benefit of being comparably mobile or easily transportable (such as a PC Tablet), meaning that they could be made available in doctor's offices, pharmacies, or nontraditional locations, such as nursing homes, community centers, shopping malls, barber shops, or other locations where individuals congregate and have easy access. Obviously, any kiosk located in a nontraditional setting would have to adhere to all necessary privacy and security requirements.

Another modality is the use of telephony. While this would eliminate the ability to use illustrations or diagrams to ensure understanding of the questionnaire, it could offer access to HRAs for individuals without Internet access, those who have difficulty travelling, or those with eyesight impairments.

The least efficient modality is a paper-based mail-in system, though it is the most appropriate in certain settings and likely would be particularly appropriate for Medicare beneficiaries. Wellsource has found that elderly individuals often prefer to complete a written questionnaire rather than an online form. A bubble fill-in form would facilitate easy entry into a database by scanning at a physician's office or at an off-site processing center. Wellsource provides secure off-site data processing services for many of its government clients.

In general, the guidance should permit provider groups to choose the method – or combination of methods – that would work best for their setting and clientele. The key to ensuring the seamless use of differing modalities is that each modality must use identical forms so that all data can be aggregated and entered into a common database.

### Cultural Appropriateness Factors

By employing a variety of modalities in various locations, any concerns about cultural appropriateness should be alleviated. If possible, illustrative pictures and diagrams should reflect the age and race of the particular individual taking the assessment. So long as each modality utilizes (as appropriate) simple reading levels, explanatory language, illustrations / diagrams, and assessments in Spanish as well as English, culturally acceptable options should be available for any group.

### Primary Care Office Capacity

#### Primary Care Office Capacity for HRAs

The primary care office capacity required to utilize HRA data in support of personalized prevention planning would depend upon the technologies currently used by the office, though in general the impact should be relatively minimal.

For an Internet-based system, office staff would need only to provide patients a link to the HRA with instructions for completing it prior to seeing the doctor. The doctor could then print out the report at the office or the patient could print it out at home and bring it to their appointment.

For a kiosk-based system, the kiosk could be a self-assessment center so that the office staff would have to commit only minimal time. While a staff member would need to be trained on the system should there be questions, the training could

be largely self administered, similar to taking an online driver's license exam. A similar level of commitment would be required of a telephone-based system.

For a paper-based system, a questionnaire could be mailed to a patient in advance of his/her appointment or handed to the patient during the appointment along with a pre-addressed return envelope. In this case, office staff would need to be trained on how to enter the paper questionnaire into a database, though this could be mechanized by utilizing bubble fill-in technologies that permit the information to be scanned, or sent to a processing center. Additionally, the information could be entered offsite by the vendor, with reports printed and returned to the doctor's office or directly to the individual.

In all cases, staff would need to be trained on how to utilize the reports generated by the HRA, including how risks are reported to the participant, how to query the database for all individuals with specific criteria (such as all patients with pre-diabetes), how to track which patients have completed an assessment, and how to generate contact lists to provide patients information on follow-up support activities. Wellsource currently provides thorough training on its HRA reporting capabilities through national seminars and online training sessions.

### Training

Training and technical assistance is necessary for effective utilization of HRAs. However, an online video training system should be adequate for training personnel. Once an online training system is in place, all staff could use the training system.

The training and technical assistance could be developed by each individual physician office, or it could be provided by the vendor (Wellsource provides training for its clients). It might be useful, however, for CMS to maintain a help-line and/or online FAQ section on its website to address broader, non-specific questions about HRA technologies.

### Community Care Transition Linkages

Typically, there are three methodologies for linking patients to appropriate follow-up care: making available printed materials (e.g., booklets and pamphlets), providing access to online intervention programs, and creating awareness of proven community programs through web links. It is best to provide a variety of avenues for patients to receive appropriate follow-up care based on their readiness to change.

Wellsource offers its clients many such resources, including a series of Guides to Healthy Living, streaming video education, a Health Activity Tracker, various online intervention programs, and a plethora of other educational materials and seminars.

Another option is the use of health coaches, who are trained to address problem areas, help identify a patient's strengths, and empower them to succeed by focusing on lifestyle-related behaviors that they want to change. By identifying and engaging one or more health coaches, physicians can track their patients' progress and help them manage priority risks identified by HRAs. Training office staff to conduct health coaching in a doctor's office setting is available through Wellsource and its affiliates for those desiring to offer their own coaching services.

### Current Practices

Even small physicians' offices are capable of utilizing HRA tools, whether Internet-based, kiosk-based, or paper-based. Patient education guides tend to work well in small offices, as would a PC Tablet preloaded with the HRA questionnaire, and a report with links to a listing of community care options.

### Consumer / Patient Perspective

#### Sharing HRA Data

There are several straightforward strategies available to primary care practices for sharing HRA data with patients. First, the physician or his/her staff could print out the report and review with the patient in the office, or, alternatively, mail it / e-mail it to the patient and follow-up with a telephone consultation. Similarly, with proper consent any appropriate ancillary provider – such as a health coach, dietitian, and exercise coach, etc. – could be provided a copy of the report.

For offices with limited staff time or availability, another option to provide patient information is to utilize a booklet, DVD, or streaming video. The benefit of this approach is that the patient can review the information multiple times in the doctor's office or at home and learn how to eat more healthfully, hear coronary health guidelines, etc. Wellsource's Healthy Living Guidelines DVD (also available via streaming video) informs the participant about how to find critical information within their

report, educates participants on prevailing health risks, discusses biometric scores, presents scientifically sound data supporting health behavior modifications, and recommends ways to minimize individual health risks. The DVD comes with an accompanying booklet for easily reviewing specific topics covered in each segment.

### Role of Incentives

Wellspring has found that incentives work well in a workplace setting to encourage completion of an HRA as part of a corporate wellness program. The use of incentives in a doctor's office environment is less tested. Typically, it works best simply for a doctor to require that an HRA be completed prior to a patient's appointment. Asking patients to complete an HRA after their doctor visit would require more incentive. The benefit of an annual wellness exam is an incentive itself and should be presented as such. If this "incentive" does not work, then it might be worthwhile for a physician's offices to seek out creative arrangements, for example, to work with a local health club to ensure that any patient completing an HRA would receive a one-month free trial membership, or a similar low-cost incentive.

### Data

#### Challenges to Information Technology (IT) Migration

The migration of IT data from non-electronic form to an EHR is a relatively simple process for organizations like Wellspring that have extensive experience with the technology. For decades, Wellspring has been processing paper questionnaires and combining such data with online and kiosk-entered data as part of a common database. The technology required for the integration of non-electronic forms with online forms is well understood, mature, and readily available.

#### Availability of Standardized and Certified Tools

There are several standardized and certified tools to assist in the migration of IT data. So long as the paper, online, and kiosk forms are identical, and the data is all entered into a common database, it can be done with relative ease. Wellspring offers an assessment that is standardized and certified across all delivery platforms – online, paper, and kiosk – and is currently integrating an IVR telephone response questionnaire into its offerings. The same questionnaire is delivered on all platforms and the results are collected and organized in a unified database.

### Certification

Wellspring encourages CDC and CMS to implement a certification process that is straightforward, easily navigable, and not burdensome. In general, CDC/CMS should certify only whether an HRA meets the minimum functionality requirements set forth in the guidance per Section 4103 of PPACA. This would ensure that the certification process is not too restrictive while still signaling to health providers whether or not an HRA instrument satisfies the requirements set forth in law.

In addition to a simple certification mechanism, CDC/CMS might consider scoring certified HRA tools, for example, by awarding one, two, or three stars based upon a set of criteria. Another option might be to permit users to score the usability of HRA tools in a wiki-type model. In general, there should be some methodology for scoring the comparable effectiveness and/or customer satisfaction for certified HRA tools.

Whatever mechanism is chosen, certification information should be made readily available on the CMS website.

### Evaluation and Quality Assurance

The HRA guidance should be reviewed biennially. Stakeholders should be offered an opportunity for broad participation in any review effort, which should look at health and wellness trends and amend the HRA guidance accordingly to ensure that the guidance is encouraging and facilitating the appropriate health and wellness activities.

Alternatively, CDC/CMS could form an advisory group made up of representatives from CDC, CMS, and stakeholder groups. The advisory group would be responsible for ongoing and/or regular review of the HRA guidance and making alterations as appropriate and necessary.

In terms of evaluating individual and population-level health outcomes, Wellspring has extensive experience in tracking the progress of individuals and groups of people. These strategies could assist in a continual evaluation of progress from a health and wellness standpoint.

### Closing and Overview

Section 4103 of PPACA offers the possibility to revolutionize wellness in this country, if the HRA program is implemented carefully and appropriately. Health risk assessments are a powerful tool, but it is critical that CDC and CMS pay close attention to several crucial components in preparing the HRA guidance.

Most importantly, the guidance should require that any certified HRA tool must be comprehensive and not simply a predictor or measure of mortality. An HRA without meaningful lifestyle components is incomplete and flawed. Additionally, the guidance must ensure that any certified HRA questionnaire is comprehensive, but no more than 10 to 20 minutes in length. CDC/CMS should resist the temptation to make the HRA guidance everything to everyone by requiring that HRA tools request more information than is necessary or prudent for effective outcomes.

#### Contact Information

As the most experienced HRA provider in the country, respected and chosen by more healthcare professionals than any other in the industry, Wellsource stands ready to assist the CDC and CMS in this effort. Please do not hesitate to contact Wellsource's Chief Operating Officer and General Counsel, Heather Tourville, JD, if you have any questions about the contents of this response to the RFI. Ms. Tourville may be reached at [heather@wellsource.com](mailto:heather@wellsource.com) or (503) 656-7446 x243.

## Sarah McMonigle

*Recv'd 12/30/10*

#### Content and design

Make it clear that dental disease is a transmissible, preventable, treatable disease.

Empower the public by giving them the information needed to stay disease free i.e.; remove 100% of bacteria/plaque/biofilm once everyday.

Inform the public of disclosing to identify what needs to be removed.

How much time it should take to remove the biofilm and the problems that make the task difficult and require more time to accomplish the task, i.e.;

when were your teeth professionally cleaned last? do you have bleeding gums?

do you have fillings/restorations? what is the quality of your dental work?

do you have decay? what is your diet? high carbohydrate? do you drink sweetened drinks? sugar free? juices? frequently snack? do you have exposed roots? smoking or other tobacco products? do you have dry mouth?

do you have arthritis or other problems with your hands that make it difficult to clean your teeth?

**THIS TOOTH CLEANING COULD TAKE 10-20 MINUTES OF MORE TO ELIMINATE THE BIOFILM**

what is the condition of your toothbrush? you will need a new toothbrush probably once a month if you need 10-20 minutes to remove all of the biofilm. Having a good soft toothbrush will make your job easier

Use fluoride to remineralize the teeth

#### MODE OF ADMINISTRATION

To employ Dental Hygienists in the schools

Develop a curriculum K-12 that is also hands-on brushing K-12

goal to grow a nation of decay free children that know the value of dental health and how to achieve it

Hygienists responsible for hands on programs and resource person for curriculum also does all prevention based treatments i.e., sealants, varnishes, referrals to dentists, x-rays. Remedial homecare help for some children

#### Primary care office capacity

This should decrease dramatically over time, most care will be evaluation and possible referral for orthodontic treatment

#### Consumer/patient perspective

This is the greatest reward when they have only the need of preventive services

data/certification/evaluation/quality assessment

This will be easy to measure because in one year with assessment of disease and optimal fluoride provided a lot of initial decay will be reversed and prevention of possible future decay.

New emphasis on diet and diet related decay and diseases will be discussed and changes made.

We will finally be educating our children as to how to live and giving them a model to live by, instead of the greed of industry getting into our schools and stealing our children's future health, for a few bucks to run sports programs. When will the adults of this world start taking responsibility for the misery they are causing our youth. We know what it takes to be healthy. Whole foods. Exercise for all, not sports for some. Caring attitude towards all. What does each child need to be successful?

In the area of dentistry it isn't more fillings that are needed it is education and prevention and access to this population.

We have a surplus of hygienists now we have dental hygiene schools dumping out record numbers of hygienist. Why aren't we thinking of ways to make use of these hygienists in their area of expertise? Prevention?

Maybe we need malcolm gladwell to talk to the ada and the adha and the cdc to have them all see the light. Prevention is the only way to solve the problem of dental disease. He spoke to the ada, if you haven't read his books you should, and bring in the pew and kellogg if they have money they really want to spend on ending this disease or are they just out to put their name out for recognition, and still keep producing the sugary cereals that are part of the problem. Keep dumping these cereals into the breakfast programs for the children who need breakfast at school to promote more decay?????

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360-379-5448

## American Society for Parenteral and Enteral Nutrition

*Recv'd 1/3/11*

The **American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.)** proposes the following comments to the The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) on the development of guidance concerning **Health Risk Assessment (HRAs)**. Section 4103 of the Affordable Care Act (ACA) (Pub. L. 111-148) requires that a health risk assessment be included in the annual wellness visit benefit authorized for Medicare beneficiaries under the ACA. The mission of **A.S.P.E.N.** is to improve patient care by advancing the science and practice of nutrition support therapy. Founded in 1976, A.S.P.E.N. is an interdisciplinary organization whose members are involved in the provision of clinical nutrition therapies, including parenteral and enteral nutrition. With more than 5,500 members from around the world, A.S.P.E.N. is a community of dietitians, nurses, pharmacists, physicians, scientists, students and other health professionals from every facet of nutrition support clinical practice, research and education. We are committed to preventing and mitigating the impact of malnutrition and to ensuring the availability of high quality, cost-effective nutrition therapy treatment options. Our organization has previously commented on the Health Risk Assessment and that nutrition screening and assessment should be an important part of any health risk assessment across the health care continuum. Screening for malnutrition should be part of the annual wellness visits and nutrition therapy treatment options should be included in the Personalized Prevention Plan Services that are Covered Under Medicare. Specifically, healthcare providers should incorporate screening for malnutrition as part of the annual wellness visits; and include the provision of medically indicated clinical nutrition services in patients' personalized prevention plan services. In accordance with Congress' focus on prevention, and on the basis of the growing literature related to the costs of malnutrition and effective treatment options, we believe that HHS should ensure that: (1) screening for malnutrition is included in the guidelines for the health risk assessment tool that will be used by health professionals during the annual wellness visits; (2) a beneficiary's personalized prevention plan reflects ongoing nutritional therapies, such as enteral or parenteral nutrition; and (3) if a health professional identifies a beneficiary as being malnourished or at risk for malnutrition, appropriate clinical nutrition services are included in the patient's personalized prevention plan.

Malnutrition often is associated with acute and chronic diseases and injury; certain diseases may cause a person to be unable to ingest or absorb nutrients, need more energy, or become undernourished due to dietary restrictions. In collaboration with the National Alliance of Infusion Therapy, A.S.P.E.N. developed a paper entitled "Disease-Related Malnutrition and Enteral Nutrition Therapy: A Significant Problem with a Cost-Effective Solution," which describes the

profound consequences of disease-related malnutrition and is available at [www.nutritioncare.org](http://www.nutritioncare.org). and *Nutrition in Clinical Practice*. <http://www.nutritioncare.org/Index.aspx?id=5696> As summarized below, there are significant costs associated with untreated malnutrition, although effective treatment options are available:

- *Malnutrition is associated with increased morbidity, risk for infections and mortality.* Studies illustrate that malnutrition increases the likelihood that patients will experience complications. For instance, malnutrition is associated with increased risk of developing nosocomial infections, pressure ulcers, and pneumonia, as well as poor health outcomes for stroke patients. In addition, malnutrition increases the likelihood of hospital mortality and post-hospital mortality in the elderly.
- *Longer hospitalizations result from malnutrition.* Studies demonstrate that patients at risk for malnutrition have longer hospitalizations than patients who are not at risk for malnutrition, malnourished patients have longer lengths of stay than well-nourished patients, and severely malnourished patients have longer hospitalizations than moderately malnourished or well-nourished patients.
- *Malnutrition increases the probability that hospitalized patients will be readmitted to a health care facility or will require home health services.* When compared with hospitalized patients who are not at risk for malnutrition, hospitalized patients at risk for malnutrition are more likely to be discharged to another facility or to use home health services if discharged to home.
- *Malnutrition leads to increased health care costs.* Several studies show that hospital costs and charges are related to patients' nutritional status: patients at risk for malnutrition have higher hospital costs than patients not at risk for malnutrition, malnourished patients have a higher mean daily expense than well-nourished patients, and patients who remain nourished while hospitalized have lower mean hospital charges than patients who experience declines in their nutritional status. Patients with a likelihood of malnutrition have excess costs associated with their care and the complications associated with malnutrition can be expensive to treat.

Clinical outcomes may be improved and cost-savings may be achieved by using annual wellness visits, the development of personalized prevention plans and the provision of services pursuant to these plans to identify malnourished patients as well as patients at risk for malnutrition, and to prevent and treat malnutrition with safe therapies, such as enteral or parenteral nutrition.

### Content and Design

Nutrition screening and assessment should be considered in all age groups and across all health care settings. Any HRA instrument and in particular, nutrition assessment elements should be culturally appropriate, at a understandable level of literacy for most patients, and should include input from the provider and the patient. A.S.P.E.N. has just developed and published Adult Patient Nutrition Screening and Assessment Guidelines which contains many valid and reliable nutrition screening and assessment tools. See link for article: (<http://www.nutritioncare.org/WorkArea/showcontent.aspx?id=5870>)

### Data

*With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non-electronic form? Are there standardized and certified tools available to support this data migration from multiple data entry sources?*

A.S.P.E.N. has endorsed a document containing a Nutrition Dataset of elements already commonly included in EMRs/PHRs be made available for nutrition evaluation and tracking in electronic medical records (EMRs) and personal health records (PHRs) in the United States. The purpose of being able to gather these suggested elements into a "nutrition flowsheet" is to improve the capture of important nutrition and health information and to facilitate data exchange between health care systems, health care professionals and patients. This dataset was developed by representatives of the American Dietetic Association and the American Academy of Family Physicians. Document is attached (Approved for endorsement by the A.S.P.E.N. Board of Directors, October 2009)

Thank you for the opportunity to comment on this request for information. If you have any questions or need additional information, please contact us through Pegg Guenter, PhD, RN, CNSN, A.S.P.E.N. Director for Clinical Practice, Advocacy, and Research Affairs at [peggig@aspen.nutr.org](mailto:peggig@aspen.nutr.org) or 610-649-7994.

## Biotechnology Industry Organization

### **Recv'd 1/3/11**

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the development of the Health Risk Assessment (HRA) by the Centers for Disease Control and Prevention (CDC). BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 30 other nations. BIO membership includes a number of small, midsize and established vaccine manufacturers, including all manufacturers of currently licensed vaccines in the United States, and many companies with novel vaccine candidates and platforms in their development pipelines.

BIO was very pleased to see the inclusion of the Personalized Prevention Plan in the Affordable Care Act (ACA). Routine use of this plan, combined with the information in a Health Risk Assessment, will help standardize preventive care for all Medicare beneficiaries. In addition, frequent utilization of the HRA and the Prevention Plan may positively impact discussion of preventive and immunization services by providers with all their adult patients, not just those in Medicare. Finally, the more these new tools can integrate with new health information technology (HIT) systems and electronic health records (EHR), the more providers of all types will use them, resulting in a potential increase in immunization services and a subsequent reduction in hospitalizations, office visits and deaths related to vaccine-preventable diseases.

### **Content and Design:**

BIO recommends that the content of the HRA form gather information on at least those underlying conditions included in the CDC's Adult Immunization Schedule, such as immunocompromised status, chronic liver or kidney disease and so on. The Advisory Committee on Immunization Practices and its CDC-directed Working Groups have evaluated the epidemiology, pathophysiology and vaccine characteristics for these infectious diseases. Their recommendations can therefore be classified by both age and risk to best direct immunizations where they will have the most significant impact on outcomes.

Thus, to best maximize the utilization of key adult immunizations, it is very important that the HRA help providers understand the underlying conditions that can increase the risk for specific, vaccine-preventable diseases. This allows providers to best prioritize the various immunizations for their patient's needs. In a study published by Johnson in *The American Journal of Medicine*, the authors found that almost half of the providers surveyed did not routinely rely on the CDC/ACIP Adult Immunization schedule to help them remember the appropriate vaccinations for their patients<sup>1</sup>. Use of an HRA based on the published CDC schedule, coupled with EHR, could provide an easy algorithm for providers and facilitate vaccination in certain populations.

### **Mode of Administration:**

The HRA should be broadly available through various delivery mechanisms and in multiple health care settings. Electronic kiosks in public locations such as pharmacies, public health clinics etc, may encourage Medicare beneficiaries to complete the Assessment and staff may be able to help beneficiaries understand its purpose. BIO's members have always been supportive of the concept of a "medical home" for every individual. However, there are preventive services that are delivered outside of the traditional medical venue that are very important for the administration of vaccines for adults.

### **Primary Care Office Capacity and Data:**

BIO recommends that the HRA and the Prevention Plan be coordinated and linked between various healthcare provider types. In addition, the HRA should be created in such a way that it reflects the accepted guidelines for electronic health records and "meaningful use." With regard to linking healthcare providers, patients should be encouraged to share their completed HRA with their primary care provider (FP/GP, Internist, NP) as well as any specialists, public health clinics and pharmacists that they see routinely. This could be highly beneficial for tracking adult immunizations as beneficiaries may, for example, get their influenza at the pharmacy, their pneumonia vaccine in the hospital and their hepatitis B or herpes zoster vaccines in the primary care office. Linking the specific health care providers for each individual should help coordinate their preventive services offered and received.

The benefits of linking or coordinating health IT systems have been well described. As stated above, systems need to be put into places that facilitate broad health care provider recommendations for adult immunizations. Linking EHR, electronic medical records (EMR), vaccine registries, hospital and pharmacy systems to the HRA should help reduce the confusion or complexity of deciding which immunization and other preventive services are appropriate for each individual. As many practices and hospitals are installing and testing new EHR/EMR systems over the next few years, the HRA should be closely coordinated with this process to help ensure provider adoption.

BIO members strongly support provisions that will help ensure access to proven preventive services, such as vaccinations. BIO looks forward to participating in the February 2011 public forum on this topic. BIO will continue to work with the CDC and other stakeholders to help maximize adoption of the preventive services and quality provisions of the Patient Protection and Affordable Care Act.

**Conclusion**

BIO appreciates the opportunity to comment on the Development of the Health Risk Assessment for Medicare Beneficiaries as created by the Affordable Care Act. We look forward to continuing to work with the CDC to address these critical issues in the future. Please feel free to contact me at 202-962-6664 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

With Sincerest Regards,

Phyllis A. Arthur

Senior Director,

Vaccines, Immunotherapeutics and Diagnostics Policy

## **American Academy of Family Physicians**

***Recv'd 12/21/10***

The American Academy of Family Physicians is supportive of the use of Health Risk Assessment (HRA) tools and is pleased to provide comments for HRA guidelines. These assessment tools are beneficial to both physicians and patients for planning care and offering advice for optimal primary, secondary and tertiary prevention. They help individuals make better decisions about lifestyle choices and medical treatments and provide suggestions for next steps to improve their chances of a healthy life.

HRA instruments, combined with health promotion strategies, are more likely to produce favorable improvements and facilitate patient engagement. Public Health messaging strategies are also needed to promote the benefits of completing an HRA.

The assessment tool should be comprehensive and cover the most frequently occurring health conditions. The results of HRAs may also identify opportunities for practice teams to enhance their system of preventive care delivery. In order to be most effective, HRA tools must be integrated into the primary care practice setting. They are an essential building block for preventive medicine and primary care.

Sincerely,

Lori Heim, M.D.

Board Chair

American Academy of Family Physicians

LH/jl

Attachment

### **Content and Design**

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

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

*How should the HRA instrument support shared decision-making by provider and patient?*

Health Risk Assessments will benefit both patients and physicians. The focus of the assessment should include primary, secondary and tertiary prevention. It will be of utmost importance to ensure brevity, where possible, while still achieving a quality assessment.

The generic elements of an HRA should include: vital signs; height, weight, BMI, waist circumference, prescription and over the counter medications, demographic information such as age, gender and race; general health indicators; specific risk factors and lifestyle issues such as dietary intake, nutritional status, exercise beyond daily routine, activity level, stress/anger, smoking, alcohol/drug use; safe sex habits; family history; safety habits such as seat belt use, fast driving/tickets, helmet use, guns in the home, child seats, sunscreen; family history of chronic diseases, cancer, causes and ages of death; patient goals and important/meaningful activities.

Some elements may need to be stratified by age, such as recommended services and medications. Assessments will need to be made on not only what needs to happen but also what is no longer necessary for the individual's age or situation, such as mammograms or PSA testing. Some of the stratifications will not only occur by age, but also by gender and ethnicity.

The HRA should be able to be completed by patients who have adequate literacy and those who have low literacy. It is not only the reading level, but also an understanding that health literacy might be quite low, even in someone with very high general literacy. If the HRA is to be a self-administered document and cannot be completed by individuals with low literacy, then they will likely need an alternative, which might be an interviewer-administered HRA.

An HRA needs to be sensitive to the cultural and linguistic needs of the patient. It may not be necessary to create a different form for each cultural group but there should be an acknowledgement that the recommendations that stem from the HRA may be more or less actionable in certain cultures and also might change, given specific beliefs or practices.

The HRA should emphasize the need for the patient to discuss any and all concerns with his or her physician. It should include a few open-ended questions to ask about any other concerns they may have including social, economic or family problems. It should provide quantitative information that can be used by a clinical decision support algorithm with calculated risks and help clinicians focus on the most effective strategies, first action steps and resources. A wellness summary and score would be valuable. The approach to HRA must use standardized questions but the suggested behavior change or action on the patient's part must be individualized. The HRA instrument should simply be a platform to inform the clinical discussion that will occur throughout that visit and future visits. If a recommendation results from the HRA, it should be a suggested path with the acknowledgement that individual circumstances might shape ultimate recommendations. For instance, a PSA might be an appropriate age-based recommendation, though the patient and physician might have certain concerns about screening and ultimately decide to decline this test.

Interventions should be prioritized based shared decision making with the patient and based on the latest evidence. HRAs should be comprehensive, covering the most frequently occurring health conditions.

### **Mode of Administration**

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

*What are the cultural appropriateness factors in patient HRA access?*

It is likely that a combination of modalities will need to be available to serve various patient preferences and cultural or linguistic needs. Information collected outside of the physician office, such as kiosks placed in pharmacies, may become problematic. Unless potential external venues for HRAs are connected with the patient's primary care office, the information may never reach the physician. To be most beneficial, the HRA should be fully integrated into a primary care practice, possibly into a wellness portal with a secure website that is connected to the practice's information system. The purpose of collecting this information is to allow for an informed conversation between the patient and the physician so that health risk management advice can be offered.

### **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?*

*Are training and technical assistance necessary for effective practice utilization of an HRA?*

*What entity should provide this technical assistance?*

*What are potential or demonstrated community care transition linkages— follow-up outside the office by other providers—that help patients and providers manage priority risks identified by the HRA?*

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

At a minimum, an office will need a skilled team member or access to both technical assistance as well as ongoing education for both current and potential users of the system. Patients may require assistance for both data input and education on the results and implications of the assessment. There will likely be an initial learning curve for the technical components of administration and scoring interpretation. There may be significant expense occurred in implementing HRAs for their maximum patient benefit. Regional extension centers may be a source of technical assistance in integrating HRAs into electronic health records.

Individual patients will benefit most from completing an HRA and having a conversation with their primary care physician. The issue will be translation of the data into useful information for the patients themselves. Risk stratification, odds ratios and relative risk weighting will clearly be important to physicians, but patients must have the information communicated in clear and understandable language without medical or statistical jargon. Integration with community resources and referrals will require additional time from the practice team. Ideally, the practice team should follow up with patients to encourage the risk reduction plan derived through shared goal setting.

The lack of standardization, difficulty of generalization of risk scoring and feedback, limited integration into the primary care delivery process and suboptimal resources for systematic patient support and follow-up are contributors to the lack of wide and systematic adoption of HRAs. When resources are not available for collection of risk assessment data, avoidable problems may not be identified. Good risk assessment helps individuals make better decisions about lifestyle and treatments.

Current use of HRAs varies widely among practice settings. HRAs are often integrated with employer health and wellness programs without clear connection to the primary care physician.

### **Consumer/Patient Perspective**

*How could HRA data be shared with the patients for their feedback and follow up in the primary care practice?*

*What role, if any, do incentives play in motivating patients to take the HRA and/or participate in follow-up interventions?*

HRA questionnaires without follow-up interventions are not an effective health management strategy. HRA instruments combined with health promotion strategies are more likely to produce favorable

improvements and facilitate a patient-centered wellness plan through patient engagement, motivation and active participation in shared decision making. Public health messaging strategies may supplement efforts to complete an HRA or act on the results. Community employers can promote the use of HRAs through incentives in the work place.

A patient feedback report with a wellness score, suggestions for first steps and awareness about their strengths, challenges and risk factors should be products of the HRA. An individualized list of preventive care recommendations should be created and prioritized for each person, based on age, gender and certain personal or cultural preferences.

HRA data could be shared in a variety of media; oral, printed or electronic, any of which can include the ability for patient feedback and follow-up:

1. Sharing by verbal communication can occur face-to-face or over the telephone. A third option, which may become more popular over time, is via video teleconference from a computer, tablet or smartphone to a receiver of some type (computer, tablet or smartphone).
2. Printed HRA information could be provided the patient via fax, in the office or via mail. Contact information for feedback, questions and follow-up would be included on the printed report.
3. Electronic sharing can occur through a variety of methods: via secure e-mail, via secure messaging or via portal to their computer, tablet or smartphone. The provider or practice sends the information to the patient via one of these methods, and the patient has the opportunity to respond with feedback or questions. As a component of the secure communication, follow-up is arranged. Of note, while documentation of this interaction is best with an EHR, it does not require one to be effective.

There is accumulating data that shows incentives, usually monetary, but something of value to the patient, does indeed modify behavior and “encourage” patients to obtain needed preventive care/assessments, such as colon cancer screening or breast cancer screening. The same is likely true of HRA’s. If the intent is to have patients take an HRA annually, then link the incentives to not only taking the HRA but following through with identified or recommended prevention activities. The HRA only identifies potential avenues for primary prevention intervention. Without implementing the prevention measures, the HRA is not very useful to anyone.

Another critical component to consider for successful follow-through of the HRA would be the patient’s willingness to change behavior. This area may need to be tailored to specific age-based recommendations, but individuals that have no interest in changing behavior may need to first be moved to the “contemplative stage” of change, rather than attempting to convince them that they need to adopt healthier habits. This intervention may require additional training of staff so that they may acquire the needed skills to help individuals move from one stage to the next.

### **Data**

*With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non-electronic form?*

*Are there standardized and certified tools available to support this data migration from multiple data entry sources?*

Ideally, HRAs should be fully integrated in the primary care office electronic health record. When this capability is not available, there is still clear value in using paper-based data collection. Although searchable fields would increase the value of HRA data in the information system, scanning a paper document is a reasonable alternative as an interim strategy.

### **Certification**

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

It would be helpful to have explicit guidance from the CDC and CMS about acceptable alternative formats and content for HRAs for various patient groups or populations.

### **Evaluation and Quality Assurance**

*How should the HRA guidance be evaluated and updated with respect to individual and population-level (practice-based panel management) health outcomes?*

In order to evaluate the effectiveness of the tool, several outcomes could be measured, including improvement of life expectancy, quality of life, preventive services delivery, patient satisfaction with care provided, patient stages of change for health behaviors and sustainability of HRAs in the primary care office.

## **National Research Corporation**

***Recv'd 1/11/11***

I'd like to request an opportunity to comment at the Public Forum on guidance around Health Risk Assessments. I represent National Research Corporation, a research firm focused exclusively on health care. We work with health care providers, systems and Medicare Advantage health plans on validated measurement and improvement tools. We have completed over 2.5 million health risk assessments with Medicare Advantage members over the past ten years.

We have expertise in the areas of Content and Design heading, as well as Mode of Administration.

A brief summary of the points I'd like to discuss follows:

### **Content and Design**

- Types of questions – specific areas that should be included: Physiological, Medical History, Chronic conditions, compliance with medications/directives, family history, demographics, lifestyle, social support
- Validated questions that are evidence-based and predictive
- Particularly with seniors, formatting and questionnaire length are important. Response is best when questions are simple and to the point, there's lots of white space, no tiny circles to fill in and open-ended questions that require a great deal of research/thought are limited
- 6<sup>th</sup> grade reading level or below is appropriate
- Benchmarks and normative data are important in understanding the population and developing systemic plans

### **Mode of Administration**

- Comfort with technology is evolving and increasing over time
- Multi-modal is appropriate and works well with seniors
- Modes that allow the respondent to begin, then pause and finish later if they get fatigued work well with seniors
- Automated interactive systems are very good when collecting sensitive information that people may otherwise be reluctant to share (eliminates perception of bias/judgment). Particularly useful for mental health/depression items that sometimes carry stigma in the elderly population.

I hope you'll agree that our expertise provides a context and insight for our comments that we believe will be helpful in developing actionable and predictive health risk assessments. Please confirm that our organization will have an opportunity to comment, and any further detail you can provide around what to expect in the forum would be most appreciated.

I look forward to the opportunity to work together to formalize guidelines around Health Risk Assessments for the Medicare Advantage population and others as well.

Thank you,  
**Jennifer Cintani**  
National Research Corporation

## Genetech

*Recv'd 12/22/10*

Genetech is writing to provide comments responsive to the Centers for Disease Control and Prevention's (CDC) request for information on the development of guidance concerning Health Risk Assessment (HRAs). Founded more than 30 years ago, Genetech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. We appreciate the leadership role that the CDC is taking to ensure that Medicare beneficiaries have improved access to necessary care. After a review of the CDC's Notice on Development of Health Risk Assessment Guidance (FR Doc. 2010-28788), published on November 16, 2010 in the Federal Register, Genetech respectfully submits the following comments regarding the required health risk assessments. Specifically, we believe that the CDC should recommend that an HRA include an assessment of risk factors for diseases that are common and costly in the Medicare population, such as various types of cancer, diabetes, and hepatitis C.

### **I. Required Health Risk Assessments Should Address Diseases Relevant to the Medicare Population**

Section 4103 of the Affordable Care Act requires that a health risk assessment be included in the annual wellness visit benefit authorized for Medicare beneficiaries.<sup>1</sup> The law further provides that a health risk assessment "...identify chronic diseases, injury risks, modifiable risk factors, and urgent health needs of the individual."<sup>2</sup>

Given this directive, it is critically important that the CDC's guidance on risk assessments for the Medicare annual wellness visit take into consideration those diseases where early diagnosis and treatment

<sup>1</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 4103 (2010).

<sup>2</sup> *Id.*

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could prevent costly and severe medical problems at a future time. In particular, there is a need for early detection and treatment for those diseases that commonly impact the Medicare population, specifically cancer, diabetes, and hepatitis C.

#### **a. Cancer**

Cancer is a disease more likely to occur in an older population. In the United States, it is estimated that 1,529,560 men and women (789,620 men and 739,940 women) will be diagnosed with cancer and 569,490 men and women will die of cancer of all sites in 2010.<sup>3</sup> From 2003-2007, the median age at diagnosis for cancer of all sites was 66 years of age.<sup>4</sup> From 2003-2007, the median age at death for cancer of all sites was 73 years of age.<sup>5</sup>

Including a risk assessment for cancer as a part of the Medicare wellness visit could help identify disease early and aid in disease and cost management. The risk factors to assess include:

Behavioral risk factors (behaviors that can be changed, such as smoking, diet, lack of exercise, and excessive alcohol consumption),

Environmental risk factors (factors found in the surrounding environment, including the sun, pollution, radon, secondhand smoke, and geographic location),

Biological risk factors (physical characteristics, such as gender, race, and age), and

Genetic risk factors (factors related to genes inherited from parents).

The table below identifies selected preventable key risk factors for cancer and illustrates the importance of a risk assessment that would address these issues.<sup>6</sup>

Selected Risk Factors for the Year 2015 if Trends Continue %

Smoking (% adults current smokers) 19

Obesity (% adults obese) 41

Red meat (% adults consuming >2 times per week) 71

Physical activity (% adults adhering to guidelines) 32

Inclusion of cancer within risk assessments is significant to safeguarding patient health.

### **b. Hepatitis C Virus**

In the United States, 2.7–3.9 million people are chronically infected with the hepatitis C virus (HCV).<sup>7</sup> However, approximately 75% of those infected are unaware of their status.<sup>8</sup> Given the asymptomatic nature of hepatitis C, some patients may not know they have the disease until they experience symptoms of more severe liver disease, which can take decades to emerge. Left untreated, hepatitis C can lead to serious chronic conditions, including liver failure, cirrhosis and liver cancer. In addition, HCV-related liver disease is a leading reason for liver transplants.<sup>9</sup>

A risk assessment for hepatitis C as part of the Medicare annual wellness visit would provide an opportunity for more patients to understand if they are at risk, as well as gain access to testing and treatment before more serious health complications arise. The at-risk population includes chronic hemodialysis patients, children born to HCV-positive mothers, and persons with known exposures to HCV.<sup>10</sup> A healthcare provider can assess many of these risk factors within a wellness visit. It is important to note that patients who are made aware of their status and do seek treatment can see a positive impact on their liver health and may be able to avoid serious medical consequences, including liver failure.

Although new HCV infections have declined in recent years, the statistics on undiagnosed patients with HCV underscores the importance of screening at-risk patients in the Medicare program. Baby boomers (the generation born between 1946 and 1964) account for two out of every three cases of HCV infection,<sup>11</sup> which means the impact to Medicare may be significant if their diseases go unrecognized and untreated. As the population ages, one study estimates that Medicare's share of chronic HCV-infected patients could increase from 12% in 2009 to 39% in 2028.<sup>12</sup> Over the next 20 years, total annual Medicare

costs associated with treating HCV infection are projected to increase substantially, from \$5 billion to \$30 billion, unless changes are made to the way these patients are identified and managed.<sup>13</sup>

The Federal Government is already well aware that hepatitis is a serious health problem in the United States. Several agencies, including the CDC, the Department of Health and Human Services Office of Minority Health and the Department of Veterans Affairs, recently sought guidance from the Institute of Medicine (IOM) in identifying missed opportunities related to the prevention and control of hepatitis. The IOM Committee tasked with this project found that risk factor screening for viral hepatitis is sparse and fragmented among entities at the federal, state, and local levels.<sup>14</sup> A key recommendation in their final report was that federal health insurance programs, like Medicare, should incorporate guidelines for risk-factor screening for hepatitis B and hepatitis C as a required core component of preventative care so that at-risk people receive serologic testing and chronically infected patients receive appropriate medical management.<sup>15</sup> The guidance that the CDC is currently developing provides an opportunity to implement this recommendation and ensure that risk assessments for hepatitis are a part of the annual Medicare wellness visit.

### **c. Diabetes**

Diabetes was the seventh leading cause of death in the United States in 2006, leading to a number of lifethreatening

complications including heart disease and stroke, high blood pressure, blindness, kidney disease, nervous system disease, amputations, dental disease, and pregnancy complications.<sup>16</sup> According to the CDC website, the number of Americans diagnosed with diabetes more than tripled (from 5.6 million to 18.1 million) from 1980 through 2008. Furthermore, people aged 65 years or older (i.e., the Medicare population) account for approximately 38% of the population with diabetes, and an estimated 32% of Medicare spending is attributed to the diabetes population.<sup>17,18</sup> Finally, the estimated diabetes costs in the United States in 2007 were \$174 billion (\$116 billion direct and \$58 billion indirect costs).<sup>19</sup> In addition, the CDC's National Diabetes Fact Sheet suggests that at least 57 million American adults had pre-diabetes in 2007, a condition in which individuals have blood glucose levels higher than normal but not high enough to be classified as diabetes. However, studies have shown that people with pre-diabetes who lose weight and increase their physical activity can prevent or delay diabetes and return their blood

glucose levels to normal.<sup>20</sup>

The Centers for Medicare & Medicaid Services (CMS) already covers diabetes screenings for beneficiaries with certain risk factors or characteristics. We applaud CDC's and CMS' work in diabetes prevention and detection and encourage you to build upon this work as you develop guidance on HRAs. In particular, for those patients who already have diabetes, it would be important to identify additional cardiovascular risk factors, including glycemia, dyslipidemia, blood pressure, and inflammatory markers in order to prevent coronary artery disease. Additionally, since diabetes is the leading cause of new cases of blindness among adults aged 20–74 years, early detection of ophthalmic complications such as diabetic retinopathy is important in helping to delay or prevent loss of eyesight. Thus, one specific component of an HRA in diabetic patients might be assessing whether they have been appropriately screened for diabetic eye disease.

## **II. Conclusion**

As you work with the Centers for Medicare & Medicaid Services to develop guidance for risk assessments, we urge the CDC to consider addressing these diseases. Assessing and identifying patients at risk for cancer, diabetes and hepatitis C could help lead to earlier diagnosis and treatment, which could help prevent costly and severe medical problems at a future time.

If you require additional information, please don't hesitate to contact Stephanie Dyson, Senior Director for Government Affairs, at 202-296-7272 or via email at [dyson.stephanie@gene.com](mailto:dyson.stephanie@gene.com).

Sincerely,

/ELM/

Evan L. Morris, Esq.

Vice President, Government Affairs

Genentech, Inc.

**Recv'd 1/3/11**



HealthRiskAssessme  
ntGuidanceDartmoutf

## **Nurtur Health, Inc.**

**Recv'd 1/3/11**

The following comments are submitted in response to the Department of Health and Human Services/CDC Request for Information on the Development of Health Risk Assessment Guidance published in the Federal Register on Nov. 16, 2010. Comments are due on or before today, Jan. 3, 2011. These comments are submitted on behalf of Nurtur Health, Inc., 20 Batterson Park Road, Farmington, CT 06032. Thank you for your consideration.

### **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?

The physician, PA, NP and others associated with direct care of the patient would be required to utilize the data.

Are training and technical assistance necessary for effective practice utilization of an HRA? What entity should provide this technical assistance?

Yes. Initial and ongoing training are necessary for ongoing support. This service should be provided by the entity that actually sells the tool. A training and support module should be developed in conjunction with CMS to ensure proper messaging.

What are potential or demonstrated community care transition linkages—follow-up outside the office by other providers—that help patients and providers manage priority risks identified by the HRA?

Employer based wellness initiatives, community health centers, hospitals, private nursing care, rehab centers and others would all need some form of access to the HRA results. Depending upon the patient's situation, these entities would benefit from the knowledge of the HRA data.

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

N/A

### **Consumer/Patient Perspective**

How could HRA data be shared with the patients for their feedback and follow up in the primary care practice?

Data should be shared via online portal as well as delivered to the patient in hard-copy during the office visit. They could also be mailed if internet access is not available.

What role, if any, do incentives play in motivating patients to take the HRA and/or participate in follow-up interventions?

Incentives play a very large role in motivating individuals to take more of an interest in their health. Incentives have also delivered better outcomes and care on the part of the physician. The bottom line is that the correct incentive mix for both patient and physician will drive better acceptance and outcomes.

### **Data**

With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the

data are entered in a non-electronic form?

Data entered into the form could be integrated using web-service applications. There would need to be development work completed up front in order for this to work fluidly. Once it is set up, the data flows in real-time.

Are there standardized and certified tools available to support this data migration from multiple data entry sources?

These data migration tools would be custom development projects.

### **Certification**

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

## **Public Health Institute**

### **Health Risk Assessment Guidance**

#### **COMMENTS**

***Submitted January 3, 2011***

### **Content and Design**

***What are generic elements of any HRA and what elements must be tailored to specific populations particularly those stratified by age?***

- Paired with electronic health records (EHRs), the health risk assessment (HRA) can support assessment, assurance, and policy development in public health. While current HIT efforts targeting public health focus on information exchange for syndromic surveillance, lab results reporting, and immunization registries, a comprehensive health data set should include social determinants of health and information about health sustaining characteristics of our communities.
- HRAs should include elements that can identify lifestyle and environmental risk factors that have the most impact on health. In the case of low-income/uninsured populations with chronic disease diagnoses, data elements that provide information concerning a community environment's health sustaining characteristics should be captured. Access to healthy food, opportunities to walk in safe areas, and factors associated with intentional injuries should be reflected in a comprehensive health risk profile.
- The HRA also serves as a tool for achieving health behavior change. Inclusion of factors that may hinder a patient's ability to attain lifestyle goals can lead to the development of a realistic lifestyle modification plan. The HRA should be integrated into the EHR, making it possible to merge risk appraisal results, clinical data, and documentation by all members of the care team. Merging the HRA with EHR functionalities can facilitate improved decision support and work flow.

- HRA data should be accessible to public health entities in order to speed the availability, analysis, and use of patient level data to create defined population/community health profiles. Pairing patient level data with data identifying fast food service oases, farmer's markets, parks, and schools that meet physical activity requirements can inform policy and practice change in a shorter time span and with greater specificity.

### **Mode of Administration**

#### **How will individuals access the HRA?**

- Cellular phones should be an option to access the HRA for the patient to initially enter information and communicate with providers. While computer ownership continues to increase, low-income families are less likely to have access to a computer in the home. However, cell phone use in low income communities is high and the growth in low-income non-white populations is the largest of any sector. A Pew Center study released in July 2010 reported that approximately 73% of adults in poverty have cell phones.

#### ***What are the cultural appropriateness factors in patient HRA access?***

- The utility of an HRA in modifying health risks is tied to a four step process: data collection, interpretation, goal setting /problem solving, and timely feedback concerning progress. HRA administration and access options should reflect this process in the context of a patient's cultural preferences including language, religion, disability status, sexual orientation, education, age, and family dynamics. Administration should be based on existing processes that ensure cultural competency in all aspects of clinic operations and patient care.

### **Consumer/Patient Perspective**

#### ***How would HRA data be shared with patients for their feedback and follow-up in the primary care practice.***

- In addition to email delivered to a personal computer, patients should be able to record health information and contact providers via cellular phone by texting. Communication with providers has been shown to be effective in improving blood pressure and blood glucose control (*JAMA* 2008 and *Diabetes Care* 2009). Integrating patient-generated communication and data into the EHR would be optimal.
- Communication via cell phone should be supported by availability of clinicians, medical assistants, or community health workers/coaches in order to respond to information needs that are not well-suited to communication via cellular phone text messaging.

#### **Contact:**

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## **Convenient Care Association**

***Recv'd 1/3/2011***

The Convenient Care Association (CCA) appreciates the opportunity to comment on the Centers for Disease Control and Prevention's (CDC) request for information (RFI) regarding the development of Health Risk Assessments (HRAs). The CCA is the national trade association representing the retail-based convenient care industry. There are currently approximately 1200 retail-based clinics in more than

30 states around the country. The industry collectively has served more than 15 million people, and has achieved strong quality outcomes and satisfaction among consumers and health care providers.

The CCA and the convenient care industry are strongly committed to providing high-quality, cost-effective and accessible health care through the operation of retail-based convenient care clinics. Retail-based health care has been demonstrated to be patient-focused, achieving better than 90% patient satisfaction rates, more cost-effective than primary care practices, urgent care centers and emergency rooms, and of equal or better quality than primary care practices, urgent care centers and emergency rooms.

Please accept comment on the following issues identified within the RFI: HRA content and design; mode of administration; primary care office capacity; consumer/patient perspective; and data.

### *HRA Content and Design*

The HRA is a valuable tool for patients and health care professionals to assess a patient's health status and begin to devise an appropriate care plan. The HRA provides patients and their providers an opportunity to discuss particular health concerns and conduct preventive care and wellness-focused interventions.

The CCA encourages the CDC to structure the HRAs in simplistic and standardized terms, to ease administration and ensure consistency in delivery of the HRA across settings. HRAs should be short in length to encourage patients to take advantage of this tool, and be sensitive to variations in patients' capacity to comprehend complex medical terms, due to either language barriers, low educational attainment, or other cognitive deficit. To the extent possible, the HRA should be conducted at a 5th-grade reading level and be administerable in multiple languages.

The CCA also recommends that the CDC consider implementing a two-part HRA, consisting of a component completed by the patient in tandem with the provider and a second component able to be completed by the patient at their convenience, which could then subsequently be reviewed with the provider. The first part would encompass all biometric and basic medical assessments, including a full personal and family medical history, basic vital signs including blood pressure, body mass index and weight, and lipid and glucose screening. The second component of the HRA would include the patient's self-report of relevant lifestyle factors, including diet, exercise, and stress management. Importantly, the HRA should also be tailored to assess the patient's willingness to adopt lifestyle changes to enhance any measures which are outside normal range and considered disease risk factors. The HRA should facilitate a conversation between patient and provider about tailored interventions to improve their health. The self-report component of the HRA should be made available electronically for patients to access and should otherwise be conveniently accessible. Patients would be encouraged to complete this assessment prior to meeting with their provider; however, this would be not be a barrier to receiving the HRA altogether.

Standardization of the HRA will contribute to the ease of administration and applicability of information collected. Though certain questions and resulting interventions will necessarily vary based on factors such as gender and age, to the extent possible the questions posed and methodology utilized should be standard across settings and over time. There are several benefits inherent to standardization. First, patients will more likely to agree to such an intervention if they understand and are familiar with its scope and utility. Second, standardization enhances the portability of the information for patients who change providers or health systems. Providers will find the information presented to be more useful if they can trust its origin and collection methodology. Outcome tracking over time will be improved, as well.

### *Mode of Administration*

The CCA encourages the CDC to consider offering access to HRAs in retail-based convenient care clinics, a novel care setting that has been demonstrated to be easily accessible to and popular with patients, as well as of high clinical quality. Ensuring that HRAs are administered in all available settings, such as retail-based convenient care clinics, will maximize uptake of this service by patients, who may otherwise be deterred from seeking this care if they are unsure how to access it or if they confront other barriers in seeing a provider.

Retail-based convenient care clinics are an ideal setting for the delivery of HRAs. They are accessible to the public; at the industry's current level of saturation, approximately 30% of Americans live within a 10-minute drive of a clinic. They are generally staffed by nurse practitioners, masters-level or greater health care professionals who are equipped to administer all components of an HRA, assess, diagnose, treat, prescribe, and provide patient counseling. The clinics have a particular focus on the wellness elements emphasized by the HRA, including assessment of chronic conditions such as diabetes, hyperlipidemia, and hypertension. Integrating delivery of HRAs into the scope of care provided by convenient care clinics would be seamless and provide a new and meaningful benefit to patients.

To enable retail-based convenient care clinics to administer HRAs, we recommend that the CDC and the federal government take steps to enable all qualified health care professionals, including nurse practitioners and physician assistants, to deliver such care, be reimbursed appropriately for its delivery, and to authorize any subsequently indicated care. Nurse practitioners and physician assistants should be equitably reimbursed as physicians are for the delivery of such important services. Barriers to practice by these health care professionals, such as restrictive on-site requirements, should be eliminated or substantially loosened, which will increase accessibility to patients, increase all health care professionals' capacity to deliver care to patients, and lower costs to patients as well as the health care delivery system.

### *Primary Care Office Capacity*

Regarding community care transition linkages, retail-based convenient care clinics are in a unique position to contribute to achievement of this important aim. As the clinics often operate as a first-line point of access for patients without a primary care provider or with limited access of the system, the clinics are poised to provide a great benefit in widespread delivery of HRAs. The results of a patient's HRA could be shared, as appropriate, with their primary care provider, and the clinic setting provides an ideal opportunity for convenient ongoing monitoring of various metrics related to chronic disease, which can subsequently be transmitted to the patient's primary care provider for appropriate continuity of care. Patients in need of ongoing, regular testing are more likely to undertake that testing if they have a convenient, easily accessible, and trusted source. As the retail clinics are open extended weekday hours and weekends, can be visited without an appointment, and are efficient for patients to use, they are a vital partner in the long-term management of a patient's chronic illness.

### *Consumer/Patient Perspective*

Patients should be encouraged to be active participants in their health care. Retail-based convenient care clinics routinely share a copy of the visit record with patients, for their use and reference, and for sharing with their primary care provider. A similar strategy is recommended in the administration of HRAs. Patients should be empowered to make positive changes in their health and lifestyle, and interactive delivery of HRAs is one important tool to do so. In addition, appropriate sharing of the assessment outcomes with a patient's primary care provider ensures continuity of care and maximizes opportunities for positive medical intervention and prevention.

### *Data*

The transferability of health information is essential to ensuring continuity and appropriateness of care. Patients should be given access to their health care information and that information should, to the extent permitted by current technological capabilities, be permitted to travel with the patient. Standardization of data and elements of the HRA will be essential in achieving these outcomes of appropriate transferability and utility of the information generated by the assessment. Currently, 100% of convenient care clinics with membership in the CCA maintain robust electronic health records. The CCA encourages the continued incentives provided to other health care providers to establish electronic health records systems, and supports the ongoing interest in establishing secure interoperable electronic health records systems. The CCA welcomes partnering with the federal government as an example of successful integration of electronic record-keeping into a health care setting, and is eager to support pilot or demonstration projects aimed at establishing adequate interoperability.

In conclusion, the CCA appreciates having the opportunity to provide comments in response to this RFI. We would like to reiterate the ever-increasing value and proven quality of retail-based clinics and the expanded recognition nationally of the capacity of non-physician providers such as nurse practitioners and physician assistants to practice with increasing autonomy. The convenient care industry is strongly committed to the enrichment of the delivery of patient-centered, high-quality, affordable and accessible care in the United States, and we look forward to continuing to work with the CDC as part of the health care reform process.

Thank you again for the opportunity to comment. I can be reached for any clarification at [caroline@ccaclinics.org](mailto:caroline@ccaclinics.org) <<mailto:caroline@ccaclinics.org>> or (267) 765-2354. Caroline Ridgway, JD

## Michigan Oral Health

### ***Recv'd 12/29/2010***

As the Michigan Oral Health Director, I would like to offer the following comments on the Federal Register Notice, Nov. 16, 2010 on the Health Risk Assessment (HRA), Section 4103 of the Affordable Care Act (ACA).

#### CONTENT

- 1) There are generic elements of the HRA that can be asked for all age groups. One is environmental--safe housing, safe and clean drinking water (oral health). Second is behavioral--smoking and tobacco use, recreational or illicit drug use, piercings and tatoos (especially oral piercings), sexual abuse, and domestic violence.
- 2) Specific oral health elements that can be asked One is their dietary habits, especially the amount of sugar drinks consumed daily. This can be stratified by age too.  
  
Infants and young children can be asked about consuming juices daily. How it is administered--sippy cups, bottles. When it is administered--snack time, all day sipping, in bottle at naptime and bedtime.  
  
Age 12 & over can be asked the amount of carbonated beverages or other sweetened drinks consumed daily.  
  
Second is the medication used and side effects experienced, especially the elderly.  
  
Do they experience dry mouth or lack of saliva?  
Do they suck on lozenges to keep mouth moist?  
Other items to help aid in keeping mouth moist?

## DESIGN

Some of the questions and answers can be set up to create a dialogue. Ask consumers about how important they think their health is to them and highlight the systems--mouth, diet, heart, lung, skin, bone, then have them rank their priorities. Then ask how confident they are in changing behaviors in these areas. That will help in developing a dialogue between the consumer and the clinician.

## ADMINISTRATION

The ideas listed are all good--kiosks or some other means in the office, Internet, mail-in paper form, kiosk in a pharmacy or other nontraditional areas. A dental office is a site that can also administer the HRA. What about senior centers? Area Agencies on Aging? or other agencies that may help with health-related issues.

Thank you for the opportunity to comment on the proposed HRA for Medicare and/or Medicaid consumers.

# National Partnership for Women & Families

*Recv'd 1/3/11*

On behalf of the National Partnership for Women & Families, I want to thank the Center for Disease Control and Prevention (CDC) for this opportunity to comment on the development of guidance for health risk assessments (HRAs). The National Partnership is dedicated to building a health care system that delivers the high quality, coordinated, and comprehensive health care that women and families deserve. To get there, we need to start with a strong foundation of primary care, enabled by health information technology (IT) and exchange that supports patient-centered care.

We believe HRAs can play an important role in supporting effective primary care. With appropriate protections in place, HRAs can be useful tools that engage patients and their caregivers in their health care. Further, HRAs can foster conversations between patients/caregivers and practitioners about the steps they can and want to take to improve or maintain their health and quality of life, as well as the role the practitioner will play in that process.

We are particularly pleased that this tool will be incorporated into the new annual wellness visit under Medicare. The HRA is a fundamental component of the prevention plan service and will help make the service more personalized than the one-size-fits-all Welcome to Medicare Visit. We do have concerns, however, about how HRAs are structured and used: it is essential that HRAs not be a vehicle for undoing critical protections. For instance, an HRA must not be used as part of an employer wellness program that might serve as a backdoor means to health status rating practices or undermine important civil rights protections, including the Genetic Information Nondiscrimination Act (GINA) and the Americans with Disabilities Act (ADA) or the Rehabilitation Act.

Following is our response to the CDC's specific questions regarding HRAs. We offer recommendations for how the potential benefits of HRAs can be maximized while ensuring patients are not unfairly penalized or discriminated against.

### **Content and Design**

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

All HRAs should identify an individual's chronic diseases, urgent health needs, cognitive impairment, functional ability (including ability to successfully perform activities of daily living), and level of safety (including fall risk and home safety). In addition, HRAs should establish or update the individual's

medical and family history, including a detailed current medications and supplements lists. As part of the medical and family history, the HRA should also identify whether or not the beneficiary is a family caregiver, i.e. whether he/she is currently providing care or assistance for someone with health problems or disabilities. A body of research over the past 30 years shows family caregivers of older adults to be a vulnerable and at-risk population themselves. Family caregivers face health risks, serious illness, poorer immune function, lower perceived health status, and increased emotional strain and mental health problems.

For older patients, HRAs should assess the level of support at home. The availability of a caregiver is an important indicator of an individual's ability to function and of their level of safety at home. If the HRA identifies that a caregiver is present, the practitioner should be encouraged to conduct a separate caregiver assessment to understand the primary caregiver's capacity. As the Affordable Care Act's (ACA's) investments in fully engaging caregivers in the care process attests, the role of caregivers is essential to the management of complex chronically ill beneficiaries, particularly those with cognitive impairments.

HRAs should also identify individuals with chronic conditions and include questions that assess how well the individual understands their illness/condition and their activation level, for instance, by using the short form Patient Activation Measure developed by Judith Hibbard and others.<sup>1</sup>

Many HRAs ask questions about an individual's lifestyle risk factors, like alcohol consumption, smoking status, and diet. These are clearly critical determinants of a person's health, and are important areas where individuals may be able to affect change. It is just as important, however, to ask questions about lifestyle risk factors which may be outside of an individual's personal control, but are just as influential on their health outcomes. Moreover, any recommendations should take into consideration such external factors because they can have a substantial impact upon individuals' ability to follow their practitioner's advice. For instance, HRAs should include questions about whether the individual, if employed, has jobprotected paid sick days, or whether a caregiver has paid leave to help that individual meet his or her healthcare needs. Nearly 40 percent of America's private sector workers – and eight in 10 of the lowestwage workers – do not have a single job-protected paid sick day<sup>2</sup> and therefore cannot leave work to seek needed medical care (including preventive care, like cancer screenings) without risking the loss of income or employment. These limitations have a significant impact on individuals' health risks and must be taken into account in structuring patient care, including scheduling and assessing patient likelihood of follow up. Similarly, HRAs should ask about access to healthy foods, neighborhood safety, places to exercise, and availability of social interactions to combat isolation.

Also critical to ensuring that the HRA informs patient-centered care are questions on patient preferences and values. While these questions will not indicate specific health risks, they will inform what actions should be taken to address identified risks. For instance, HRAs could ask the patient about areas in which the patient most wishes to see health status improvement (and which areas are a low priority), and what time and financial investment, if any, they would be willing to make to improve. The HRA should also ask questions that would provide information on what are the most effective ways to communicate with the patient/caregiver, such as whether they like information provided one-on-one by a counselor, visual formats (like videos), and/or written materials (like brochures) with personal follow-up. In addition, HRAs could ask about the patient/caregiver's computer/technological literacy, so that the HRA can be linked to a person's electronic health record (EHR) or personal health record (PHR) and treatments and care management can be tailored to the patient/caregiver's comfort with using computers, social networks, and other electronic tools.

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

Medicare or Medicaid practitioners are subject to Title VI the Civil Rights Act of 1964 and must follow the revised Department of Health and Human Services (HHS) Limited English Proficiency (LEP) Guidance, released in 2004. Practitioners should follow this guidance as appropriate to provide meaningful access to HRAs to LEP individuals. To the extent feasible, practitioners should be encouraged to make available translated HRAs or facilitate access to competent oral interpreters. Ultimately the onus of translation should fall on HRA vendors so translation only needs to be done once for each HRA, rather than many

times over by each practitioner or employer offering an HRA. To ensure that HRAs are not only translated accurately but are also culturally appropriate, vendors should involve target audiences, including representatives of major ethnic groups, in the development and translation processes. Regardless of language, HRAs should use clear, concise language written at the lowest reasonable education level.

The option of in-person assistance should also always be made available in conjunction with a paper or online HRA. Many existing HRAs are lengthy questionnaires that can easily overwhelm individuals with limited literacy, including health and computer literacy, and cognitive or intellectual disabilities, or individuals from other cultures and backgrounds for whom concepts behind the HRA may not be familiar and could be intimidating. Older adults with multiple chronic conditions may especially find such forms difficult if not impossible to fill out on their own. Such assistance should also be available with any written reports or recommendations that result from the HRA. The CDC should explore how it can assist practitioners in finding human resources to provide these services

To further ensure that cultural appropriateness factors are integrated into the design, CDC should reach out to representatives of health disparity populations, including women, racial and ethnic minorities, LEP populations, people with disabilities, and the LGBT community, to encourage their participation in the February public forum on HRAs referenced in this notice.

### **How should the HRA instrument support shared decision-making by provider and patient?**

For patients, HRAs should not simply be a series of questions collecting information from them, but should provide information back to them and their caregivers based on patient responses. For example, HRA results could provide summary information with specific actions to take, patient-specific educational materials, a list of risks indicated by their answers, and suggested questions or items to discuss with their practitioners. For practitioners, HRA results should be linked to their clinical decision support system to prompt them to discuss specific recommendations with the individual taking the assessment. If the HRA is comprehensive and addresses the range of areas we suggest above, it can provide critical insight into the patient's preferences, values, culture, and living circumstances. This information help the patient/caregiver and her practitioners work together to identify those risks that the patient/caregiver wants to prioritize going forward and those she does not, what type of intervention they would prefer, and how best to present this information to the patient/caregiver.

### **Mode of Administration**

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

Individuals should have multiple modes by which they can access HRAs. Electronic modes should be prioritized, backed by standards that allow for compilation and integration of responses into electronic health records (EHRs), regardless of mode. Examples of modes are PHRs, web-based portals, kiosks, cell phone/SMS texts, etc. There should be an option of paper for those who cannot make use of electronic modes, however.

Because HRAs will require individuals to enter personal information, privacy and security protections are crucial. Consumers must be informed of how their information will be used and when and to whom it may be disclosed. This is particularly important for HRAs that are a part of employer wellness programs. Consistent with federal and state law, steps should be taken to ensure the privacy and security of consumer information. Privacy and security policies should be made available to the consumer in a clear and simple manner that is not unnecessarily alarming or laden with legalese before and at the time of HRA completion.

#### **What are the cultural appropriateness factors in patient HRA access?**

Electronic HRAs should be robust enough for high-end users but simple enough for low literacy or LEP users, available in multiple languages, and accessible to individuals with disabilities. It is important to remember that low-income and other under-served communities disproportionately lack computer or Internet access, or only have access through alternative means. HRAs should be accessible through mobile phone technology, as low-income people are increasingly accessing the Internet through these tools. Strategies should also be implemented to broaden the availability of secure access through the availability of kiosks at health practitioner offices, including at community health centers. However these strategies should incorporate a warning to individuals that indicates the greater risk that comes when using public computers and unsecured internet connections and inform individuals of how and where they can get paper forms.

### **Primary Care Office Capacity**

The entire care team or, at a minimum, the patient's point person on the care team needs to play a role in using HRA data to support personalized prevention planning. HRA data must be integrated into EHRs and clinical decision support systems, and, if separate, into e-prescribing systems. Looking forward, there will need to be the capacity for connecting an individual with community supports that are both inside and outside the health care system, based on needs indicated by HRA responses. These linkages could be as simple as flagging a specific support or resource need, which is then addressed by a care team member, or as advanced as building actual electronic systems that enable referrals both within and outside of the health care system.

Primary care practices, especially those participating in traditional (fee-for-service) Medicare, will need significant assistance for using the information gathered by HRAs. While practitioners collect some similar information on questionnaires offered to new patients, primary care practices will need help in understanding how to make use of this information in the course of their practice, as well as help in redesigning workflows and renegotiating staff roles to ensure that the information is collected, viewed and interpreted, and acted upon. Physicians do not need to be the only practitioners taking a role in this process. The use of HRA information by primary care practitioners complements the movement towards patient-centered medical homes. Finally, as quality measures begin to reflect information gathered or impacted by HRAs, primary care practices will need assistance in assessing and improving performance through their use.

### **Consumer/Patient Perspective**

#### **How could HRA data be shared with the patients for their feedback and follow up in the primary care practice?**

HRA data should be shared with patients in multiple modes, per their preference. This data should be made useful to them by providing comparisons in the form of a "health position" relative to others with similar characteristics (age, community data, etc). Results should also be accompanied by summary information with specific actions to take, patient-specific educational materials, a list of risks indicated by their answers, and suggested questions or items to discuss with their practitioners. All information should be shared within the context of how and where help and guidance can be provided to allow them to improve their health.

#### **What role, if any, do incentives play in motivating patients to take the HRA and/or participate in follow-up interventions?**

##### *Privacy & Discrimination*

HRAs are heavily used in wellness incentive programs. While we certainly support the use of wellness programs to improve health, we have serious concerns about the use of financial incentives in wellness programs, in particular if they are used to compel participants to disclose personal health information for which they may then suffer adverse consequences. Privacy issues and the potential for discrimination are of significant concern when employers implement wellness programs, especially those that ask

employees and their family members to fill out HRAs. While employers are subject to privacy protections restricting the release of personal medical information, vendors and other companies that employers contract with to offer questionnaires or screenings may not be. Some HRAs are lengthy and invasive, both for the individual and their families. Under current law, failure to provide this information or even complete an HRA can result in higher premiums, even in participation-only programs.

Wellness programs should be voluntary, and employers or plan sponsors cannot or should not be able to make incentives contingent upon providing certain private medical information. For example, GINA affords some protections here: wellness program incentives should not be contingent on disclosure of protected genetic information by employees or family members of employees. The final regulations issued by the U.S. Equal Employment Opportunity Commission for GINA clearly explain that when an HRA asks questions about genetic information that are protected under the law, such an assessment must be bifurcated. Additionally, employers and practitioners must take steps to safeguard the confidentiality of such information. Other types of personal health information, including information about disabilities, mental health and reproductive and sexual health, should also be clearly safeguarded and potentially bifurcated from incentive structures. For example, civil rights issues will also arise regarding questions about individuals' disabilities which may be covered under the ADA or the Rehabilitation Act (as well as nondiscrimination provisions of the Health Insurance Portability and Accountability Act), or with respect to questions and programs that may have a disparate impact based upon age or sex.

Guidance should indicate that HRAs should include specific and stringent privacy protections and the scope of those protections should be explained clearly and simply to the individual completing the form. In those cases where an HRA asks for information that may violate the protections afforded by civil rights laws, questions should clearly indicate that an individual need not complete these answers to receive the incentive. In addition, guidance should make clear that any HRA must comply with and be used in a manner that complies with existing civil rights protections, such as Title VI of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the ADA (as amended by the Americans with Disabilities Amendments Act), and the Rehabilitation Act, as well as applicable State laws that provide additional protections against discrimination. This also includes, where applicable, section 1557 of the ACA which generally prohibits discrimination based on age, race, national origin, disability, and sex in federally funded activities, or by programs administered by an executive agency, or any entity established under Title I of the ACA

### *Affordability*

We also have grave concerns about the use of incentives in wellness programs that are based on whether or not a participant satisfies a specific health status standard, such as achieving a targeted body mass index or a certain cholesterol level, and thus can be used as a back door means of health status rating. While this issue is broader than just HRAs, HRAs are often a key component of such programs. Section 1201 of the ACA permits employer wellness programs to offer financial incentives worth up to 30 percent of the cost of the employee's health insurance coverage (i.e., the employee's premium plus the employer's contribution) and gives the Secretaries of HHS, Labor, and Treasury the discretion to allow incentives up to 50 percent.

In 2009, the average premium for a family plan in 2009 totaled \$13,375, which, using the 30 percent threshold, would allow employers to vary premiums by an average \$4,012.50. If the Secretaries were to

allow premiums to vary by 50 percent, families could see an average swing of \$6,688. These premium adjustments will be additive to those already allowed for age and tobacco use, and could include a range of measures including weight, blood pressure, high cholesterol, waist circumference or others. There are no specific limits in the regulations pertaining to the kinds of risk factors that may be included as long as they "have a reasonable chance of improving the health of or preventing disease in participating individuals."

Affordability becomes a critical issue when the costs of providing incentives to one group of employees is financed by raising base costs of the policies – harming in particular those who fail to qualify for the wellness incentives. This can be a significant problem for low-income individuals who may have more

than one job, manage work and family, or have limited access to healthy food or safe places to exercise. These are the individuals that need coverage the most to help them address risk factors for chronic disease and other health issues, and extensive research demonstrates that patients are far less able to manage chronic conditions such as hypertension or diabetes when their deductibles or co-payments are too high.

## **Data**

**With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non-electronic form?**

While lengthy and detailed HRAs will pose challenges in a non-electronic environment, as we move to an increasingly IT-enabled health information system such services will become significantly easier and we will be able to make great strides forward. The CDC should coordinate with the Office of the National Coordinator (ONC) and the National Quality Form (NQF) to ensure that HRA data can populate EHRs. ONC and NQF are developing a “Quality Data Set,” which, when finalized, will provide a common technological framework for defining the clinical data necessary to measure performance and accelerate improvement in patients’ quality of care. CDC should work with NQF and ONC to ensure that there will be data points that link to all questions in a model HRA, so that the data does not fall through the cracks.

**Are there standardized and certified tools available to support this data migration from multiple data entry sources?**

The CDC should refer to work being done by the Quality Alliance Steering Committee, which has been piloting data aggregation models that combine health plan, chart abstraction, and laboratory data to see how best the three sources can be aggregated.

## **Evaluation and Quality Assurance**

**How should the HRA guidance be evaluated and updated with respect to individual and population-level (practice-based panel management) health outcomes?**

HRA guidance should be evaluated and updated on a regular basis. Broadly, GAO could conduct an audit of how the program is working and CMS should specifically evaluate whether the use of HRAs in the Medicare population is leading to demonstrable improvements in health outcomes. In addition to changes indicated by such evaluations, updates should integrate advances in medical and scientific evidence about both medical and lifestyle risk factors, including by incorporating questions on new screenings and prophylactics, like vaccines. HRA guidance should also be updated to reflect national health priorities, identified by the National Prevention and Health Promotion Strategy, the National Quality Strategy and Plan, Healthy People 2020, and other similar initiatives.

In addition, as quality measures begin to reflect information gathered or impacted by HRAs, primary care practices will need assistance in assessing and improving performance through their use. Future guidance should investigate methods and opportunities for providing such assistance.

## **Conclusion**

We greatly appreciate this opportunity to contribute to the development of guidance on HRAs. As we have discussed above, HRAs can be an important tool for engaging patients/caregivers and fostering collaboration between patients/caregivers and their health care practitioners. But they can also be abused; information collected may be used to discriminate against employees in employer health and wellness programs based on health status. We look forward to working with you going forward to make sure HRAs have a positive impact on consumers.

Sincerely,  
Debra L. Ness, President

# University of California

**Recv'd 12/14/10**

Below are a few suggestions for the CDC HRA guidance document to consider.

1. Domains of risk assessment could include the following:
  - a. Medication adherence
  - b. Medication costs/insurance (eligibility and enrollment in an appropriate Medicare Part D plan and low income subsidy through social security)
  - c. Vaccination history (flu, pneumococcal)
  - d. Biometric measures (e.g., weight, blood pressure, cholesterol, HgbA1c, etc.)
  - e. Tobacco use
  - f. Falls assessment (how many falls in the last year? Any balance or gait issues)
  - g. Depression screening
  - h. Cancer screens (breast, colorectal, etc.)
  - i. Pain
  - j. Urinary incontinence/BPH
  - k. Self-assessment of current health status
  - l. Diet/nutrition
  - m. Physical activity
  - n. Perhaps specific risk assessments for certain chronic conditions (diabetes, hypertension, dementia, osteoarthritis, asthma/copd, etc.)
  - o. Many of these risk assessments could follow assessments of specific clinical practice guidelines for common conditions.
2. Health literacy should be considered, perhaps a 5<sup>th</sup> grade reading level, to facilitate understanding of the HRA among a diverse population.
3. The HRA instrument could foster shared decision-making by patient and provider by giving the patient internet links and/or printed resources/summaries of pertinent information to discuss with their providers based on answers to the HRA.
4. Individuals could access the HRA by internet, computer, mobile applications (cell phone), or telephone or paper based surveys. Multiple formats would achieve better reach and adoption. This could be in the form of computer kiosks in clinics and pharmacies at the point of care, but also by websites and portals so patients can do this at their convenience in their own home. For those who do not have a computer or internet access, telephone or paper based surveys could be used.
5. Answers to the HRA should be incorporated into the medical record, ideally by electronic means, but could also be by paper. This depends on the format of the HRA used and interoperability with EMRs.
6. Standardization of HRAs is important regarding both, what is measured and how it is integrated into clinical practice and the medical record. I don't have an answer on how to do this, but that we strive to achieve standards for doing so.
7. Use of HRA tools that have been validated would be ideal (e.g., have good sensitivity and specificity, that is they measure what they intend to measure with good accuracy and reliability but there are good tools that are available that have not been validated).

Let me know if you have any questions.

Many thanks,  
Kirby Lee

Kirby Lee, PharmD, MA, MAS  
Assistant Professor of Clinical Pharmacy

## National Kidney Foundation

*Recv'd 12/28/10*

The National Kidney Foundation (NKF), the oldest and largest organization representing kidney patients in the United States, is pleased to respond to the request for information regarding development of a health risk assessment guidance that was published in the Federal Register for November 16, 2010. The Affordable Care Act authorizes and Annual Wellness Visit for Medicare beneficiaries including a health risk assessment. In addition, the statute requires that health care assessments be designed to identify chronic diseases, and modifiable risk factors for which primary, secondary, or tertiary prevention interventions are recommended or are underway. We suggest that health care assessments address the inter-relationship between chronic diseases. This would be consistent with the DHHS Strategic Framework for Multiple Chronic Conditions.

Chronic kidney disease (CKD) is both a chronic disease as well as the complication of other chronic diseases such as hypertension, diabetes, malignancies, and heart disease. For this reason, CKD should be identified as a chronic disease for which screening is warranted as well as be identified within multiple chronic diseases as a complication for which the same screening should be performed. For example, the prevalence of chronic kidney disease (CKD) among adults who are at increased risk for CKD because of hypertension or diabetes, is considerably higher than in the general population. (Josef Coresh, et al. "Prevalence of Chronic Kidney Disease in the United States," *JAMA*, November 7, 2007). Furthermore, CKD multiplies the risk of diabetes complications and increases the complexity of caring for the patient with diabetes.

As a result of these findings, the Division of Diabetes Translation at the Centers for Disease Control and Prevention established a CKD program. In addition, NKF promulgated new practice guidelines and practice recommendations for diabetes and CKD as part of its Kidney Disease Outcomes Quality Initiative (KDOQI) program. (National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice

Recommendations for Diabetes and Chronic Kidney Disease. *American Journal of Kidney Diseases*, Vol 49, No 2 (February), 2007 (suppl 2), S 27.) Similarly, there is an independent, graded association between reductions in kidney function and the risk of death, cardiovascular events, and hospitalization. (Alan S. Go, et al. Chronic Kidney Disease and the Risks of Death, Cardiovascular Events, and Hospitalization. *New England Journal of Medicine* 351:13; September 23, 2004.). Therefore, detection and treatment of CKD should be part of a comprehensive approach to the management of diabetes and cardiovascular disease.

Speaking to the utility of screening for CKD as both a primary chronic disease as well as a complication of a multitude of other chronic diseases, there is evidence from randomized controlled trials that, for adults who are at increased risk of CKD because of hypertension and/or diabetes, interventions to slow the progression of CKD are effective. These interventions include the use of angiotensin converting enzyme inhibitors (ACEs) and angiotensin receptor blockers (ARBs), and tight control of diabetes. (See, for example, the Diabetes Control and Complications Trial, the U.K. Prospective Diabetes Study, the RENAAL trial, The Collaborative Study Group, "The Effect of Angiotensin-Converting-Enzyme Inhibition on Diabetic Nephropathy," *New England Journal of Medicine*, November 11, 1993.) The efficacy of these interventions indicate that systematic screening for CKD in adults with diabetes and/or hypertension is warranted. An analysis of a cost-effectiveness model simulating disease progression concludes that microalbuminuria screening followed by ACE/ARB treatment for those with CKD is cost-effective for persons with diabetes or hypertension. Based upon the same model microalbuminuria screening for persons with neither diabetes nor hypertension does not appear warranted from a cost-effectiveness perspective. T. J. Hoerger, et al. "A Health Policy Model of CKD: 2. The Cost-Effectiveness of Microalbuminuria Screening." *American Journal of Kidney Diseases*, Vol 55, No 3 (March), 2010, pp 463-473.

HealthMedia, Inc., a Johnson and Johnson company, provides a comprehensive, integrated suite of web-based digital health coaching programs that combine advanced proprietary technology and behavioral science to emulate the experience of a confidential live health coaching or counseling session.

The HealthMedia NCQA (HIP -1 & HIP 2) certified Health Risk Assessment (HRA) helps physicians fulfill the requirements for the new Medicare annual visit more effectively and efficiently by delivering a concise health summary. The health summary reflects where that beneficiary resides on the health continuum and assists the physician in delivering a more informed and targeted consult.

HealthMedia (HMI) has been delivering behavior change with demonstrable positive behavior outcomes for over 13 years and has a participation level of over 2 million lives with our HRA.

The HMI HRA blends behavior change science theories with nationally recognized guidelines for health and wellness to address prioritized risks based on need, want (motivation) and can (self-confidence). The HMI HRA creates a uniquely tailored plan for each Medicare beneficiary.

The HMI HRA empowers the Medicare beneficiary by identifying the appropriate behavior change and incorporating individual motivation and self-confidence into prioritized risk stratification and it identifies the Medicare beneficiary's behaviors where participants are doing well and encourages and guides positive behavior.

The HMI HRA provides the HCP and the Medicare beneficiary a one page health summary that assesses 10 key health behaviors including weight, nutrition, physical activity, tobacco, stress, symptoms of depression, insomnia, alcohol consumption, skin protection, injury prevention. Health Summary segments include- Lifestyle score, Biometrics, Behavior Prioritizations and Health Screening recommendations.

The HMI HRA can be accessed via the web, IVR or print and the information can be electronically transmitted to their medical records, integrating claims and biometric data.

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### Requested Information

#### Content and Design

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

#### **GENERIC HRA ELEMENTS:**

Weight  
Nutrition  
Physical Activity  
Tobacco  
Symptoms of depression  
Insomnia  
Alcohol consumption  
Health Screening  
Recommendations  
Skin protection  
Gender  
Personal disease  
history  
Stress  
Pain  
Women's health  
Screenings &  
immunizations  
Injury prevention  
Demographics  
Quality of life  
Quality of health  
Productivity – WPAI  
Biometrics  
Behavior Prioritizations

#### **GENERIC HRA ELEMENTS (personal disease history)**

Heart attack  
Angina  
High blood pressure  
Coronary Heart Disease  
Congestive Heart Failure  
Other Heart Disease  
Stroke  
TIA

Peripheral Vascular Disease  
Emphysema  
Chronic bronchitis  
Asthma  
Colorectal cancer  
Skin cancer  
Breast cancer  
Cervical cancer  
Prostate cancer  
High cholesterol  
High blood sugar  
Hepatitis B  
STD (sexually transmitted disease)  
Diabetes  
Metabolic Syndrome  
Obesity  
Osteoporosis  
Chronic pain  
Back pain  
Depression  
Insomnia

**DESIGN:**

The main objective of an HRA should be to gather the information needed to accurately assess health status and lifestyle behaviors and to incorporate tailored messaging to encourage a participant to change their behavior.

The HealthMedia® Health Risk Assessment is one of the only HRA's that provides maximum value for a participant by measuring and identifying health risks by epidemiological need, stage of change, motivation, self-confidence, and barriers.

In addition to assessing the generic elements above, HMI's HRA collects detailed information for modifiable lifestyle behaviors, including meeting recognized clinical guidelines; stage of change; motivation, confidence and situational barriers to change. Each behavior is scored for meeting guidelines and scores are combined to calculate an overall Lifestyle Score. Behaviors are also

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prioritized by using an algorithm that combines need – meeting guidelines, want – motivation to change and can – confidence to be able to change.

As each participant navigates through the questionnaire, question sets are dynamically changed based on individual responses to previous questions - pinpointing measures of motivation and self-confidence. As opposed to typical “skip patterns,” this method more closely mimics a health coaching session—ensuring the right understanding for each individual's need/want/can - prompting more successful behavior change action of those behaviors that most critically impact current and long term health.

The scoring methodology for each of the Succeed behaviors includes an analysis of behaviorspecific questions asked in each category.

- a. Each behavioral topic will be scored based on the degree to which the individual deviates from what is recommended for that behavior. This will serve to quantify the individual's need to change a particular behavior based on clinical guidelines.
- b. Embedded within the psychosocial assessment section of each of the behavioral areas will be an item to assess motivation, or how much the individual wants to change the behavior.
- c. Also embedded within the psychosocial assessment section of each of the behaviors will be a self-efficacy item. This item will evaluate whether or not an individual can change a given behavior.
- d. The resulting prioritized behavior list can be used to recruit participants into health coaching programs – whether it is a HealthMedia® DIGITAL HEALTH COACHING™

(Digital Health Coaching) programs or other programs. This can be done through a tailored outreach to the participant based on what was learned in the HRA. Every participant is treated individually and every engagement begins with unique, tailored feedback, down to the sentence fragment. HealthMedia identifies the participant's stage of readiness, level of motivation, confidence, and their relevant barriers and triggers and uses this information to provide meaningful, individualized guidance to start addressing the modifiable behaviors.

The plan the participant receives start with a Health Summary Dashboard – which provides the high level overview of lifestyle score, prioritized behaviors, biometrics and screenings and immunizations. Each area will have action items for the participant to follow. The plan continues to provide more detailed tailored action items designed to start the behavior change process for each of the prioritized behaviors. These are tailored to the individual based on information gathered including factors such as disease state and biometrics, using a variety of behavior change models. The plan then closes with specific action items for the participant to follow.

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The following screen example shows the behavioral change science that HealthMedia generates for each individually personalized program's tailoring:

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

Based on HMI research and current educational reporting we target the reading level at the 6th grade and it is available in both English and in Spanish.

Engaging at a group level, ethnicity is simply the most basic form of the individualized tailoring that drives the HealthMedia programs. Our tailoring technology allows us to focus on the unique aspects for each individual so we tailor not only the text but also the imagery which includes

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ethnicity, demographic, culture, gender, race and age. Included in the tailoring is health literacy that allows the end user to consider individual, ethnic and cultural factors.

Example of the actual HealthMedia Health Risk Assessment (HRA) format.

**How should the HRA instrument support shared decision-making by provider and patient?**

An HRA must be accurate in following the most up-to-date national guidelines and recommendations, such that dialogue between patient and provider begin on a common ground. Our HRA follows national guidelines for prevention, screenings and immunizations. We have on staff a full time Preventive Medicine physician to oversee all of our content and recommendations, tailored to age, gender, ethnicity and personal health history.

The information should be made available to the patient so they can share the data with their provider. Our HRA is designed to be printer friendly, such that patients can easily print their individual guide and share the information with their provider. We also have worked with health

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plans such as Kaiser Permanente, where the information from an HRA is loaded into an EMR for both patient and provider to access.

As people progress from our HRA into programs related to health conditions, these programs allocate significant portions to assessing and then working with the patient to improve their communication and relationship with their health care team, including PCP, specialists and pharmacists. For example, in our program for chronic illness self-management, in comparing selfreport baseline to 90 day follow-up, patients show significant increases in trust in their provider, better understanding and recall of their recommendations, and improved overall satisfaction with their provider. In addition, they are significantly more likely to begin actively interacting with their pharmacist and making them part of their healthcare team.

One of the many ways we achieve these results is by assessing at baseline the patient's current relationship to their PCP (collaborative, paternalistic, consumerist) and comparing it to how they would ideally like the relationship to be. We then offer information, education, tips and techniques

for improving their PCP relationship.

#### **Mode of Administration**

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

An HRA should be accessible in all the communication venues described above including nontraditional. HealthMedia's HRA can be accessed on the web through a personnel computer, at a physician's office, kiosk at a pharmacy or other healthcare facility or at the public library. Additional access to HealthMedia's HRA includes (IVR) Interactive Voice Recognition as well as print. The completed individually tailored HealthMedia HRA plan can be transmitted electronically to the patient printed, faxed or email directly to their physician. If the HRA is completed in our print form it could be faxed or mailed for processing and returned to the beneficiary with copies to their providers. The HealthMedia HRA Information can be electronically transmitted to their medical records, integrating claims and biometric data that provide the beneficiary and HCP a comprehensive view of their health.

#### **What are the cultural appropriateness factors in patient HRA access?**

As described earlier, our tailoring technology allows us to focus on the unique aspects for each individual so we tailor not only the text but also the imagery which includes ethnicity, demographic, culture, gender, race and age. Included in the tailoring is health literacy that allows the end user to consider individual, ethnic and cultural factors. The HealthMedia HRA is available via the web, IVR and print. In addition to our standard HRA we also have a short form HRA called HealthMedia® SUCCEED SNAPSHOT™ (Snapshot). The short form, Snapshot expands access beyond the web, IVR and print. Snapshot provides an additional beneficiary access point with a telephonic interface.

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#### **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?**

The office would need to have web access. The HRA would reside on the HealthMedia servers and as such there would be no maintenance required of the physician office personnel other than providing a computer with access to the internet and a printer to review the results with the patient. The data from the HRA can be integrated with EMR or PHR applications.

#### **Are training and technical assistance necessary for effective practice utilization of an HRA?**

**What entity should provide this technical assistance?**

The HMI HRA will not require technical assistance or training. The four key areas PRIORITIZED BEHAVIORS, LIFESTYLE, BIOMETRICS and SCREENING are being delivered in a clear and concise format, designed for the beneficiary and the HCP. The HCP will be able to incorporate his assessment of the bio-metrics and combined these with the HRA and his own clinical evaluation of the beneficiary.

**What are potential or demonstrated community care transition linkages— follow-up outside the office by other providers—that help patients and providers manage priority risks identified by the HRA?**

The HealthMedia HRA is only one part of a suite of integrated coaching solutions that the beneficiary can pursue. Included in the beneficiary driven HRA is a list called BEHAVIOR PRIORITIZATIONS. The beneficiary has the ability to move forward and engage a uniquely tailored program that helps them self-manage the identified behavior changes they have created through the HRA. Additionally, we continue to support the participant with tools and resources to help them support and facilitate their success. We all know that good coaches do more than teach. They listen, learn, watch, and ask questions. Then, drawing on their experience and expertise, they provide each individual with the personal guidance and tools he or she needs to reach their highest level of performance. Just one exciting tool designed to support Digital Health Coaching is HealthMedia® STEP BY STEP™, a state-of-the-art, proven goal-setting and progress-tracking tool that reinforces healthy, positive behavior changes within the Digital Health Coaching sessions. The HealthMedia® STEP BY STEP™ tracker provides a compass to a healthier life!

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In addition to the tools and resources we continue to offer support as an important part of the

ongoing success through email communications. These communications are also tailored visually to connect with the participant's unique personal characteristics and lifestyle. Links to other resources outside of HealthMedia can also be provided within the HRA and any subsequent programs.

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

The HealthMedia HRA is a scalable solution offered via the internet and therefore is available to a solo practice or virtually any size practice or practice management group. We have partners that have physician practice management offerings that have been embedded in the HealthMedia HRA and other Digital Health Coaching programs as part of their solution. The HealthMedia HRA is scalable across all communication venues, including web, IVR & print.

**Consumer/Patient Perspective**

**How could HRA data be shared with the patients for their feedback and follow up in the primary care practice?**

HRA data is shared with patients in the form of a tailored report that outlines their personal history, goals, emotional triggers, barriers, will power, beliefs, current stage of change, overall lifestyle score, biometrics and prioritized behavior risks. The personalized plan also acknowledges and encourages healthy behaviors and social support. Additionally, communications are tailored visually to connect with the patient's unique personal characteristics and lifestyle. These reports are available in PDF and can be printed and taken to the patient's next doctors visit to be reviewed with their physician.

**What role, if any, do incentives play in motivating patients to take the HRA and/or participate in follow-up interventions?**

Depending on the method of delivery, HealthMedia has found the following incentive value in correlation to HRA participation:

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HealthMedia has launched hundreds of successful incentive strategies. These strategies are capable of incorporating unique and specific population differentials. These incentive strategies can be deployed in any combination including financial, non-financial, disincentives or multiple alternative types of recruitment approaches.

HealthMedia has the capability through our Strategic Account Managers and Connect consultants to help design and build web-based incentive tracking systems specifically to meet your needs.

Our services include strategy, rules, criteria, user interface, tracking and reporting.

We offer easy-to-implement incentive solutions to drive participation. These tools include the ability for beneficiaries to complete multiple programs and receive incentives as simple as a congratulatory message that tracks their progression to a much more aligned solution that has been jointly developed for the beneficiary to deliver optimum commitment and participation.

We know what works based on our success with other health plans and employer groups from financial based incentives to a non-financial strategy.

**Incentive Facts**

Correlation between Incentive Value and HRA Participation

**Impact on Engagement**

0 20 40 60 80 100

**\$0**

**\$25**

**\$50**

**\$75**

**\$100**

**\$250**

**\$500**

**Incentive Values**

**Participation %**

Source: Deloitte Center for Health Solutions, 2009

## Data

**With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non-electronic form?**

All modes of delivery, including print, are provided electronically and are available for export through batch export or real time web services. This includes the ability to export HRA information to a Personal Health Record or Electronic Medical Record.

The resulting HRA dataset can then be forwarded either real time or in batch to other systems. Our customers have integrated the Succeed HRA data with EMR systems (Kaiser Permanente), disease management and telephonic outreach programs. Other customers are using the HRA data to triage or stratify the member and then route them to telephonic coaching services if appropriate.

**Are there standardized and certified tools available to support this data migration from multiple data entry sources?**

We employ a variety of data export and data exchange options. HealthMedia provides both a standard data extract format as well as the capability to create a customized extract based on specific customer requirements. We have interfaced with diverse environments and are conversant in Web Services, XML, and HL-7 environments.

## Certification

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

Essential elements of an HRA include:

NCQA (HIP-1, HIP -2) Certification (National Committee on Quality Assurance).

The ability to provide access to the beneficiary through multi-modal delivery capabilities (web, mobile, IVR, print).

The ability to share output and data with the HCP through Electronic Medical Records (EMR), Patient Health Records (PHR), and other electronic patient records.

Provide an individualized tailored wellness and prevention plan specifically addressing the unique needs of the Medicare beneficiary, including the beneficiaries need to change, want to change, and the belief that "I" can be successful in making a change.

Provide a tailored summary of individual wellness risk factors and recommendations for reducing those risks along with references and resources.

Provide tailored immunization and preventive screening recommendations to match national guidelines and individual factors, including age, gender, ethnicity, and personal health history.

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Be configurable, so that custom questions can be developed specifically for the needs of Medicare beneficiaries for data gathering, and identified research purposes.

Be able to provide an individual with an annual comparison or benchmark from previous HRA results.

A natural conduit for offering recipient additional programs and services to assist with lifestyle behavior change, behavioral health and medical condition self-management.

Published studies that capture clinical and financial outcomes providing the foundation and validation for an effective HRA.

Vendor must be a science driven, evidence-based organization with the ability to deliver robust aggregate reporting and the capability to partner with CDC and CMS to conduct ongoing research.

Vendor must be 508 Compliant.

Vendor must be able demonstrate capability in data security, participant consent and disclosure, with the ability to verify completion of HRA for valid reimbursement.

Vendor must have capacity to quickly revise HRA program information, recommendations and guidelines as new medical evidence emerges.

## Evaluation and Quality Assurance

**How should the HRA guidance be evaluated and updated with respect to individual and**

### **population-level (practice-based panel management) health outcomes?**

Our HRA is NCQA HIP1& HIP2 certified and follows a rigorous and regulated process for ongoing review and update. If you would like a complete description of this certification, we are happy to provide it.

All of HealthMedia Programs are reviewed on an annual basis. Specific programs are reviewed in each quarter.

Our Medical Head of Content Research, Dr. Janet Greenhut is oversees reviews of the evidence based guidelines. Updates may also be made on an as-needed or urgent basis, according to remarkable guideline developments. Specific processes are outlined as follows:

#### **Review Schedule**

o For one year prior, there is a continuous monitoring of the medical and behavioral science literature by the medical consultant and behavioral scientist to check for updates to the evidence base. Publications and sites monitored include but are not limited to the following:

- JAMA
- *Annals of Internal Medicine*

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- *New England Journal of Medicine*
- *American Journal of Preventive Medicine*
- *Archives of Internal Medicine*
- *Diabetes Care*
- *Circulation*
- *Medicine and Science in Sports and Exercise*
- *American Journal of Clinical Nutrition*
- *Obesity*
- *Chest*
- *Tobacco Control*
- *Health Psychology*
- *Annals of Behavioral Medicine*
- *Addiction*
- *Archives of General Psychiatry*
- National Guideline Clearinghouse
- Agency for Healthcare Research and Quality
- Centers for Disease Control and Prevention

o Within one month prior to planned review, a targeted literature search is done by the medical consultant and behavioral scientist to check for any changes that were missed in the informal review that relate to the program up for review. Pertinent articles and guidelines are pulled from the HealthMedia library.

o Standards and guidelines are obtained from governmental agencies and professional associations, including but not limited to the following:

- *U.S. Preventive Services Task Force*
- *Joint National Committee on Prevention, Detection, and Treatment of High Blood Pressure*
- *Adult Treatment Panel of the National Cholesterol Education Program*
- *American Diabetes Association*
- *Office of the U.S. Surgeon General*
- *USDA/USDHHS Dietary Recommendations*
- *Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention*
- *National Heart, Lung, and Blood Institute*
- *National Institute of Mental Health*
- *American Heart Association*
- *American College of Sports Medicine*

#### **Materials Review**

o At the beginning of each quarter, over a period of four weeks, the following program

materials are assessed for each program up for review. They are evaluated for accuracy, topicality, relevance, and functionality:

- Content messages
  - Graphics that contain content
  - Baseline questionnaire
  - Evaluations
- 

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- References
- Resources
- Tools

o Usability testing is done and results are documented.

o The materials are reviewed by:

- Behavioral Scientist
- Medical Consultant
- Content Developer
- Graphic Designer

o Client Services submits program feedback from customers and provides a report to the Tailored Media Group pertaining to the program up for review, including:

- Customer feedback
- User feedback

o Issues from the Defect Tracking Tool are compiled by the content reviewers and the project manager for the program up for review.

o Reviewers document recommended content changes based on literature reviews and customer requests and prioritize updates into three groups (high, medium, and low).

o Issue for programs with scoring

- Review feedback from customers and end users regarding scoring and prioritization.

- Any changes are documented.

o Recommendations are compiled into a requirements document with the input of the Product Manager.

o The requirements document is presented to the Steering Committee for comments.

o Proposed changes to the programs are reviewed and to planned for implementation.

#### **Implementation of Changes**

o Content developer is responsible for implementing changes and preliminary testing of:

- Messages in MTDs (Master Tailoring Document)
- Questions in baseline questionnaire and evaluations

o Content developer also updates references and resources as needed.

- References are updated in MTDs

o Program bibliography is updated and placed in SourceSafe.

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o Graphic designer implements design changes.

o Coders revise code where necessary.

o SQA tests changes.

o Changes are documented in a program-specific report by reviewers.

o Release notes are compiled by Director of Tailored Media and Content Developer.

o Changes to Spanish versions are implemented and tested the following quarter.

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#### **HealthMedia Background**

HealthMedia has been providing behavior change solutions since our inception in 1998. Our approach to behavior change is based on more than 30 years of academic research by HealthMedia's founder and Chief Science Officer, Dr. Vic Strecher, and his colleagues. Dr. Strecher is an industry-recognized expert and thought leader in tailored behavior change and health education. HealthMedia has successfully

deployed commercial applications of his research and methodologies for over twelve years. HealthMedia uniquely blends nine behavior change science models in our programs. These include:

- One to One Communication (Tailoring)
- Health Belief Model
- Social Learning Theory
- Transtheoretical Model (Stages of Change)
- Motivational Interviewing
- Solution-focused Therapy
- Motivation and Self-confidence Matrix
- Self-regulation Theory
- Theory of Planned Behavior

In addition to the behavior change models used above, our HRA has been validated through numerous randomized control trials and studies. In these clinical trials and studies, HealthMedia's programs have proven to:

- Provide superior behavior change outcome results;
- Reduce utilization and healthcare expense;
- Increase treatment and medication compliance; and
- Increase productivity through decreased absenteeism and presenteeism.

Full copies of our randomized control trials and studies are available upon request.

The HealthMedia programming is based on a proprietary technology engine, called "*Fusion*", the singularly powerful and effective technology available for delivering richly tailored, one-to-one, high-reach health behavior improvement programs and tailored messaging. There is no other technology like this in the market for incorporating a wide range of data plus self-reported behavioral information that leads to high levels of recruitment, individually tailored action plans and behavior change of each individual. The Fusion technology serves as the foundation for off-the-shelf programming, custom specialty solutions, tailored messaging, and external integration.

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Today, the majority of U.S. health care dollars are spent on chronic diseases.<sup>1</sup> While it is critically important to support the highest risk participants who suffer from chronic disease and represent the highest cost claims, it is equally important to help all participants stay well and remain at the low end of the risk spectrum or reverse their trend toward unhealthy behaviors. It's also critically important to recognize and address the needs of each individual which may include lifestyle behaviors, chronic conditions and mental health issues. This is what we mean by "Population Health" – the ability to provide coaching and support to every employee or member, no matter where they are on the health continuum across wellness, disease management and behavioral health.

You're thinking about providing solutions for your participants that will improve their health, right? Everybody is thinking about it. By requesting and reviewing this proposal, you are actually doing something about it. Do you want your participants to feel better? Would you like to increase their satisfaction with the programs and support you provide for them? We know that until now, there were basically two ways your participants could get help in changing their health and their lives for the better. *The first way* was through information gathering. The Web is a powerful research tool, but just knowing more doesn't really help you change what you actually do. *The second way*, working with a health coach, in person or over the phone, is more effective, but the coaches aren't always there when you need them most. That's where the HealthMedia® revolution begins. Imagine the positive impact to your organization if you could offer a high-quality health coaching solution that could effectively change behaviors for multiple health conditions and risk factors, scale to your entire population, and help maintain healthy behaviors over time. You can support and facilitate this positive change with HealthMedia® Digital Coaching™, a scalable solution for population health with proven outcomes.

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Our Digital Health Coaching produces **six** related outcomes. First, we can get **substantial participation rates** in coaching. Next, because we carefully emulate what a health counselor or coach does, we can get the **desired behavior change**. The behavior change then impacts the other four outcomes: **prevalence rates, projected productivity increases, medical cost reduction, and user satisfaction**. We strive in all cases to show our customers each of these six outcomes for every program we implement for them. Whether it is losing weight, reducing binge eating, getting more sleep, reducing depression

symptoms, lowering A1C levels, reducing blood pressure or chronic pain symptoms, the outcomes reported by our participants speak volumes:

Participants reported a 90% improvement in their ability to improve back pain  
88% of participants reported improvements in doctor-patient communications and 86% said their health improved

70% of participants reported improvements in medication adherence

60% of participants reported reduced stress

39% decrease in average Center for Epidemiologic Studies Depression Scale (CES-D) scores from 5.29 to 3.24

50% of participants reported they lost weight

60% of participants reported they improved their nutrition habits

40% decrease in difficulty falling asleep ratings

\$1,000 demonstrated projected productivity savings for participants with chronic conditions (per participant, per year)

### **Succeed Health Risk Assessment**

*Over 50% of premature death and disease is caused by unhealthy behaviors that can be changed.*

*Learning to make healthy lifestyle choices is a key to living a longer, healthier, happier life. 2*

**HealthMedia® SUCCEED®**, an NCQA certified health behavior assessment and care plan, will introduce you to the relationship between your behavior and your health. The program will begin by assessing your health-related behaviors such as nutrition, weight, physical activity, stress, and skin protection. According to your unique makeup, a

2 McGinnis JM, Foege WH: **Actual causes of death in the United States.** *JAMA* 1993, **270**:2207-2212

customized action plan will be created just for you. The plan will recommend healthy behavior choices and offer guidance and support toward making positive lifestyle changes.

**HealthMedia® Teen Succeed™** - is a comprehensive health program that extensively counsels 13 to 19-year-olds on health issues such as tobacco, alcohol, drug use, nutrition, weight management, eating disorders, physical activity, health care, sex, relationships, violence, stress, depression, suicide and safety.

**HealthMedia® Succeed Snapshot®**: Having a participant engage in Succeed is the ideal situation for all parties involved. However, for employers and health plans struggling to get their population to participate in an online HRA due to lack of time or internet access, we are pleased to offer HealthMedia® Succeed Snapshot™! Although Succeed Snapshot does not provide the same level of depth and insight as its parent version, it does provide a condensed format that captures basic information and is quick and easy to deliver.

Ten reasons why our Succeed Health Risk Assessment is one of the best HRA's in the industry:

1. **Succeed** produces a tailored plan to help individuals successfully change behaviors that contribute to health risks and reduce productivity.
2. **Succeed** is based on need to change, want to change, and the individual's belief that "I" can be successful in making change, as opposed to epidemiological need, resulting in greater likelihood that participants will achieve successful behavior change.
3. **Succeed** has been the focus of two published studies proving that it builds the foundation for producing a positive ROI.
4. **Succeed** received a high score from NCQA's certification process.
5. **Succeed** is fortified by the most comprehensive tool set in the industry including a recipe library, exercise library, medical library.
6. **Succeed** has built-in validated productivity metrics and has a productivity dashboard that allows customers to understand the relationship between health risks and productivity impairment within their populations.
7. **Succeed** has been successfully integrated with EMRs, PHRs, and other electronic patient records, and can use data from biometric screening, claims, etc. to pre-populate and tailor HRA responses.
8. **Succeed** is fully configurable to match the needs of any specific client.

9. **Succeed** has the very best reporting package, including an Executive Summary Report, Productivity Dashboard, multi-dimensional data visualizer, and standard Power Point outcomes presentation for maximum reporting value.

10. **Succeed** provides a full Intelligent Recruitment data set for driving participation in other HealthMedia or client programs, including need, stage of change, motivation, self-confidence, and barriers to each health risk.

### **Digital Coaching**

#### **The Digital Coaching Framework**

HealthMedia® Digital Coaching™ programs emulate a live coaching or counseling session. They combine proprietary information technology with advanced behavioral science to deliver highly personalized plans and advice that address each individual's personal motivations, confidence level and barriers to success. The programs are so highly personalized that no two coaching plans will ever be the same, just as no two individuals

**Recv'd 1/3/11**



AHIP Comments to  
CDC - CMS Guidance

## **URAC**

**Recv'd 1/3/11**

This letter comments on the Request for Information (RFI) published in the *Federal Register* on November 16 concerning the development of guidance for health risk assessments (HRAs). These comments are offered on behalf of URAC, an independent, nonprofit organization promoting health care quality through accreditation, education and measurement programs. URAC accreditation is recognized by 46 states, the District of Columbia and five federal agencies, including the Centers for Medicare and Medicaid Services (CMS).

In 2010, URAC worked with an industry-spanning expert advisory group to develop its Patient Centered Health Care Home (PCHCH) Program Toolkit, providing health care practices with a step-wise roadmap and standards for implementing a patientcentered model of care. The PCHCH Program Toolkit is based on a set of principles governing the provision of patient centered care and function as a resource to help health plans and providers evaluate the patient-centeredness of their networks and

practices, respectively. The principles include a strong focus on wellness and prevention, with the overall goal of maintaining patient health.

The wellness and health promotion standards are excerpted below as a resource to assist the CDC in the development of guidance for HRAs conducted as part of the Medicare Wellness Visit. URAC also offers accreditation standards and measures for commercial wellness organizations that may help to inform more broadly applicable HRA guidance.

#### **Wellness and Health Promotion Standards for Health Care Practices**

URAC's Patient Centered Health Care Home (PCHCH) Program Toolkit includes eight standards, shown below, specific to wellness and health promotion within the health care practice setting. The standards are not prescriptive on the mode of administration or content for annual HRAs, but rather emphasize a process built on: Open communication with the patient about the use of HRA information;

1220 L STREET NW, SUITE 400 – WASHINGTON, D.C. 20005 – PHONE (202) 216-9010 – FAX (202) 216-9006 – [www.URAC.org](http://www.URAC.org)

Annual assessment of risk factors relevant to the target population's physical and behavioral health;

Evidence-based preventive care guidelines;

Patient education; and

The development of an individualized plan of care to address any specific risk factors identified through the HRA.

URAC's PCHCH Program Toolkit provides a framework for effective implementation of an HRA process as part of a patient centered model of care. The toolkit is available at

[www.urac.org](http://www.urac.org) to health care practices both within and outside of the Medicare program that seek to implement an HRA process for their patients.

### **URAC PCHCH Program Toolkit Wellness and Health Promotion Standards with Interpretive Commentary**

© URAC 2010

The goal of the following standards is to ensure patients receive all appropriate wellness and preventive services, utilizing screening, active counseling, and outreach efforts to inform and educate patients about the value of preventive care.

#### **Standard WHP-1: Promoting Wellness**

The Practice is proactive in promoting wellness and preventive care, which includes:

- (a) Use of health assessment tools; and
- (b) Information about lifestyle changes and risk factors.

#### **Interpretive Information/Points to Remember**

The annual completion of a health assessment tool is an important component of wellness and preventive care. It identifies patients' health risks, allowing them to be proactive in making lifestyle changes and seeking appropriate care.

For more information, refer to the U.S. Preventive Services Task Force (USPSTF) for additional information and recommendations on clinical preventive services (available at: [www.ahrq.gov/uspstfix.htm](http://www.ahrq.gov/uspstfix.htm)).

The Practice has the ability to provide wellness services, which include preventive services.

- o The health assessment process is intended to aid the Practice in evaluating its population. A comprehensive health risk assessment (HRA) is one of the basic tools the Practice can consider using to evaluate the patient population. The process will identify all risk types and risk factors associated with the target population.
- o For example, a program designed across all risk-types should include comprehensive questions about relevant risk factors, family history, health status indicators and condition/disease states that could affect the target population's physical and behavioral health (e.g., cardiac health, tobacco cessation, depression, weight management).

#### **Standard WHP-2: Wellness and Prevention Services**

1220 L STREET NW, SUITE 400 – WASHINGTON, D.C. 20005 – PHONE (202) 216-9010 – FAX (202) 216-9006 – [www.URAC.org](http://www.URAC.org)

The Practice has standing wellness and preventive services order protocols and ensures:

- (a) All patients receive appropriate wellness and preventive care information about:
  - (i) Personal health lifestyle behaviors; and
  - (ii) Reducing risk of disease and injury;
- (b) All patients receive appropriate well care visits and preventive screenings; and
- (c) Practice care team members are allowed to authorize and deliver preventive services according to clinician-approved protocols without examination by a clinician.

#### **Interpretive Information/Points to Remember**

The Practice has a process in place to provide wellness and preventive information to its patients. For example:

- o Practice can provide wellness and preventive educational brochures, appropriate Web sites (if patient has access), etc.
- o This information may be provided to patients via phone, mail, fax, email, a Website,

or other communications modality, or a combination thereof.

o This can also include paper/hardcopy materials, online information, or mass communication approaches.

The Practice has standing orders for well care visits or health screenings which may include, but are not limited to, basic biometric data collection, such as blood pressure, heart rate, weight, and height. Additional risk factor measures are also acceptable (e.g., cholesterol; family and medical history, etc.).

Refer to the PCHCH Program Toolkit's Health Literacy standard for more information related to using appropriate language and literacy level when communicating with patients.

For additional information, refer to the following:

o Centers for Disease Control (CDC; [www.cdc.gov](http://www.cdc.gov)) for information regarding wellness and preventive guidelines and information regarding primary, secondary and tertiary prevention.

o U.S. Preventive Services Task Force (USPSTF) for additional information and recommendations on clinical preventive services. (available at: [www.ahrq.gov/uspstfix.htm](http://www.ahrq.gov/uspstfix.htm))

o Guide to Community Preventive Services, also available through the CDC ([www.thecommunityguide.org](http://www.thecommunityguide.org))

Standard WHP-3: Comprehensive Health Risk Assessment

The Practice conducts a baseline comprehensive health risk assessment for all patients to help identify health risks and needs as a foundation for establishing an individualized plan of care.

Interpretive Information/Points to Remember

A health risk assessment is a critical first step in engaging and assessing risk and health status in a target population. At a minimum, the assessment should be tailored to the program's purpose and patient risk-type(s). For example, an assessment designed across all risk-types should include questions that are comprehensive of relevant risk factors, health status indicators and condition/disease states that could affect the target

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population's physical and behavioral health (e.g., cardiac health, tobacco cessation, depression, weight management).

A health risk assessment may be administered electronically (including online), in written form, or verbally. If administered verbally the results should be captured on paper or electronically for use in analysis, reporting, and record keeping.

Note: The Practice can design its own assessment toolkit or use an existing toolkit.

However, the assessment and questions contained within it should be based on sound peer-reviewed research and clinical evidence that is academically credible. It is not the intention of URAC to limit or constrain a Practice's development of a health risk assessment tool. One tool will not be favored over another, nor will any particular research set be viewed as more relevant. Instead, it will be the responsibility of the Practice to provide URAC with appropriate evidence and rationale behind their choices in using a particular strategy or research set.

If the Practice provides care for pediatric patients, it assesses these patients with the appropriate pediatric assessment tool. This includes a tool incorporating the appropriate guidelines for behaviors and age specific development guidelines addressing all age groups served by the Practice. Practice may use checklists and conduct anticipatory evaluation/guidance.

In addition, the HRA is to be comprehensive; for instance, the Framingham risk score would complement an additional HRA.

Standard WHP-4: Wellness Information and Materials

The Practice provides information and/or materials about wellness and health promotion to its patients, which:

(a) Are evidence-based;

(b) Inform and educate patient/caregiver about how the wellness services works;

(c) Describe the benefits, the potential outcomes, and the interventions associated with the wellness program;

(d) Are accessible and available to patients through multiple formats; and

(e) Supports patient advocacy and empowerment.

Interpretive Information/Points to Remember

Practice has protocols in place based on evidence-based medicine for preventive care and management of risk factors providing standing order guidance for practitioners.

Standard WHP-5: Documentation of Resources

The Practice documents educational resources provided to individual patients.

Interpretive Information/Points to Remember

The Practice has a process in place to document educational information for individual patients.

Standard WHP-6: Secondary Prevention Program

The Practice has secondary prevention programs in place to identify and treat both symptomatic and asymptomatic persons who have already developed risk factors or preclinical disease, but in whom the disease itself has not become fully clinically established.

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Interpretive Information/Points to Remember

The Practice has secondary prevention programs in place to utilize biometric screening and other screening results.

The Practice reviews the health screening information with the patient and documents the appropriate information in the patient's health record.

Standard WHP-7: Collection of Wellness-Related Health Encounter Patient Data

The Practice has a process in place to:

(a) Disclose to the patient the purpose(s) and use of all data collected and used during the wellness assessment process; and

(b) Inquire about a patient's outside wellness-related health encounters and has the capability to incorporate information in a patient tracking system registry or medical record.

Interpretive Information/Points to Remember

The Practice's process for collecting health encounter information may include asking patients questions regarding immunizations they may have received at their local supermarket or community pharmacy, such as the flu shot, H1N1 shot, etc.

Patients' record should be updated with appropriate information. The Practice's registry may also be updated if applicable.

Standard WHP-8: Patient Reminders

The Practice sends reminders to appropriate patients:

(a) For relevant preventive care;

(b) Who did not schedule appropriate care within a specified timeframe, and

(c) Who were previously contacted by a PCHCH team member.

Interpretive Information/Points to Remember

The Practice has a process in place to appropriately remind patients about wellness and preventive visits. Examples may include:

o Tracking system.

o Log of reminders.

o Workflow based on encounter data.

### **Commercial Wellness Standards**

The criteria and measures presented above are drawn from URAC's research and expert advisory group input in developing its PCHCH Program Toolkit. As a leading health care accreditation organization, URAC also offers standards and performance measures applicable to commercially offered comprehensive wellness programs. Twelve wellness organizations serving employers nationwide currently hold the distinction of URAC Comprehensive Wellness Accreditation.

This year, URAC accredited wellness organizations began reporting to URAC on a set of program-specific performance measures.

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The following URAC Comprehensive Wellness Accreditation standards are particularly instructive to two issues raised by the RFI: the content and design of HRAs and the consumer/patient perspective.

### **URAC Comprehensive Wellness Accreditation Standards**

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#### **Wellness Standard 3 - Health Risk Assessment Process**

- (a) Identifies, at an individual level, the risk types and risk factors present in the target population;
- (b) Defines the method of evaluation for inclusion of participants;
- (c) Is linked to the wellness program's interventions;
- (d) Encompasses, at a minimum, all risk-types relevant to the wellness program(s);
- (e) Collects information about the risk factors associated with the relevant risk-types;
- (f) Is evidence-based; and
- (g) Is approved by the wellness organization's senior clinical officer, clinical advisor, or clinical oversight body as appropriate.

#### **Wellness Standard 4 - Health Risk Assessment Tool**

As part of the health risk assessment process, the wellness organization provides a health risk assessment tool that:

- (a) Encompasses, at a minimum, all risk-types relevant to the wellness program(s);
- (b) Collects information about the risk factors associated with the relevant risk-types;
- (c) Is evidence-based;
- (d) Is approved by the wellness organization's senior clinical officer, clinical advisor, or clinical oversight body as appropriate;
- (e) Reports to the individual participant an overall health risk assessment tool score; and
- (f) Utilizes biometric screening and other screening results.

#### **Wellness Standard 7 - Individual Participant Assessment**

The wellness organization has a process to:

- (a) Conduct and document an individualized assessment of each program participant;
- (b) Make available to each participant individualized feedback that is relevant to the participant's risk factors; and
- (c) Disclose to the participant the purpose(s) and use of all data collected and used during the assessment process.

#### **Wellness Standard 10 - Review of HRA Tool**

The wellness organization:

- (a) Has an on-going process that modifies the health risk assessment tool in response to a significant change in the evidence or in evidence-based guidelines and
- (b) At a minimum, every two years, formally reviews the health risk assessment tool and the scientific evidence upon which the tool is based.

#### **Wellness Standard 21 - Dissemination of Participant's Assessment Results**

The wellness organization provides a participant's assessment process results:

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- (a) To the participant and
- (b) Upon request by the participant, provide a summary of the health risk assessment to the participant which can be shared with the participating provider.

#### **Wellness Standard 22 - Information Regarding Other Resources and Providers**

The wellness organization has a policy and procedure to provide information to participants who:

- (a) May benefit from other potentially available internal resource programs offered by the purchaser and
- (b) Need care from a provider within the external health care system.

URAC is pleased to provide further information on our commercial accreditation program as CDC develops more broadly applicable guidance for HRAs offered to privately insured patients. URAC appreciates the opportunity to provide input to the CDC on standards for HRAs, and looks forward to an ongoing dialogue with the CDC and CMS through the implementation of the Medicare Wellness Visit. If we can answer any questions about URAC accreditation or our

PCHCH Toolkits, please feel free to contact Michele Johnson, Director of Federal Relations at [mjohnson@urac.org](mailto:mjohnson@urac.org) or by calling (202) 962-8835. Thank you for your consideration.

## The Solutions Group

### **Recv'd 11/17/10**

Our company is a wellness provider for businesses throughout the state of New Mexico. We have used three HRAs over the past 10 year. Our first experience was with Summex which was eventually bought by WebMD. The product was nice, reliable and easy to use though we constantly received feedback that the reports were negative. We had one year of experience with the Wellsorce HRA. This HRA was not very successful as the forms were tedious and the reports had some unnecessary information. We currently use the University of Michigan Health Management Resource Center's HRA. This is by far the best HRA I have seen. The process and the reports are simple and straight forward. It shows the individual what they are doing well and where they need to improve.

Thank you for your time,

Liz Chavez

Wellness Program Manager

(505)254-3555

**The Solutions Group**

## U.S. Chamber of Commerce

### **Recv'd 1/3/11**

The U.S. Chamber of Commerce (the "Chamber") is submitting these comments in response to the Development of Health Risk Assessment Guidance ("Guidance" or "RFI") and the Notice of Public Meeting ("Public Forum Notice"), which were published in the Federal Register on November 16, 2010 and December 30, 2010, respectively.<sup>1</sup> In issuing the Guidance and Public Forum Notice ("Publications"), the Centers for Disease Control and Prevention (CDC) is seeking public comment on the development of Guidance concerning Health Risk Assessments (HRAs), in accordance with the requirement in the Patient Protection and Affordable Care Act (PPACA) that a health risk assessment be included in the annual wellness visit benefit authorized for Medicare beneficiaries.<sup>2</sup>

The Chamber is the world's largest business federation, representing the interests of more than three million businesses and organizations of every size, sector and region, with substantial membership in all 50 states. These comments have been developed with the input of member companies with an interest in improving the healthcare system.

### **Employer Flexibility in Developing Health Risk Assessments is Critical**

As acknowledged by the Publications,<sup>3</sup> employers and group health plans currently offer health risk assessments (HRAs) to promote awareness, provide health screening, and to help employees identify and manage health risk factors. Private plan HRAs can serve to inform beneficiaries or

<sup>1</sup> Development of Health Risk Assessment Guidance, 75 Fed. Reg. 70009-10 (November 16, 2010) [hereinafter Guidance or RFI]; Development of Health Risk Assessment Guidance, Public Forum, 75 Fed. Reg. 82400-82402

(December 30, 2010) [hereinafter Public Forum Notice].

<sup>2</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 4103, 124 Stat. 119 (2010), amended by

Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2301(a), 124 Stat. 1029 (2010);

Guidance, 75 Fed. Reg. at 70009. “This guidance is also intended to be useful for HRAs conducted in other patient populations..., including those persons covered by employer healthcare plans.”

3 Guidance, 75 Fed. Reg. at 70009. “This guidance is also intended to be useful for HRAs conducted in other patient populations..., including those persons covered by employer healthcare plans.”

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employees about the disease management programs and help employers or vendors to appropriately tailor such programs to the needs of its recipients. HRAs have become integral tools in strategies for identifying those in need of preventive or condition management programs, and directing them to the health services they may need.

As the Publications and the PPACA also recognize, HRAs are invaluable tools. Many of the leading causes of disability and premature death in the United States are potentially avoidable or controllable, including most injuries, many serious acute and chronic conditions, many forms of heart disease, and some cancers. Because important risk factors are controllable, often simply by modifying health habits, behavioral changes can improve health and productivity. Early illness detection can simplify treatment and increase chances for a complete recovery.<sup>4</sup>

The focus of many employer-sponsored programs has evolved from simply maintaining general health and well-being to proactively identifying, managing or reducing specific health risks. Well-conceived health and wellness programs that focus on prevention, self-care, risk factor reduction, and disease management can produce substantial benefits for employers and their employees. These strategically designed programs can reduce both direct and indirect healthcare costs.<sup>5</sup> Beyond financial benefits, these programs permit companies to differentiate themselves from competitors by increasing productivity, cutting costs, and establishing a healthier work environment. These improvements are valued by current and prospective employees.<sup>6</sup> Health and wellness programs are not only appreciated by employees, they have proven successful at reducing healthcare costs.

While PPACA looks to expand HRA availability to the Medicare population, we urge the CDC to refrain from placing any restrictions on HRAs offered in the private plan or employersponsored healthcare spheres. Although, as the Guidance noted, “there is considerable variation in available HRAs with the majority of assessments created to support employer health and wellness programs,” we believe this variation must be permitted to continue. Flexibility is critical and the Statute does not contemplate restricting this variation in HRAs offered in the private plan or employer-sponsored healthcare spheres.

#### **Statutory Language Is Clear**

As the Guidance and Public Forum Notice state, Section 4103 of PPACA requires that a health risk assessment be included in the annual wellness visit benefit authorized for **Medicare beneficiaries** under the PPACA.<sup>7</sup> We appreciate the recognition by these Publications that

<sup>4</sup> See Partnership for Prevention, “Healthy Workforce 2010.” Available at

[http://www.prevent.org/images/stories/Files/publications/Healthy\\_Workforce\\_2010.pdf](http://www.prevent.org/images/stories/Files/publications/Healthy_Workforce_2010.pdf).

<sup>5</sup> See Ronald Ozminkowski, et al. “Long-Term Impact of Johnson & Johnson’s Health & Wellness Program on

Health Care Utilization and Expenditures,” *Journal of Occupational and Environmental Medicine*, Vol. 44, No. 1,

pp. 21-29 (Jan. 2002). Johnson & Johnson has administered wellness initiatives since 1979, and the present Health

and Wellness Services offering, which began in 1995, includes occupational health and wellness, employee

assistance and disability management professionals. The company administers HRAs to employees and offers

assistance to deal with problem areas. Benchmarks and goals aim to reduce smoking/tobacco use, high blood

pressure, cholesterol and inactivity. The results of the program include savings of more than \$38 million from 1995-

1999, about \$9.10 - \$9.43 million per year; overall savings per employee per year of \$225; 90 percent participation of eligible employees (approx. 43,000) in the HRA or intervention programs; and reduction in medical utilization

(\$3.96 million) and administrative expenses (\$5.22 million).

6 Edelman, "Finding Wealth Through Wellness: How Engaging Employees in Preventive Care Can Reduce Healthcare

Costs," Fall 2006. *Available at*

[http://www.edelman.com/image/insights/content/Wellness\\_White\\_Paper.pdf](http://www.edelman.com/image/insights/content/Wellness_White_Paper.pdf).

7 Guidance, 75 Fed. Reg. at 70009. (emphasis added)

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employer-sponsored healthcare plans and healthcare insurers often offer Health Risk Assessments. However, we respectfully remind the CDC, as it develops HRA Guidance, that Section 4103 only amends Section 1861 of the Social Security Act; it does not amend the Public Health Services Act or the Employee Retirement Income Security Act. HRA guidelines pursuant to PPACA Section 4103 are only to be applicable to Medicare coverage and beneficiaries.

We respectfully register this point because of our concern raised by the following provisions in the publications:

"This guidance is also intended to be *useful for HRAs conducted in other patient populations such as privately insured populations, including those persons covered by employer healthcare plans.*"<sup>8</sup>

"Currently there is considerable variation in available HRAs, with the majority of assessments created to support employer-based health and wellness programs. Several instruments have been created for use in research and are not available in the marketplace; and the scientific rigor of HRA tools is not always evident. Therefore, the *development of HRA guidance is essential* for effective implementation of this part of the Medicare wellness visit and *to support broader HRA use within primary care.*"<sup>9</sup>

While it is possible that Guidance may be "useful" to HRAs conducted in other patient populations, the PPACA provision to which these publications relate is clear: HRA Guidance established by the Secretary (of HHS) applies to HRAs for Medicare beneficiaries. As such, this should not be construed as an opportunity to further regulate or dictate employer plans on how or if Health Risk Assessments are incorporated or offered.

### **Conclusion**

We appreciate the opportunity to comment on the Guidance and Public Forum Notice and applaud the CDC's efforts to solicit broad input on the development of HRA Guidance, a tool that the employer community has utilized effectively for years. We are happy to discuss any of our comments informally, or by way of testimony. However, we remain concerned that in developing this HRA Guidance for Medicare beneficiaries, the Secretary and the CDC will disrupt and restrict private plan and employer healthcare plan practices and innovation in an attempt to standardize "broader HRA use."<sup>10</sup> We look forward to working with you to protect the fundamental goals of health reform that we jointly support.

## **American College of Cardiology**

***Recv'd 1/3/11***

The American College of Cardiology (ACC) is pleased to submit comments to the Centers for Disease Control and Prevention (CDC) on the development of guidance concerning Health Risk Assessments (HRAs). The College is a 39,000-member nonprofit medical society composed of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The ACC is a leader in the formulation of health policy, standards and guidelines, and is a staunch

supporter of cardiovascular research. The College provides professional education and operates national registries for the measurement and improvement of quality care. We appreciate the opportunity to comment on the notice of development of guidance concerning HRAs as required by the Affordable Care Act for inclusion in the annual wellness visit benefit authorized for Medicare beneficiaries.

### **General concerns**

While there is currently no clear definition of an HRA, CDC defines it as a tool used to evaluate an individual's health. It could include a survey or questionnaire, physical examination or laboratory tests resulting in a profile of individual health risks often with accompanying advice or strategies to reduce risks. Even this definition is fairly vague and non-descript. As such, the ACC recommends that the CDC more clearly and narrowly define what is meant by an HRA and what it is intended to address. With such a broad definition, the list of potential questions is too lengthy to be of use. The College believes it is unrealistic to create one document that will be able to address all possible health risks across an individual's entire lifespan. It would be next to impossible to create a single comprehensive tool that could serve patients of all ages to detect all possible health risks – from smoking to not wearing seat belts, from checking cholesterol to PAP smears, from driving drunk to eating too much salt and more.

Instead, the College recommends that more specialized and focused screening assessment tools be created. In this way, questionnaires can be developed to target specific populations by age, cultural appropriateness and risk factors. For instance, as part of the Pediatric Cardiovascular Risk Reduction Initiative sponsored by the National Heart, Lung and Blood Institute (NHLBI), age-appropriate screening guidelines for all cardiovascular risk factors were developed and graded based on the available scientific evidence. These guidelines will be released in early 2011 and will be useful in developing age-related HRAs. Such an approach would also allow for the creation of an HRA both useful for and manageable by Medicare patients. A complex and cumbersome document might be too difficult for Medicare patients and too time-consuming for physicians to administer to them.

It would also be helpful if the CDC were to more narrowly define the purpose of the HRA.

Would it be trying to ascertain disease risk? Event risk? Risk for factors that predispose an individual to a particular disease? What is the time frame of prediction (current risk, five years, 10 years, lifetime, etc.)? Additionally, it is critical that the CDC determine what is to be done with the information. Is the intention that the results be informational only, or should they be actionable? If they should be actionable, by whom should they be actionable and for what purpose? Without the answers to these questions, it is difficult to make more specific recommendations regarding content and structure.

As the CDC develops the HRA, the ACC also encourages the Agency to consider the ability of the health care system to address risks as they are identified. It is critical that the infrastructure be in place before action can be taken to address those risks. Thus, the CDC must work with other components of the Department of Health and Human Services (HHS) and Congress to ensure that the appropriate incentives are in place to increase the size of the healthcare workforce. It is widely recognized that this country faces a shortage of physicians and other clinicians in the coming years. A nursing shortage already exists, as does a shortage of primary care physicians. Cardiologists are not far behind. Identifying risks that the health care system is not capable to deal with is dangerous. The ACC urges CDC and the other agencies within HHS to work to ensure that patients will be able to receive the services identified through HRAs.

Of course, the ultimate purpose of an HRA is to improve health outcomes. While a universal instrument in some form would be desirable, an individualized instrument is critical to identifying key risk factors for each patient. Given that people are unique, they will possess a varied set of risk factors, regardless of age, gender or background. Thus, the ACC recommends that the instrument be adaptable and scenario-driven, rather than a static document.

### **Content and Design**

#### *Risk assessment domains*

As discussed above, the ACC believes that it would be difficult to create one document to address all ages and populations. Instead, the College would support the creation of more focused risk assessments. For instance, cardiovascular risk tends to increase with age. Thus, it would be beneficial to increase the number of questions focusing on cardiovascular risk on HRAs for those patients approaching middle age and beyond. That said, it is important to be aware of certain cardiovascular risk factors, such as weight and tobacco usage at earlier ages, given the evidence that childhood obesity and tobacco usage early in life can play a role in long-term cardiovascular health.

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### **Mode of Administration**

#### *Access to HRA*

How individuals access HRAs will vary based on the medical practice and setting. While a few physicians' offices might have the resources to install kiosks in the offices that would allow patients to complete the HRA electronically, far more will rely on a paper-based form. Many physician practices have websites and request that patients complete certain forms in advance of their visit. Those practices will likely add the HRA to that list of forms. Most physician practices simply do not have the resources to create an electronic program that is scenario-driven and adaptable to specific populations. Instead, it is more likely that the practice will either rely on a standard HRA or create HRAs focused on specific populations and refer patients to the

#### *appropriate one. Cultural appropriateness in HRA access*

It is critical to recognize that certain populations may need to be furnished with alternative mechanisms for completing HRAs. For instance, elderly patients are traditionally less comfortable with technology. Thus, if there is an electronic-based HRA, physician practices may either need to assist patients with them or provide an alternative method of completion. In rural and small practices, accessing the Internet may be more difficult or impossible, so an Internet based approach may not be appropriate for those practices.

### **Primary Care Office Capacity**

#### *Support to utilize results*

While the notice asks for feedback regarding primary office capacity to utilize HRA data effectively, it is important to recognize that for some patients, a specialist might actually be functioning as the medical home and coordinating all of their care. Given this, specialists will also need to have the appropriate resources to utilize the data for personalized prevention planning. These resources include additional clinical personnel, such as nurses, physician assistants and nurse practitioners to provide services that may not require the direct involvement of a physician. This means that additional funding may be needed to pay for services that are not traditionally paid for.

#### *Training and technical assistance*

Effective practice utilization of an HRA will require technical assistance and training. For those risks identified through the HRA, physicians and clinical support personnel must ensure that they are properly educated on the risk factors covered in the HRA and how to create prevention plans for the various diseases and conditions. This education should be incorporated into medical school and residency training programs, as well as the appropriate medical board examinations. For physicians and clinical support personnel already in practice, continuing medical education programs should be created. Additionally, the Agency for Healthcare Research and Quality has created a number of tools focusing on prevention. Bringing those tools, as well as others created as needed, together and distributing them to physicians would also be beneficial.

### **Consumer/Patient Perspective**

#### *Data sharing*

It is crucial that patients understand the risks to their health and how they can act to prevent the onset of diseases, such as diabetes, before they occur. Given this, physicians or other clinical personnel should review the results of HRAs on an individual basis with their patients and work with the patients to schedule appropriate follow-up care. However, in the current payment environment, physicians do not have the time to conduct individual or group patient education sessions. Thus, the ACC urges CDC to work with the other components of HHS to develop methods of reimbursing physicians for these necessary services.

Another method of sharing this information with patients is through prepared materials that

discuss the different diseases or conditions identified as part of the risk assessment. The ACC has a patient-facing website, [cardiosmart.org](http://cardiosmart.org), aimed at educating patients regarding cardiovascular diseases and conditions. Widespread distribution of educational materials can help patients better understand the risks that they face. Additionally, these materials can be the basis of group educational sessions held by state agencies, nursing homes and others whose focus it is to improve the public health.

#### **Data**

##### *Use of health IT for HRA*

Given that it is unlikely that HRAs will be administered electronically, it will be administratively burdensome to incorporate the HRA data into an electronic health record (EHR). The easiest method of adding the information is using a scanner; however, then the HRA becomes an attachment to the record, rather than the data being incorporated into the record. Manually entering the data into the appropriate fields would be administratively burdensome and would require additional staff whose sole purpose would be to enter the HRA data. However, if the data is not truly incorporated into the medical record, it is also more difficult to ensure that the physician's office acts upon the information. The ACC urges CDC to create an HRA that requires limited additional resources to incorporate into the medical record.

#### **Conclusion**

The ACC appreciates the opportunity provide these comment to the CDC on the development of HRAs and looks forward to working with the CDC on this and future related issues. Please direct any questions or concerns to Lisa P. Goldstein at (202) 375-6527 or [lgoldstein@acc.org](mailto:lgoldstein@acc.org).

Sincerely,

Ralph G. Brindis, M.D., M.P.H., F.A.C.C.

## **WorkWell, Inc.**

***Recv'd 1/3/11***

Please accept our comments on the HRA that was developed within our department:

The LiveWell Survey is a health risk appraisal developed by the Nebraska Department of Health and Human Services and WorkWell, Inc. Beta tested for three and a half years, it is in alignment with the Behavioral Risk Factor Surveillance System (targeting identical questions in some of the risk areas) and allows for benchmarking against local, state, and national normative data. While the survey was created for use in a business setting, simple modifications could be made for use in the Medicare/Medicaid setting. The survey has built in skip patterns to account for age and gender, as well as field restrictions to minimize error. The LiveWell Survey is available in both English and Spanish.

Dan Cillessen MSW Administrator  
Public Health Promotion

## **HIV Prevention Action Coalition**

***Recv'd 1/3/11***

On behalf of HIV Prevention Action Coalition (HPAC) and the HIV Testing Reimbursement Subcommittee of the HIV Health Care Access Working Group (HCAWG), the undersigned organizations are pleased to comment on the above-referenced request for information. We understand that this guidance is also intended to inform Health Risk Assessments (HRA) conducted in other patient populations such as privately insured populations, including those persons covered by employer healthcare plans. We agree that the development of such guidance is essential for effective implementation of this part of the Medicare wellness visit and to support adoption of HRAs within primary care. We offer comments below

on questions particularly relevant to preventing the transmission of HIV and other sexually transmitted infections.

## CONTENT AND DESIGN

*What are generic elements of any HRA and what elements must be tailored to specific populations, particularly those stratified by age?*

We strongly urge inclusion of sexual health and substance or drug use history as a routine part of the initial assessment and annual review for each Medicare beneficiary. For preventive care to be comprehensive, it must include a thorough assessment of an individual's risk factors, to the extent they are known, for HIV and other sexually transmitted infections. Undiagnosed and late diagnosed HIV/AIDS, viral hepatitis, and other STDs impose health and economic consequences of enormous proportions, partly due to the fact that STD-related risk assessment and counseling are not routinely performed by most primary care clinicians.<sup>1</sup> The health risk assessment component of the annual wellness visit provides a prime opportunity to reduce the harms associated with these diseases.

The U.S. Preventative Services task Force (USPSTF) recommends high-intensity behavioral counseling for all sexually active adolescents and for adults at increased risk for STDs and HIV. Older Americans are not immune from risk factors for HIV and other STDs. Research indicates that 10% of all AIDS cases diagnosed and 30% of individuals living with the disease in the United States are age 50 or older, and that Americans past the age of 50 years were one-sixth as likely to use condoms during sex and one fifth as likely to have been tested for HIV as a comparison group of at-risk individuals in their 20s.<sup>ii</sup> All providers, including those serving the Medicare population, should routinely obtain a sexual history, offer an HIV test to their patients, and encourage risk-reduction using various strategies. Effective delivery of prevention messages requires that providers communicate general risk-reduction messages relevant to the client and that providers educate the client about specific actions that can reduce the risk for STD/HIV transmission.

Also, for those eight million Medicare beneficiaries under age 65 who qualify for Medicare due to disability, the HRA should include routine offering of HIV testing and appropriate counseling as recommended by the CDC. Despite the current USPSTF recommendation for routine testing for those at "increased risk" for HIV – which encompasses those with individual risk factors; those receiving care in a high-risk clinical setting; and those receiving care in a high-prevalence clinical setting – many people at risk for or living with HIV are simply not being tested. Instead, the significant logistical and practical difficulties of identifying individual risk factors and high risk and high prevalence settings act as barriers to testing. Moreover, even with full implementation of the current USPSTF recommendations, routine testing only for those determined to be at "increased risk" still falls far short of ensuring that individuals are tested early and are immediately linked to care. As a result, over a third of people with HIV in the U.S. progress to AIDS within 12 months of diagnosis. Five percent die within a month of testing.<sup>1</sup> For this reason, routinely offering an HIV test is an essential component of the health risk assessment.

In recognition that 21 percent of people with HIV disease are unaware of their HIV status, the National HIV/AIDS Strategy (NHAS) for the United States, the NHAS emphasizes the important treatment and preventive benefits of early diagnosis and linkage to care through routine HIV testing. One of the principal goals of the Strategy is to increase by 2015 the number of people with HIV who know their serostatus from 79 percent to 90 percent. Including routine HIV testing within the Medicare HRA protocol will help the nation reach this goal.

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

Reluctance of clinicians to discuss sexual health issues may be especially problematic among older clinicians and patients in same-sex partnerships. Inadequate training, provider stigma and poor

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<sup>1</sup> CDC. New Estimates of U.S. HIV Prevalence. October 2008.  
<http://www.cdc.gov/nchhstp/newsroom/docs/prevalence.pdf>

awareness of STDs perpetuate the lack of involvement in prevention activities, such as evaluation and treatment of sex partners, by health plans and private practice clinicians. The failure to adequately diagnose and treat STDs or become involved in certain prevention activities, therefore, leads to lost clinical opportunities to prevent STDs, and thus, to incomplete or fragmented clinical services.

Patient-centered consultation skills, characterized by respect, compassion, and a nonjudgmental attitude toward all patients, are essential to obtaining a thorough sexual history and to delivering prevention messages effectively. Guidance in obtaining a sexual history is available in the curriculum provided by CDC's STD/HIV Prevention Training Centers (<http://depts.washington.edu/nnptc/index.html>) and from the Association of Reproductive Health Professionals (<http://www.arhp.org/publications-and-resources/clinical-fact-sheets/sexuality-and-sexual-health>).

## MODE OF ADMINISTRATION

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

A comparison of written and audio methods for assessing STD/HIV Risk in the STD Clinic setting suggests that self-administered questionnaires (SAQ) were more effective and reliable than traditional face-to-face-interviews in eliciting and identifying risk.<sup>iii</sup> The study further suggested that audio SAQ obtained more complete data and better identified HIV risk than written SAQ, particularly among persons with less education. These findings should be considered when developing methods for sexual health risk assessment.

*What are the cultural appropriateness factors in patient HRA access?*

Assessment of HIV and STD risk as well as prevention counseling are most effective if provided in a nonjudgmental and empathetic manner appropriate to the patient's culture, religion, language, gender, sexual orientation, age, and comprehension level. Patients have been even more receptive when this counseling has been provided by individuals that are peers or by members of a community that they identify with. Providers should ensure that policies and procedures guiding HRA process are tailored to respond to the cultural and linguistic norms and needs of the communities being served. When eliciting health history and communicating with patients about their health, providers should be sensitive to the diverse perspectives communities have regarding communication of personal health issues such as sexual history. HRA guidance should also stress the importance of providing verbal communication and written notices at language comprehension levels consistent with abilities of the communities being served.

As HRA guidance is developed, it is imperative that community stakeholder input include diverse membership that is reflective of the diversity of populations served.

## PRIMARY CARE OFFICE CAPACITY

Several mechanisms exist to ensure effective client linkages to appropriate clinical and behavioral health services – chief among them are the effective use of electronic health records (EHRs) to track referrals and follow-up, quality improvement strategies, and patient-centered clinician communication skills. EHRs are essential to the interdisciplinary approach, to enable clinical and administrative staffs to work on different elements of the HRA simultaneously. EHRs make interdisciplinary assessment possible and data entry should be done in real time. HRA referrals should be tracked and supervised by a senior manager in the clinic. Continuous quality improvement through case conferencing and clinical and administrative supervision are critical to the evolution of effective HRAs. The multilevel management will ensure that every element of the process receives the needed priority.

Patient-centered approaches by clinicians foster positive client and clinician relationships and build the trust and open communication lines between clients and clinicians that are critical to conducting accurate

risk assessments. Monitoring time between referral and follow up appointments is critical to improving care and treatment adherence.

## EVALUATION AND QUALITY ASSURANCE

*How should the HRA guidance be evaluated and updated with respect to individual and population-level (practice-based panel management) health outcomes?*

The U.S. Preventative Services Task Force (USPSTF) recommends high-intensity behavioral counseling for all sexually active adolescents and for adults at increased risk for STDs and HIV.<sup>iv, v</sup> In addition, the CDC periodically (approximately every three to four years) updates its *Sexually Transmitted Diseases Treatment Guidelines*, using a scientific, evidence-based process that includes CDC and external expert review of current scientific literature. The 2010 *STD Guidelines*, which update the 2006 *Guidelines*, serve as a source of clinical guidance and advise health care providers on the most effective treatment regimens, screening procedures, and prevention and vaccination strategies for STDs ([www.cdc.gov/std/treatment/2010/](http://www.cdc.gov/std/treatment/2010/)).

These screening recommendations should be incorporated in the HRA guidance and reflected in performance and outcome measures. In addition, we urge the use of a process measure for HIV screening of “high-risk” patients, as endorsed by the National Quality Forum and the US Preventive Services Task Force (level “A” recommendation). We would hope to see this measure modified when coverage is expanded to include routine HIV screening, consistent with the recommendations of the Centers for Disease Control and Prevention (CDC).

Thank you for your consideration of our views. We look forward to working with you to ensure the effectiveness of health risk assessments as a tool for HIV and STD prevention and sexual health promotion. Please count on us as a resource, and contact us through Kimberly Crump of the HIV Medicine Association ([kcrump@hivma.org](mailto:kcrump@hivma.org) or 703.740.4957) if we can be of assistance.

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## HAPPEN, LLC

**Recv'd 1/3/11**

I am responding to the request for comments on the new Health Risk Assessment Guidance proposed for Medicare.

I believe the most useful and comprehensive assessment tool for older adults is the Oral Health Impact Profile (OHIP). A body of literature developed by Gary Slade (UNC Chapel Hill) is available regarding this oral health related quality of life assessment tool and studies related to it.

I had the opportunity to use the short form (OHIP-14) in a multicenter NIH supported study. We used it as a means to do a qualitative assessment along with quantitative data from the survey to support our findings.

Please see link below for background and references on the OHIP.

If you have any questions please contact me as needed.

[http://www.dental.pitt.edu/research/cohra\\_resources/COHRA%20Write-ups%20\(11.06\)/OHIP/ORAL%20HEALTH%20IMPACT%20PROFILE.doc](http://www.dental.pitt.edu/research/cohra_resources/COHRA%20Write-ups%20(11.06)/OHIP/ORAL%20HEALTH%20IMPACT%20PROFILE.doc)

Thanks for the opportunity to contribute

Dionne J Richardson, DDS, MPH

## Healthways

*Recv'd 1/3/11*

Healthways appreciates the opportunity to comment on the Request for Health Risk Assessment Guidance. We strongly support the aims of the Affordable Care Act and we applaud the Centers for Disease Control (CDC) and Department of Health and Human Services (HHS) for moving forward quickly to provide guidance on health risk assessment (HRA) tools. In this letter, we provide answers to the specific questions posed in the Request for Comment.

As the industry leader in well-being improvement, we currently provide our health promotion, chronic care management, wellness and prevention services, both domestically and internationally, to approximately 40 million people on behalf of over 1,000 employers and more than 100 health plans. Our mission is to create a healthier world by delivering solutions that:

1. Keep healthy people healthy
2. Reduce health-related risks
3. Assure the provision of evidence-based care to those who are ill

Healthways has provided health risk appraisals for over 25 years. Our current instrument – which is based on the latest evidence based behavioral science available, including the work of Dee Edington, PhD, University of Michigan, James and Janice Prochaska PhD, University of Rhode Island; Ron Kessler, PhD, Health Management Research Center, and Gallup, the leading international behavioral economics organization – is the Healthways Well-Being Assessment™ (WBA). The WBA is a comprehensive tool that captures both “traditional” HRA information and relevant information about an individual’s home and/or environments and their access to basic essentials needed for achieving and maintaining health and well-being. The WBA is configurable for different populations and is certified by the National Committee for Quality Assurance (NCQA). The WBA is currently being used by over four million individuals Request for Health Risk Assessment Guidance January 3, 2011 Page 2 of 9

including employees at the Federal Government’s Office of Personnel Management, Department of Interior and the General Services Administration who are eligible to participate in the Wellness Works program we are piloting with those agencies.

The WBA also includes questions from the Gallup-Healthways Well-Being Index (G-HWBI), a validated national survey that measures an individual’s social, emotional and physical well-being. Gallup completes 1,000 WBI surveys every day and the current data base contains information from the more than one million surveys completed to date. The GH-WBI data base contains both benchmark and current data on a national, state and community basis to which target populations can be compared. Through regular ongoing completion of the WBA, we are able to provide our customers with an organizational base-line for their populations, individual well-being improvement plans for each member of their populations and a consistent measure of both individual and organizational improvement over time. We are pleased to have the opportunity to share our insights with the CDC as it develops standards for health risk assessments in support of the newly expanded Medicare wellness benefit.

**Question 1: Risk assessment domains: What are generic elements of any HRA and what elements must be tailored to specific populations, particularly those stratified by age?**

The primary focus of the HRA is to identify modifiable lifestyle behaviors and the stage of the individual’s readiness to change. A typical HRA includes questions that cover demographics, health status, healthcare use, emotional health and lifestyle behaviors, such as smoking, exercise, nutrition, stress, depression, safety and prevention habits. Ideally, an HRA also incorporates a biometric screening to gather or validate survey based health information. Without biometrics, it is very difficult to accurately assess the immediacy of health risks. We also find that objective data serve as a catalyst for action, both

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by individuals and providers, when the results are suboptimal and serves as validation for staying the course when the results are in range.

Based on the best current research, we believe that HRA survey questions and biometric information should also be linked to larger constructs or domains that can offer insight into an individual's social and emotional health, work environment, and other closely linked well-being constructs in order to understand and promote the necessary behavior changes required to improve or maintain optimal health. The Healthways WBA links individuals' information to six domains:

- Life Evaluation: evaluation of present and anticipated life situation five years from now.
- Emotional Health: identification of depression as well as a composite of daily emotional experiences including happiness, enjoyment, worry, sadness, anger and stress.
- Physical Health: history of disease and daily health experiences for each individual.
- Healthy Behavior: questions regarding lifestyle habits with established relationships to health outcomes.
- Work Environment: questions regarding job satisfaction and engagement.
- Basic Access: questions regarding access to food, shelter, healthcare, and a safe and satisfying place to live.

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There are a number of elements of an HRA that can and should be tailored to specific populations. For example, preventative services questions should be based on the U.S. Preventive Task Force recommendations which vary by age, gender and risk profile. HRA questions should also be tailored based on the work status of the individual. For instance, the Healthways WBA for commercially insured individuals includes questions about work environment, which strongly influences both individual well-being and readiness to change for working age populations. However, questions related to work environment are likely less important for Medicare beneficiaries, many of whom do not work at all or do so on a limited basis, and thus are often removed for use with this population.

Through our work with the WBA we have found that understanding the context of an individual's daily life, health and lifestyle behaviors that otherwise may seem irrational, may actually be rooted in specific circumstances identified by one or more of the WBA domains (which may not be related to physical or emotional health per se). By arraying personal information over specific domains, the WBA enables a comprehensive view of an individual's well-being and provides important context for developing interventions to improve both health and overall well-being.

**Question 2: How should literacy and other cultural appropriateness factors be factored into the design?**

The HRA survey tool and the report of results should be easily understandable, both for the individual completing it and his or her health care provider(s). For example, the Healthways WBA and results report are written at approximately a sixth grade reading level to provide ease of understanding across a varied audience while maintaining the necessary health related language. Another important factor related to cultural appropriateness of an HRA is availability in multiple languages. The WBA is available in both Spanish and English.

The data captured from the WBA has created the largest database in the country through which health status can be studied in the context of cultural attributes like race, religion, religious practice, work, age, diet, exercise, and life satisfaction. We have also determined through our deployments of the Healthways WBA that it is important to take into consideration the potential implications of the environment in which the HRA is being administered. By analyzing the data we have collected, we have learned that an individual's culture and life situation can affect his or her answers to the questions included in an HRA. For example, within some cultures there may be barriers that make it less likely an individual will admit to certain health conditions or behaviors. As a result, the normative range for particular answers may vary by race, ethnicity or other situational factors.

In order to ensure an HRA can accommodate the needs of a range of populations, we recommend the CDC develop guidance that ensures:

- HRAs are understandable to individuals with relatively low levels of basic literacy

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- HRAs are available in at least both English and Spanish
  - Specific questions on an HRA can be “turned on” or “turned off” and behavior modification recommendations can be modified as appropriate based on individual circumstances

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**Question 3: How should the HRA instrument support shared decision-making by provider and patient?**

The purpose of an HRA is to identify modifiable health risks or behaviors that drive unnecessary utilization or care while maximizing one’s quality of life and human performance. HRA report information should be shared with individuals in a way that is easily usable, digestible and has some demonstrated probability of actually motivating the individual to change. It is essential this information be available at the point of care so it can provide a framework for discussion between and individual and his or her provider.

In our experience, it is helpful to provide individuals with not only information about their own health and risks, but also comparative information about how their health and risk factors compare to others of their age and to the general population. The goals of shared decision making are to engage patients in their care plans to help move them from a pre-contemplative or contemplative state of behavioral change to an action mode and to facilitate making fully-informed choices.

Ideally, providers will have easy access to this data so they can incorporate these findings into the care plans of their patients. Individual reports and behavior modification recommendations can be supported by telephonic, online and/or face-to-face community health resources that will enable patients to better self-manage their lifestyles. When possible, the assessment data should be stored in Electronic Medical Records (EMR/Provider) and Personal Health Records (PHR/Patient) to facilitate joint review and planning by the patient and his or her provider.

Determining the extent to which the patient is prepared to pursue healthy lifestyle changes, guiding them in how to approach that process, and supporting them in achieving their goals for change, are ongoing tasks that do not require the advanced clinical skills of physicians. The implementation and conduct of the wellness/well-being plan recommended through the HRA process should be carried out by appropriately trained (but less costly) health care professionals who have the tools, processes, and infrastructure to assure the delivery of the requisite support services through whichever modality is best suited for the patient. These professionals should have access to processes, infrastructure and other professional resources that:

- 1.) Have been demonstrated to be effective in creating and sustaining behavior change, and
- 2.) Can be brought to bear at a scale that ensures both a reasonable cost and the likelihood of actual savings over time.

**Question 4: How will individuals access the HRA (e.g., via kiosk or some other means in the physician’s office, Internet, mail-in paper form, other nontraditional healthcare locations, such as, kiosk in a pharmacy)?**

Healthways has geared our solutions to support the provider/patient relationship by making the assessments, reports and supporting interventional tools available in both paper and online formats. Automated voice response is another possible mode of access for HRAs, but we have found that many individuals find this method difficult and it is generally not well utilized. Healthways can support the CDC to identify ways to ensure easy access to the HRA and related results by leveraging technologies and community resources.

Healthways’ primary and preferred means of offering the WBA is online; allowing access from anywhere an individual has a computer and Internet connection. Healthways recommends the Request for Health Risk Assessment Guidance January 3, 2011 Page 5 of 9

CDC guidelines include paper versions as well as online options where kiosks or tablets can easily be installed at designated locations to reach individuals in the community, at home, at the worksite, or in the providers’ offices, as well as at locations where those with special needs can be supported.

**Question 5: What are the cultural appropriateness factors in patient HRA access?**

Ensuring individuals are able to easily understand the HRA survey and report is crucial. For that reason, we reiterate our earlier recommendations that the CDC guidelines ensure HRAs are clearly written at a reading level that is widely accessible to those with basic literacy skills and that HRAs be available in at least English and Spanish.

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The CDC should also consider the fact that some individuals may be less comfortable with online tools or may not have easy access to a computer or the internet. This issue may be particularly true for individuals whose age or socioeconomic status may limit their familiarity and comfort with or access to technology. In addition, individuals with visual impairment may have difficulty accessing an online HRA. We recommend that the CDC guidelines encourage the use of electronic or online tools for reasons of administrative efficiency, while allowing and facilitating other modes of administration when necessary to accommodate differing individual needs.

**Question 6: What primary care office capacity (personnel, Information Technology (IT), etc) is required to utilize HRA data effectively in support of personalized prevention planning?**

Ideally, individuals and providers will be able to access the HRA online. In order to do this efficiently, providers will need to have a computer workstation and Internet access in their offices. Providers may also want to be able to print out a copy of an individual's HRA report to review with the individual during an office visit, so access to a printer is also recommended. In order for the data to be actionable, it has to be available in the individual's medical record in a manner that is readily available to the provider. We do not believe that additional staffing would be required.

Some providers may choose to deploy more sophisticated technology and tools to provide real-time online report access to patients, or allow patients to complete the HRA in-office. Providers that choose to do this may require additional IT or support staff, patient-accessible kiosks or computers and a private area for individuals to complete their HRAs online. We do not suggest, however, the CDC require providers to do this because it would be a significant burden for many.

**Question 7: Are training and technical assistance necessary for effective practice utilization of an HRA? What entity should provide this technical assistance?**

Our experience has shown the amount of training and technical assistance necessary is minimal, and can be provided online, on-demand to maximize efficiency. In general, the providers/vendors of HRA tools and related services will be prepared to support the HRA and systems that allow its administration and utilization. It is likely that some new development may be required to create standardized provider and patient IDs based on the environments in which the HRA is being distributed. Regardless, most comprehensive systems that exist today will Request for Health Risk Assessment Guidance January 3, 2011 Page 6 of 9

require very little modification to meet the anticipated requirements. In any case, necessary training is generally a core competency of these companies and is routinely provided since HRAs currently are commonly deployed remotely to employers, health plans, providers and benefits brokers.

**Question 8: What are potential or demonstrated community care transition linkages— follow-up outside the office by other providers—that help patients and providers manage priority risks identified by the HRA?**

In our experience, in order for health, wellness, prevention and chronic care management programs to be effective, individuals must have ready access to a range of community based services. These services vary by market but generally exist in some form to support patients nationwide. For example, many senior citizen-oriented resources such as meals on wheels, community centers and other non traditional "providers" present possible opportunities to help providers and patients manage priority risks.

One highly successful wellness program geared toward Medicare beneficiaries is Healthways Silver Sneakers® Fitness Program, where mature adults can access community-based fitness centers for exercise and socialization. There are currently more than 12,000 fitness centers in the Silver Sneakers network, many of which can offer additional programming to support this population. In addition to Silver Sneakers, Healthways is present in hundreds of markets across the country and, as part of our telephonic patient support, we work with the Area Agencies for the Aging that provide programs such as care transitions and home health .

In addition, in our work with the Medicare Health Support program Healthways developed strong partnerships with a range of state and local agencies and community resources, including Area Agencies on Aging, AARP, State and local public health and social service departments, Medicaid waiver providers, Alzheimer's Association chapters, transportation systems and hospitals and physician groups. These organizations can support efforts to modify behavioral risks by supporting the implementation of the plan. This can include services such as home delivered meals, transportation to purchase nutritious groceries, eligibility or benefit counseling, information and referral to key services, translation services or respite

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care. These support services can assure a successful plan is implemented and coordinated with the physician as well as the beneficiary and care provider.

**Question 9: What is the current practice of HRA in medical practices of various sizes, particularly those with five or fewer physicians?**

In many instances medical practices, particularly smaller ones, do not use true HRAs today. However, almost all practices have individuals complete a medical history form at least annually and these forms do contain some information that helps providers identify at least some health risks.

**Question 10: How could HRA data be shared with the patients for their feedback and follow up in the primary care practice?**

It is critical that the HRA report provided to the individual and the primary care provider is easily accessible, comprehensive and usable at the time of their next interaction with each other without disrupting the provider's workflow. We strongly recommend the reports also include Request for Health Risk Assessment Guidance January 3, 2011 Page 7 of 9

comparative data to engender patient interest. In our experience, the ability to compare one's health to peers can be a powerful motivator for behavior change. The report should be structured in a way that naturally creates several "launching points" from which a participant or physician can begin communication. For example, Healthways WBA reporting provides specific recommendations and prioritizes the results of the assessment based upon the most prevalent health risks and negative well-being factors for each individual. By offering WBA completion online, Healthways' WBA results are typically available immediately within our online portal, creating an opportunity for swift consultation and follow up action with the individual's physician.

**Question 11: What role, if any, do incentives play in motivating patients to take the HRA and/or participate in follow-up interventions?**

Healthways continues to be an industry leader in the development and use of new and innovative incentive models and strongly encourages the CDC to consider the use of incentives that have been proven effective as part of the HRA program. It is important to create incentives not only to complete the HRA, but also to create and sustain the behavior change necessary to maintain or improve health status. Because every population and every individual is different, it is necessary to create and implement incentives that are appropriate to the unique population using the HRA tool, that match and support the achievement of the overall health and financial outcome goals, and that help individuals achieve their health goals.

Healthways recently acquired HealthHonors (<http://www.healthhonors.com>), a behavioral economics company focused on helping people achieve their best possible health. HealthHonors has developed a web-based application (and IVR system for those without Internet access) that provides users with economic and non-economic reinforcement (incentives) for performing healthy behaviors. The HealthHonors' system leverages this science to help users make consistently good choices and have fun in the process. It has been used successfully to increase medication adherence rates for pharmaceutical manufacturers, retail pharmacy and health plan sponsors. HealthHonors has an impressive engagement rate over time and has documented increased medication adherence rates of 33-50%. A recent publication describing the results of a HealthHonors incentive program is attached for your review.

In addition, the HealthHonors solution has a scientifically designed incentive approach that "optimizes" the award amount to the lowest threshold required to sustain desired levels of engagement. The incentive optimization methodology has demonstrated abilities to keep high rates of engagement while reducing the incentive amounts substantially. Given that the typical employer sets aside hundreds of dollars per employee to motivate healthy behavior, the magnitude of incentive savings achievable by Healthways' HealthHonors solution has the potential to significantly offset the cost of a comprehensive population management solution. Request for Health Risk Assessment Guidance January 3, 2011 Page 8 of 9

**Question 12: With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non-electronic form?**

and

**Question 13: Are there standardized and certified tools available to support this data migration from multiple data entry sources?**

There are many standardized tools available to support data migration from multiple data entry sources. For example, through their practice management and billing systems many provider offices currently use

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clearinghouse services or translation tools to exchange administrative information. In addition, as more communities establish frameworks for health information exchange, many rely on similar tools to support exchange of clinical information. We believe these tools can be used, with modification if necessary, to support HRA data migration as well. To help facilitate this capability, we recommend that CDC work with the Office of the National Coordinator to issue guidance on data format and publish a data dictionary for HRAs.

**Question 14: What certification tools and processes should complement the HRA guidance and how should they be made available to support primary care office selection of an HRA instrument?**

Healthways encourages the CDC to consider only allowing the use of HRAs or well-being assessments that are certified by recognized external quality evaluation organizations, such as NCQA and URAC, and that 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

**Question 15: How should the HRA guidance be evaluated and updated with respect to individual and population-level (practice-based panel management) health outcomes?**

The data collected in the HRA drives the creation of a prioritized plan for each individual and the validity of the data will certainly impact the effectiveness of the plan, but the real determinant of success of the HRA will be the ability of support programs to achieve the desired outcomes. The first step in achieving success is ensuring that individuals participate in the HRA and that providers follow through in discussing results with them. We recommend that the CDC guidance include standardized methods and metrics for identifying the relative success of different providers in encouraging individuals to complete an HRA, identify and prioritize risks, follow through on related behavior modifications, and achieve success in reducing risk factors and maintaining or improving health. Request for Health Risk Assessment Guidance January 3, 2011 Page 9 of 9

Thank you for the opportunity to offer comments regarding the creation of a Health Risk Assessment tool. We are also attaching several references that may be of interest on the association of HRA scores and claims costs, the accuracy of self-reported HRA information and the importance of including biometric information, and two papers on strategies for using incentives to encourage wellness and prevention.

Our philosophy acknowledges objective, honest assessments of well-being across populations is an important step forward in achieving effective behavior change and we applaud the Agency's efforts to improve well-being for Americans across the nation.

Sincerely,

John Harris

Vice President and Chief Wellness Officer  
Healthways, Inc.

## **Pacific Business Group on Health**

***Recv'd 1/7/11***

The Pacific Business Group on Health (PBGH) appreciates the opportunity to comment on the RFI regarding guidance on design for Health Risk Assessment (HRA). PBGH is a business coalition of 50 purchasers that seeks to improve the quality and availability of health care while moderating cost. Since 1989, PBGH has played a leading role both nationally and statewide in health care measurement, trend moderation, and provider accountability through public reporting. Working with the members of PBGH, we have gathered thoughts around essential guiding principles for the design of an effective HRA.

Furthermore, PBGH emphasizes that the benefits of a HRA will be best realized when it is accompanied by a strong incentive program that promotes participation as well as follow up care management discussions with physicians. Specific comments on design principles, incentives and cultural competency.

### **Design Principles**

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From a design standpoint, Health Risk Assessments (HRA's) do not need to be long questionnaires. Instead, the critical point is to ask what risk factors is the HRA designed to identify and how will the information be used. HRA should be a tool that is used to support the care management of an employee and considerations should be given to how the HRA will actually be used between a health professional and the patient. A series of basic questions can be illuminating to assessing the patient's health when it is targeted for a specific purpose, whether that is for chronic disease management, wellness, or generating single care plans for an individual to close gaps of care.

Good design principles for the HRA should address ease of completion, brevity for implementation, and ultimately, be geared to the specific condition(s) and risk(s) that it is designed to identify. The critical goal is to capture baseline biometric information along with the employee's basic health background (e.g. weight, diabetic, smoker, etc.), which then can be used to identify deeper issues. It is better to start with a generic design that is simple to implement and can be applied to everyone, which allows a care provider to ask deeper level questions.

From the employer perspective, additional elements that are tailored to the demographic and health profile of its working population can be very helpful in coordinating care management. For example, Hepatitis B specific HRA questions for employer groups with a high population of Asian American employees or factors related to coronary artery disease for the aging employees. Again, the guiding principle should revolve around what is the purpose for the HRA, what health risk is it identifying, and how will the information be used to coordinate care.

A crucial issue to consider is around requesting information from the employee on the family's medical history. This information is highly valuable when used in conjunction with the employee's biometric and health data. However, under current regulation, this information cannot be requested if financial incentives are provided for participating in the HRA. This creates a tradeoff between quality of data gained from the HRA and improving the participation rates in the HRA program.

#### **Incentives for Adoption**

The success of the HRA is dependent upon the employee participation in the program and ultimately, on the follow-up care with the primary care physician or other care provider. Incentive design plays a crucial part in this, both the total amount of reward provided as well as how it is accrued. Current employer HRA programs focus more on driving adoption of HRA, often with incentives tied to completion of the HRA and additional incentives for completing certain wellness goals. Less focus has been placed on the follow-up interventions, but this will change overtime. The guiding principles around incentive design should be: 1) It is scaled appropriately for the desired behavior (larger reward for harder goals or further out goals); 2) One time gain on the reward is preferable to spreading out the same amount over time; 3) It is easy to understand for the employee.

Incentives come in various forms, such as cash, funding for FSA account, premium deduction, and drawings for televisions or vacations. Incentives that are substantial and immediate (e.g. \$100 for completion of HRA) are effective in driving adoption. If the goal and reward is further away in time, then the larger the reward is required to drive the preferred behavior. Thus, incentive for improving some measure of health status, such as BMI, may require both a cash outlay and a potential to win a larger reward. Similarly, the same concept can be applied to incentivize follow-up care. Equally important is the communication of any incentive. Furthermore, incentives should follow value based design philosophies. As the risk profile for people who have completed HRA is tracked overtime, additional incentives can be incorporated into the employee's benefit design based on their intervention plans.

#### **HRA survey access and cultural appropriateness factors in patient HRA access**

To promote use of HRA tools, many large employers have made available kiosks or other access points for individuals whose workplace is not in a traditional office setting. Increased attention needs to be focused not only on multi-lingual capabilities, but also the design of questions in conjunction with cultural appropriateness to elicit accurate responses and support consumer engagement. In many instances, we have seen Spanish language translations available only on paper to be used in conjunction with English Web-based surveys. Similarly, in the limited circumstances where translated HRAs are available online, they are often not easily found. We appreciate the opportunity to provide input.

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# Health Fitness Corporation

Recv'd 1/5/11

## Content and Design- *Health Fitness Corporation*

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

It is possible to argue that most potential HRA elements have to be tailored to specific populations – especially if one assumes that the purpose of the assessment is to put a numerical estimate on the likelihood of death in a defined period of time, say the next 10 years. However, assessment of the likelihood of death is far from the most important thing that we can share with those who take our assessments. The more pressing question is what risk are we trying to assess and evaluate? Other than death we could be looking at risk of developing a chronic disease or even multiple chronic diseases, effectiveness in self-management of pro-health behaviors or a lack thereof, psychosocial risks, or even risk of a breakdown in shared decision making based on participant characteristics. One might even argue, successfully, that the current state of a lack of a standardized HRA is not “bad,” but that it simply reflects the diversity of applications in which an HRA is being used.

Perhaps a behavioral approach is called for; one that compares current personal behavior and biometric measurements to science-based, “good health” recommendations from the appropriate integrative, government science agencies such as the NIH and CDC, as well as expert panels such as ATP-3, JNC-7 and Dietary Guidelines for Americans 2005 and their soon to be released, updated versions. In these cases, the expert panels and agencies usually release adjusted good health recommendations for age, gender and sometimes racial characteristics that they determine will impact people’s health. A solid example are the 3 categories of recommendations released by CDC in the last round of physical activity recommendations in August of 2008 – children, adults and elderly.

HealthFitness developed and uses a senior focused HRA as part of the CMS’ SRRD project. This HRA underwent cognitive testing as part of its design criteria. Always remembering that the questions on an HRA must be limited in number, consider at least the following as areas from which to select assessment elements:

1. Tobacco use (Generic)
2. Engaging in physical activity, both aerobic and strength building activities (age and medical condition tailored or at least acknowledged)
3. Nutrition variables including: (largely generic)
  - a. Fruit and vegetable consumption
  - b. Healthy and unhealthy fat consumption
  - c. Sodium intake (hard to do on an HRA) or perhaps sodium control behaviors
4. Psychosocial variables such as experiencing depression and stress, life and job satisfaction, child and elder care stresses, and potentially anxiety and anger. (largely generic)
5. Self-rated overall health.
6. Framingham CVD risk
7. Primary prevention strategies such as sun exposure control in its various forms, brushing teeth and flossing, seat belt and helmet use, and appropriate hand washing (hygiene). (generic) Other safety issues such as smoke detectors, home fire extinguishers, non-skid bath mats and cell phone use while driving are often covered. However, as people

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seem to want shorter and shorter instruments, the question of prioritizing all the preventive strategies about which vendors could ask is coming to the fore. The HRA cannot contain everything we would like to know.

8. Secondary prevention (early detection) strategies such as screening colonoscopy, appropriate mammogram and pap smear screenings, etc. (frequently referred to as Preventive Health Services, and often age and gender tailored)
  9. Measures which make “outside of good health” behaviors and physical and mental states clear – for example, BMI or related measures, other physical measures such as blood pressure, and relevant blood chemistries. (Some of these will be secondary prevention actions and some indicate states in need of tertiary prevention programming. (largely generic, but at times tailored, especially to age)
  10. Alcohol consumption and presence or absence of binge drinking can clearly represent health strengths or significant risks. There is some concern about the accuracy of these self-reports in the broad employer-based surveys where much HRA experience has been obtained. (recommendations tailored to gender and age)
  11. Personal medical history and medication use (A mix of generic and tailored questions)
  12. Potentially using family history, although the interaction of HIPAA, ADA and GINA is making the determination of whether to use or not to use family history much more difficult. There is little or no question that family history of various diseases would assist in tailoring feedback to participants.
  13. Senior instruments can and perhaps should include some questions on end-of-life decision making. While not a risk in the conventional sense, end-of-life decision instruments can reduce the trauma of a loved one’s death by knowing that we are at least acting within the bounds their loved one deemed most personally important. This might also free the medical establishment to easily honor family directives.
  14. Minimally, the HRA should use one or more of the basic behavioral approaches, for example the Transtheoretical Model (Prochaska et. al) or self-efficacy (Bandura and his colleagues) to ascertain the participant’s openness to attempting change and their likelihood for sustaining behavior change efforts should they initiate them. There are, of course, other health behavior theories and distinctions that can also form part of the design framework of an HRA.
- **How should literacy and other cultural appropriateness factors be factored into the design?** Minimally, reading levels should be determined, although the algorithms in Fleisch-Kincaid and similar are hard to use when looking at brief questions. General low-literacy approaches to both questionnaire and report should be considered when possible. Tailoring food examples and problem descriptions to the participant’s culture can be useful, but can also be daunting in highly culturally diverse settings. We must strive to find the right balance without the need to develop dozens of highly culturally specific HRA instruments.
  - **How should the HRA instrument support shared decision-making by provider and patient?** Every effort should be made to make health risk information available to both the person and their personal physician in an equivalent timeframe. Additionally, some generic health recommendations, and even those that appear targeted, must be adjusted by a physician who knows and respects the person taking the HRA. The basic philosophy should be that the HRA does not replace the participant’s physician and that in fact sharing the assessment with them is appropriate and even wise.

#### **Mode of Administration**

- **How will individuals access the HRA (e.g., via kiosk or some other means in the physician’s office, Internet, mail-in paper form, other non-traditional healthcare locations, such as, kiosk in a pharmacy)?** Multiple modes are a must. These should especially focus on Internet (from homes, physician offices and workplace) and other cost-effective electronic means.

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HRAs can be offered via kiosks in a wide variety of settings including workplace, pharmacy, and physician's office. Kiosks can also be sited in community settings. Depending on the complexity of the HRA, phone-based systems are also possible, as are physician office electronic check-in systems if they can be engaged to deliver an HRA as well as fulfill their primary purpose. Paper may always be with us, but the cost effectiveness of paper and the generally slow pace of report delivery from paper questionnaires suggest that paper is not a preferred route.

- **What are the cultural appropriateness factors in patient HRA access?**

The factors are probably less cultural than practical. Like working out at a fitness facility, few people will travel far from home or work to take an HRA. Exceptions are if HRA is made available in doctors' offices, places of worship and sites of frequent community activity. If the intent is to reach the bulk of America's adult population, HRA delivery has to be made relatively easy and be available in the primary languages of the participants (NO SMALL TASK). Variables which carry a clearly cultural factor include preferred cultural foods and the food supply which various levels of SEC can regularly access. Also, depending on how broad the use of HRA actually becomes the government and HRA vendors may find themselves attempting to assess risk based on relative lack instead of on relative abundance. This could present its own very real set of challenges.

### **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?** If the HRA is to be used in physician offices for personalized prevention planning, results should be available to the physician and their staff early in the office visit. Thus the patient would complete the HRA prior to the office appointment or very early in the office process flow. This can require anywhere from little support other than attaching a brief physician's report to the chart prior to the physician seeing their patient, to adding a nurse or other health professional to the loop because the doctor(s) in that practice do not have the time for preventive health coaching/counseling. At a minimum, the office would benefit from the IT necessary to use an internet HRA or desktop package that makes the report available to the staff in a timely fashion.
- **Are training and technical assistance necessary for effective practice utilization of an HRA? What entity should provide this technical assistance?** Substantial training and technical support will be necessary for some offices and staff, less for others and almost none for those who already have in office expertise on preventive health services and IT systems. Vendors can likely roll the training for their own systems into an overall package for the physician office.
- **What are potential or demonstrated community care transition linkages—follow-up outside the office by other providers—that help patients and providers manage priority risks identified by the HRA?** This question expresses the desire to use the HRA risk information to help patients and providers assess a broad range of extended and professional community resources. HealthFitness and we assume other providers are making this capability available to interested clients. However, few if any vendors will have the staff to forge working relationships throughout the thousands of local medical and community networks around the country. If we are interpreting this question properly, it will require a strong public-private partnership and the willingness to devote substantial resources.
- **What is the current practice of HRA in medical practices of various sizes, particularly those with five or fewer physicians?** Regular use of HRA has low penetration into the broad physician and medical community. Smaller sized offices probably have lower penetration than large offices and clinics, but we have no hard data to share on this concern.

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## Consumer/Patient Perspective

- **How could HRA data be shared with the patients for their feedback and follow up in the primary care practice?** 1. When the nurse preps the patient for their visit with the physician. 2. When the doctor sees the patient and works the results of the HRA into the overall visit. 3. Either professional could return the report or the report could be returned earlier with the patient being invited by the nurse or doctor into a discussion of health strengths and risks and the appropriate use of both preventive and intervention services.
- **What role, if any, do incentives play in motivating patients to take the HRA and/or participate in follow-up interventions?** Incentives to take an HRA, participate in a biometric screening and then join any number of health improvement programs, often play a strong role in the employer sector. Other venues, such as the physician's office, may require little or no incentive to achieve high rates of participation. A lot likely depends on how the HRA program is structured and communicated to the consumer/patient. Most of us are used to filling out long medical history and insurance forms at our physicians' offices. If the HRA is just one more form, paper or electronic, that we complete in the physician's office, it is possible that it will just become part of the flow. Any hope of behavior change, however, depends on the timely return of an HRA report and the relatively easy availability of some interpretation and follow-on programs for most people.

## Data

- **With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non-electronic form?** When not entered electronically, the obvious issues are that conversion to electronic format is highly desirable and that the conversion is just another costly step that is fraught with its own reliability and validity problems.
- Are there standardized and certified tools available to support this data migration from multiple data entry sources? Most major vendors have a hand entry or scanning process (either mark sense or optical character recognition), for converting paper forms to electronic data. These processes are unlikely to be standard across vendors.

## Certification

- **What certification tools and processes should complement the HRA guidance and how should they be made available to support primary care office selection of an HRA instrument?** A most interesting question in its implications. There has never been a widely sanctioned or accepted standard for the appropriate dissemination of HRA guidance from medical or health promotion staff to patients or participants. However, HealthFitness and probably other major vendors provide sustained training to their own health advising staff, including scripts and supervision. There is an opportunity to develop an industry-wide certification for HRA feedback based on sound educational and behavior change principles. NCQA and others have initiated efforts in this direction with HRA certification and Wellness/Health Promotion accreditation programs.

## Evaluation and Quality Assurance

- **How should the HRA guidance be evaluated and updated with respect to individual and population-level (practice-based panel management) health outcomes?** Most vendors will have a standard or semi-standard review and update process in place. These processes are often triggered by changes in recommendations from government panels and/or agencies. For

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example, most significant vendors transitioned from, or at least made available versions of their HRAs with the CDC's 2008 release of its physical activity guidelines within 18 months following their publication. While this sounds slow, the change from an emphasis on frequency of physical activity to volume of physical activity demanded a marked change in many vendors' question sets and reporting. The expectation is clear that when ATP-3 transitions to ATP-4, or when JNC-7 transitions to JNC-8, vendors will transition their tools to use the new guidance within 180 days, perhaps in as little as 30-60 days depending on the scope of the changes that are announced. Population level reporting is included in these adjustments, whether the population be a physician practice or more typically an employer site.

Over time reporting for individuals and populations is already a part of all major vendors' standard reporting. Many even apply statistical tests of significance in order to separate out significant changes from minor variations. How to use this information to guide development, refinement and targeting of interventions at both the individual and population level is usually a part of a vendor's standard service packages, or at least in one or more of the options.

## Medco Health Solutions

*Recv'd 1/3/11*

The attached comments from Medco Health Solutions are in response to the CDC's request for information regarding the Health Risk Assessment Guidance. Please let me know if you have any questions. Thank you very much,

--Andy Friedell, *Director, Northeast Region, Medco Government Affairs*

We appreciate the opportunity to provide comments regarding the Centers for Disease Control and Prevention's (CDC) recently released request for information regarding the development of guidance relating to the Health Risk Assessment (HRA). Medco looks forward to working with the CDC on implementing this new program.

Medco Health Solutions is a leading health care company that is advancing the practice of pharmacy and serving the needs of approximately 65 million people. Medco provides clinically driven pharmacy services designed to improve the quality of care and lower total health care costs for private and public employers, health plans, labor unions, government agencies of all sizes, and for individuals served by Medicare Part D Prescription Drug Plans. About one third of the companies on the Fortune 500 list are Medco clients.

We would like to focus our comments on two areas: 1) pharmacy must be an integral part of the Health Risk Assessment; and 2) in order to ensure widespread adoption, the HRA must be relatively simple to complete and easily accessible to patients, providers and pharmacies.

***The Importance of Pharmacy:***

In order for the Health Risk Assessment to provide a meaningful and comprehensive view into a patient's condition, the tool must embrace pharmacy care and appreciate the value of pharmacy as a critical tool for both assessing and treating a wide range of conditions. Consider that fifty percent of the U.S. population accounts for ninety six percent of all drug costs and seventy five percent of all medical spending.<sup>1</sup> And for eighty eight percent of all chronic conditions, medication is a first line of treatment.<sup>2</sup> Furthermore, according to Medco's data non-compliance

<sup>1</sup> Source: Medco data and data from the Centers for Disease Control

<sup>2</sup> Source: Medco data

rates are often above fifty percent after one year of drug therapy and thirty three percent of patients experience an omission in drug therapy based on the best available scientific treatment guidelines.<sup>3</sup> These facts underscore the notion that pharmacy care should be an integral component of any well-managed health care system; we even see it as the gateway to achieving

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better outcomes overall.

In fact, we have found that improving adherence and reducing omissions or gaps in care offer some of the greatest opportunities for improving overall patient outcomes. For example, a 2005 study found that patients with hypercholesterolemia, whose adherence rates were 1-19 percent, had medical costs more than double those of patients whose adherence rates were 80-100 percent.<sup>4</sup> In addition, our data also shows that every extra dollar invested in drug therapy for a diabetes patient (based on closing evidence-based gaps in care) yields seven dollars of savings on the medical benefit side.<sup>5</sup>

These facts underscore the need to include pharmacy information at the heart of the Health Risk Assessment. In fact, the HRA should provide visibility into the patient age and include all drugs being taken by the patient across all prescribers and pharmacies (including over-the-counter drugs and supplements), as well as to identify allergies and other existing medical conditions that may affect or interact with certain drug therapies. Drug safety interventions, such as systems-based drug utilization review (or DUR) programs, can play an important role in helping to avoid potential adverse drug events such as drug-to-drug or drug-to-disease interactions.

***Accessibility of the HRA:***

In addition to stressing the importance of pharmacy within the HRA, we also believe that in order to ensure widespread adoption, the HRA must be relatively simple to complete and easily accessible to patients, providers and pharmacies. In order to achieve this goal, we feel that the HRA must be electronic or be easily accessible through an electronic format that uses widely accepted technology standards. The HRA must also be easily accessible to patients via a secure internet channel as well as to a wide cross-section of providers. Pharmacies, including both mail and retail pharmacies, need to be included in the provider mix. Finally, it is important that the HRA not be overly burdensome to complete. In fact, wide acceptance and adoption of the HRA should be viewed as being more important than the level of detail captured within the assessment itself.

Again, we appreciate your willingness to consider our comments on the above mentioned request for information and look forward to working with the CDC to promote the successful implementation of these new programs in the future.

## **Geoffrey B. Crawford**

***Recv'd 1/7/11***

Thank you for seeking public comment on the development of guidance concerning health risk assessment (HRAs).

As a preventive medicine resident, I spent three months rotating at the Centers for Medicare and Medicaid Services (CMS; Baltimore, Maryland) in the Coverage and Analysis group. During my rotation, I devoted considerable time and effort to reviewing and analyzing available literature regarding HRA use in the clinical setting (particularly among Medicare beneficiaries). I would like to briefly express my conclusions.

Please note that the opinions herein are solely those of the author, and do not represent, or intend to represent those of CMS (either at present, or during my rotation; Fall 2010) or the Department of Health and Human Services.

### Content and Design

Evidence for both the efficacy and effectiveness of available HRA instruments is principally absent; thus at present, there is serious uncertainty whether the potential benefits of available HRAs outweigh the potential harms. Because HRAs are, in essence, a collection of screening tests, effective implementation

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of HRAs should be based on current and accepted secondary prevention guidelines, such as those from the United States Preventive Services Task Force (USPSTF).

To demonstrate the simplicity, brevity, and clinical bearing of such an instrument, an *example* Medicare-based HRA developed strictly on USPSTF A and B recommendations and components of the Medicare wellness visit is provided (see Appendix 1).

#### Mode and Administration

Notable disparities and gaps in access to services exist among patients by race, poverty status, or geography. Specific racial and socio-economic groups may perceive HRAs differentially, and differential utilization of HRAs and subsequent interventions may potentially worsen or ignore existing disparities.

Currently, few studies exist in the literature that target or can be used to address the specific needs of the populations not classically identified for HRA implementation (white healthy employees of higher socio-economic status).

As noted in the Federal Register notice, cultural appropriateness factors must be factored into the design of HRAs. Pending further research, interim compromises might include providing several modes of HRA administration (e.g. web-based, paper, and telephonic) and offering intervention approaches in agreement with current USPSTF guidelines (where in most cases recommendations apply equally to populations irrespective of race, poverty status, or geography).

#### Primary Care Office Capacity

If HRAs are comprised of *only* evidence-based screening questions (such as those supported by current USPSTF guidelines), subsequent interventions should be consistent with standard of care practices. Such an approach will not impede busy clinicians, but instead make certain comprehensive clinical preventive care.

#### Data

Data from a USPSTF-based HRA will be standardized (in accordance with the guideline recommendations) and should not vary drastically in content, format and scoring.

#### Evaluation and Quality Assurance

Future research demands high quality prospective data to demonstrate the utility of HRA topics not addressed by the USPSTF.

#### Author Recommendations

HRAs must be convincing and appealing to patients, clinicians and health administrators alike, and should maximize positive health outcomes in patients, minimize physician inconvenience, and diminish health care costs overall.

It is the author's opinion that HRAs should be offered to patients as a means of:

1. Supplementing limited physician and care-giver interaction time;
2. Providing interactive and individualized risk assessment and recommendations; and
3. Enriching physician or provider patient data in a continuing manner.

Enhanced utility and clinical acceptability of HRAs are likely affected by the following factors:

1. Duration of HRA completion/convenience;
2. Evidence of questions and quality of intervention; and
3. Continuity with current or prospective medical care and direct follow-up contact.

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Thus, specific related author recommendations include:

1. Keeping initial HRAs brief, and expanding HRA instruments when illness-specific risks are identified;
2. Keeping prototype HRAs strictly evidence-based until further research is conducted;
3. Linking HRA results to clinical intervention, including screening and diagnostic tests; and providing direct patient feedback (depending on the particular risk, this may range from a trained-worker telephone conversion to an appointment with a health-care provider).

Despite an abundance of available HRA instruments, no data exists to support their widespread adoption, as required by Section 4103 of the Affordable Care Act. Per previously stated conclusions, the author believes a straightforward HRA instrument based on current and accepted secondary prevention guidelines, such as those from the USPSTF, offers overall, and at present, the most reasonable approach to developing a standardized HRA instrument.

Geoffrey B. Crawford, M.D., M.S.

## Weight Watchers International

### *Recv'd 1/7/11*

Transformation of our nation's health care system from an illness-treatment system to a health and wellness system is a vital and achievable goal. Tools to empower and enable consumers to make healthy choices will be key to this transformation. The evidence is clear, small advances in healthy living, such as sustained weight loss of just 10%, reduces the likelihood of type II diabetes by 50%<sup>1</sup> and reduces lifetime medical costs by \$22002. Health Risk Assessments (HRA), used by a number of employers as a means to establish personalized programs to promote and maintain wellness, provide an initial component to prevention. The published guidance does an excellent job of setting out the process of incorporating HRAs into the health system. But, in order to truly make a difference in health and wellness the system cannot simply be limited to the completion and documentation of an HRA. Rather, the HRA needs to be acted upon with appropriate referrals and measurements of health outcomes, such as change in body mass index, reduced visceral fat, blood pressure or other health measure. We suggest that CDC's guidance for HRA's specify that primary care providers provide referrals and evaluate HRA performance with outcomes (as opposed to process) measures. In summary, we recommend that outcome measures include health outcomes measures vital to the success of HRAs. Specifically:

Rate of referral to appropriate providers for tobacco cessation, high intensity weight control programs, or other life-style management;

Rate of participation in appropriate programs such as tobacco cessation, obesity treatment or other life-style management; and

Change in key health outcomes like blood pressure or body mass index.

Weight Watchers' 45 years of experience providing education, tools, and support to empower people to manage their weight for healthy outcomes understands the vital role primary care providers play in helping patients identify and understand their health risks **and take action to address those risks**. We believe a broad array of effective, scaleable, scientifically proven solutions for dietary and healthy living must be made consistently available to individuals. HRAs, as tools to assist primary care providers, will be effective only in combination with referrals and measurements of health outcomes. We applaud the agency's work to promote and ensure tools exist to support primary care providers in

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moving to an evidence based health and wellness system that includes a range of healthy living and weight management support for those with obesity and weight related chronic illness.

Sincerely,

Karen Miller-Kovach, MBA, MS, RD

Chief Scientific Officer

Weight Watchers International

## Care Continuum Alliance

Recv'd 1/3/11

On behalf of the Care Continuum Alliance, I respectfully submit the following comments to the Centers for Disease Control and Prevention in response to its Nov. 16, 2010, *Federal Register* Request for Information (RFI) on the development of Health Risk Assessment (HRA) Guidance. Care Continuum Alliance members provide services across the entire continuum of care, from wellness and prevention to chronic care and complex case management. Care Continuum Alliance members include wellness and population health management organizations, health plans, physician groups, hospitals, labor unions, employer organizations, pharmaceutical manufacturers, pharmacy benefit managers, health information technology (HIT) service and device suppliers, academics and others. These diverse organizations share the vision of aligning all stakeholders toward improving the health of populations. Our members seek to improve health care quality and contain health care costs at a population level by providing targeted interventions and services to individuals who are well, at-risk for or already managing one or more chronic conditions or acute episodes of care. Through advocacy, research and promotion of best practices, the Care Continuum Alliance advances evidence-based strategies to improve quality, health outcomes and create efficiency in the marketplace.

As we stated in our response to the proposed Medicare physician payment rule issued July 13, 2010, the new Medicare annual wellness visit presents an important opportunity to improve the health and well-being of Medicare beneficiaries. The ability to identify individuals at risk for chronic conditions and design "personalized prevention plans" for them greatly increases the likelihood of early detection of disease. Particularly important, the cost savings associated with healthier beneficiaries can contribute to Medicare's long-term sustainability. <sup>1</sup>

The HRA is essential to identifying individuals at risk for, or currently managing, chronic illness. The HRA tool is a mechanism to survey patient health status and health behaviors and to better understand and evaluate risk factors. These important tools provide individualized feedback, as well guidance on who would benefit from a wellness program. The use of sophisticated HRA tools enables targeted programs designed to benefit these individuals and provide services and support based on current health status. The development of a personalized prevention plan and targeted programs for Medicare beneficiaries is the key goal of Section 4103. These tools have Evidence report and evidence-based recommendations: health risk appraisals and medicare. Baltimore (MD): Centers for Medicare and Medicaid Services; 2003. Contract no. 500-98-0281. been shown to improve health care status and quality and reduce health care costs. Numerous studies have demonstrated the value of the HRA in identifying risks, particularly in older adults and Medicare beneficiaries. HRAs increase patient engagement and lead to medical cost savings are particularly compelling with respect to the Medicare population.

The Care Continuum Alliance supports the collaboration between the CDC and Centers for Medicare and Medicaid Services (CMS) to develop guidance on HRA use in conjunction with the annual wellness visit authorized for Medicare beneficiaries under Section 4103. This guidance will be useful in developing appropriate HRA tools for use in various practice and health care delivery settings and with varied segments of the Medicare population. The Care Continuum Alliance strongly recommends that the CDC and CMS not develop a standardized

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HRA tool for universal use among physician practices, health care delivery settings and patient populations. The RFI appropriately notes “considerable” variation in HRAs in the commercial marketplace. A “standard HRA” designed for universal application would not allow flexibility in the design for differing populations in both the Medicare fee-for-service program and in commercial Medicare Part C programs.

As a starting point, we strongly urge CDC to consider allowing the use of HRAs that have been accredited or certified by nationally recognized independent quality organizations, such as the National Committee for Quality Assurance (NCQA) and URAC. HRA standards are part of both NCQA and URAC’s accreditation for wellness programs and companies. Accreditation allows for continued evaluation, updating and flexibility as new evidence becomes available and allows standards to evolve. In addition, accreditation provides the flexibility to design and use HRAs that meet the needs of differing patient populations. Considering the positive relationship between HRA use and health promotion participation, reduced medical costs, healthful behaviors and improved health status<sup>5</sup>, CDC should move quickly to allow the use of accredited HRA tools. The RFI queries the capacity of primary care offices to administer, assess and utilize HRAs effectively. The RFI also considers entities to provide technical assistance with these tasks. Care Continuum Alliance members can play a vital role in supporting and assisting physician offices and other care delivery sites with these tasks. Health support services, as well as HIT capabilities, are critical to effectively support personalized prevention planning for patients by primary care physician offices.

The RFI queries the role, if any, incentives play in motivating patients to take the HRA and/or participate in follow-up interventions. Care Continuum Alliance strongly supports the use of incentives to increase HRA participation rates. Incentives significantly enhance HRA participation among patients. These incentives prove to be particularly effective when operating in tandem with coordinated workplace “health promotion” plans that include follow-up. This evidence demonstrates the central role of incentives in driving HRA participation, given the positive and strong link between incentives and patient engagement in wellness programs.

Finally, the Care Continuum Alliance recognizes the importance of patient and family engagement in managing one’s health. Completion of an HRA is a critical step in providing a baseline of health risk status but also contributes to greater patient education and self management and supports informed decision making by providers and patients. The Care Continuum alliance recognizes the crucial role of individuals in managing their health care, especially those with chronic conditions. We define self management as: “ongoing processes and actions taken to manage/control one’s own condition, with the goal of improving clinical outcomes, health status and quality of life.”<sup>8</sup> A recent study of the association between repeat participation in health risk appraisal and change in health status examined the use of an HRA that contained more than 60 questions, including those about lifestyle behaviors, medical conditions and use of preventive services. The researchers found that taking an HRA more than once was associated with desired changes in health status. They concluded that, “Combined with other education and intervention programs, HRAs can be useful tools in promoting and maintaining healthy lifestyles.

We appreciate the opportunity to provide comments on this request for information and would be pleased to provide additional information.

Sincerely,

Tracey Moorhead  
President and CEO

**Kaiser Permanente**

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*Recv'd1/4/11*

Kaiser Permanente appreciates the opportunity to comment on the implementation of Section 4103 of the Affordable Care Act (ACA), which requires that a health risk assessment (HRA) be included in the annual wellness visit benefit covered for Medicare beneficiaries under the ACA.

Kaiser Permanente is an integrated delivery system with a comprehensive electronic health record and clinical information system, robust research capacity, and a commitment to providing evidence-based care. Kaiser Permanente serves almost one million Medicare beneficiaries who are enrolled in our Medicare Advantage and Medicare Cost plans, and offers these Medicare members and all its other 7.6 million members an online, standardized HRA. The Kaiser Permanente HRA, called the Total Health Assessment, is a tool our members voluntarily complete at their convenience. Completed Assessments are linked to broader health promotion, education and outreach activities that Kaiser Permanente offers, including an electronic health coaching program.

Kaiser Permanente recommends that the CDC's guidance for HRAs be grounded in the following principles:

The HRA should strive to collect information for effective patient engagement and prediction of risk that is actionable on the part of the patient and/or clinician;

The HRA should be aligned with performance improvement goals and measures for Medicare plans and providers (i.e. falls prevention, Health Outcomes Survey). This alignment should avoid redundancy and inefficiencies that arise from multiple, disparate requirements across the Medicare program;

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The core questions posed by the HRA should be parsimonious and prioritized, with the capability to tailor or “drill down” with additional questions for patients depending on patient responses and conditions (branch chain logic);

The core questions posed by the HRA should emphasize current health and functional status relevant to the Medicare population as well as health risks, prioritizing opportunities for significant improvement. All risks are not the same in terms of impact or ability to mitigate;

The CDC should acknowledge that other tools for assessing patients and making predictions may be more effective for population health interventions than the HRA. While the HRA is valuable for patient self-assessment, clinicians in integrated delivery systems may have other, more accurate electronic tools for predictive risk modeling to drive successful clinical interventions.

## **Aspects of Health Risk Assessments**

### Content and Design

To increase the likelihood that beneficiaries will complete the HRA, it should be limited to a core set of questions focusing on behaviors that have the greatest impact on health, and should be available in formats that are accessible to beneficiaries with limited health literacy and limited English proficiency. The HRA should also be “smart” and include additional questions that are triggered by answers indicating the presence of disease, frailty, or elevated risk. The ideal HRA should function on its own by giving prompt, tailored, actionable information directly to the beneficiary after completion, thus providing a motivated beneficiary completing the tool immediate feedback on his/her responses. In this regard, a completed HRA is both a health education document as well as a means to help patient and clinician address the beneficiary’s clinical needs more effectively. The completed HRA tool should generate summary reports focused on actionable items for the physician, and be easily importable into electronic health records.

### Mode of Administration

Multiple modes of administration should be permitted and evaluated. To minimize cost and maximize completion rates, automated telephone outreach to administer the HRA, online administration and completion, and kiosks or handheld devices that are available in waiting rooms are modes that can be effective. Electronic forms of administration should be encouraged over paper based assessments to make the information usable (and trendable) over time. Regular reminders similar to patient reminders for screenings can also be used to encourage beneficiaries to refresh their HRA annually. Outreach to new members

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enrolling in Medicare managed care plans to encourage the completion of the HRA in advance of their initial visit would likely improve the effectiveness of, and satisfaction with, the annual wellness visit.

#### Primary Care Capacity

The HRA should help improve health outcomes and primary care performance, but if not designed and administered effectively, it could distract or overwhelm primary care clinicians with information that may not help them focus on relevant, high value interventions. Reports generated by the HRA should be automatically shared with the beneficiary's primary care physician unless the beneficiary affirmatively "opts out" of such sharing. Because one essential role of the HRA is to serve as a health education tool and thereby facilitate a beneficiary's self-care, the HRA should also be linked with up-to-date health education and promotion materials tailored to the beneficiary's responses. Any preventive screenings or vaccinations prompted by the HRA should be age appropriate and reflect USPSTF A or B recommendations. Disease management programs that may be coordinated with the HRA should also be integrated with the primary care practice and the patient's care plan. Primary care practices should have the flexibility to manage and use information generated by the HRA in a manner appropriate for the practice.

The HRA should not be viewed as the only, or the ideal, tool to perform certain functions. Physicians and other members of the care team may utilize other tools to identify and stratify risk, engage patients, perform outreach and follow up, etc. KP HealthConnect, Kaiser Permanente's comprehensive electronic health information system, offers our clinicians more robust tools than a HRA to provide complete and proactive care as well as patient engagement and convenience through mechanisms such as an after-visit summary, emailing to and from clinicians, outreach letters or other modes of communication (e.g. IVR) and electronic prescription re-fills. In short, the HRA may be a more valuable tool for beneficiaries than for clinicians. While HRAs are effective for understanding the beneficiary's perspective and perceptions, additional information can and should be sought and used by clinicians forming care plans. We would not support requirements on how clinicians must use the isolated data contained within the HRA.

#### Consumer/Patient Perspective

The HRA is a tool that reflects beneficiary self-reported information and should be controlled by the beneficiary. Appropriate privacy protections are important to promote beneficiary trust. The HRA can contribute to patient engagement or activation, and can help a beneficiary better prepare to interact with his or her physician or other clinician. By informing the beneficiary that his/her completed HRA will be shared automatically with his/her primary care physician unless he/she affirmatively "opts out", the beneficiary can be assured of having the

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used, validated, and useful for benchmarking and prediction. In contrast, HRAs are non-standard and proprietary, and have not been subjected to rigorous external or peer review. Kaiser Permanente recommends that HHS incorporate the components of the HOS and similar instruments with the strongest evidence base into the design of the HRA to leverage the potential of both tools to enable clinicians to focus high value interventions on the appropriate beneficiaries. In addition, we recommend that HHS invest in additional research to identify the features and factors that can improve the effectiveness of the HRA for beneficiaries and clinicians.

Sincerely,



Amy Compton-Phillips, M.D.  
Associate Executive Director, Quality  
The Permanente Federation, LLC



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Senior Vice President, Quality and Care Delivery Excellence  
Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals

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## Group Health Cooperative

Group Health Cooperative (“Group Health”) appreciates the opportunity to comment on Section 4103 of the Affordable Care Act (ACA), which requires that a health risk assessment (HRA) be included in the annual wellness visit benefit authorized for Medicare beneficiaries.

Group Health is one of America’s oldest and largest consumer-governed health care organizations. Founded in Seattle in 1947, the organization is governed by consumers. It’s a leader in integrated care, and an important voice for health care reform. We provide coverage and care to more than 628,000 residents in Washington State and Northern Idaho who are covered by our health plans and get their care from Group Health physicians and nurses in one of our medical centers or from our more than 9,000 contracted community providers.

Group Health has been a leader and innovator in the use of health information technology to improve and enhance quality and access to care. We began converting to electronic medical records (EMRs) in 2000, and today have a full suite of tools to help ensure that our patients get the right care at the right time. Beginning in 2007, Group Health developed and integrated an evidence-based health risk appraisal (the “Health Profile”) into its system-wide electronic medical record. Since that time, more than 125,000 adult enrollees have completed the Health Profile that integrates their personal health risk information into their electronic records for shared use with their clinical teams.

Group Health believes HRAs are key in empowering patients to improve their health by providing personalized messages that link them with appropriate resources and programs. Furthermore, we believe that providing the information obtained in the HRA to clinicians through the EMR interface is important, given clinicians central role in engaging patients in evidence-based health promotion, prevention, and chronic illness care. Based upon our considerable experience with HRAs in the clinical environment, HRAs should offer immediate recommended actions to patients and decision support to providers, along with general estimates of health risk and health care needs. This can enable the application of best available evidence with respect to primary, secondary, and tertiary prevention.

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Moreover, Group Health strongly supports the development and application of patient-centered and evidence-based HRAs that comprehensively meet the ongoing health needs of Medicare patients. HRA topics for Medicare patients should address risky health behaviors (e.g., alcohol use, physical inactivity, tobacco use, overweight/obesity), chronic illness management (e.g. diabetes, congestive heart failure), mental health (e.g. depression), preventive screenings (e.g. abdominal aortic aneurysm), immunizations (e.g., influenza, pneumococcal disease, herpes zoster), chemoprophylaxis (e.g., aspirin, statins, calcium), frailty (e.g., difficulty with household tasks), medication management, and advance directives. HRAs should also be behaviorally based to support patient self-management. The selection of questions and scales for the Medicare population should be based on best available evidence about psychometric validity, reliability, and responsiveness to effective clinical interventions for this population. Because the Centers for Medicare and Medicaid Services (CMS) links its prevention coverage policies to the United States Preventive Services Task Force (USPSTF) recommendations, we also recommend that an HRA recommend, at a minimum, those screenings, behavioral counseling interventions, and prophylactic medications that have received either an 'A' or 'B' recommendation from the USPSTF. Those services that have received a 'C' recommendation should encourage patients to discuss carefully the risks and benefits of these preventive services, and those with a "D" recommendation not be encouraged in the feedback report.

The design of HRAs must also take into account the burden laid upon the elderly Medicare population for completing the series of questions within the HRA. To alleviate this burden, Group Health strongly advocates for sophisticated and tailored branching logic to be applied to the questionnaire in order to avoid irrelevant questions being presented to individuals. In addition, we recommend that questions are only included if they address health issues for which there is strong scientific evidence for their immediate clinical utility.

Finally, we also believe that, to the maximum extent possible, HRAs should be integrated with EMRs with a two-way data flow. A two-way flow model takes advantage of prior medical information (e.g. prior blood pressure readings imported from EMRs), to help reduce the burden on the patient to gather information from various sources and input in a separate system. Additionally, a two-way flow model promotes the identification and documentation of health risk by clinical teams and assists with prompting the application of evidence-based care.

We appreciate the opportunity to provide the following comments (Attachment A) for your consideration, and your willingness to consider these comments as you develop the objectives and measures for HRAs.

Sincerely,



Megan Grover  
Director, Regulatory Affairs  
Group Health Cooperative