



## **Interim Guidance for Health Risk Assessments and their Modes of Provision for Medicare Beneficiaries**

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## **Introduction**

The Patient Protection and Affordable Care Act of 2010 (Affordable Care Act)<sup>1</sup> authorized an annual wellness visit (AWV) for Medicare beneficiaries. The Affordable Care Act specifies that a health risk assessment (HRA) be included as part of that visit. The HRA is a collection of health-related data a medical provider can use to evaluate the health status and the health risk of an individual. An HRA will identify health behaviors and risk factors known only to the patient (e.g., smoking, physical activity and nutritional habits) for which the medical provider can provide tailored feedback in an approach to reduce the risk factors as well as the potential inevitability of the diseases to which they are related. At the request of the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC) is providing initial guidance to CMS regarding HRAs and their modes of provision for Medicare beneficiaries.

This HRA guidance incorporates the best available evidence and expert advice from those working in the field of HRA and wellness as well as the general public. A citation to a compilation of proceedings from the development process conducted by Partnership for Prevention, a CDC grantee, is provided in the reference section of this document.<sup>2</sup> Partnership for Prevention is a non-profit organization whose focus is to ensure the prevention of disease and the promotion of health, based on the best scientific evidence, is the first priority for policy makers, decision-makers and practitioners.

## **Affordable Care Act Requirements**

Affordable Care Act Section 4103(b)<sup>1</sup> states that an HRA is to be completed before, or as part of, an annual wellness visit with a health professional who may be a physician, medical practitioner, medical professional (e.g., health educator, registered dietician, nutrition professional) or a team of medical professionals. The law specifies that the HRA:

- 1) must identify chronic diseases, injury risks, modifiable risk factors, and urgent health needs of an individual (Element 1)
- 2) may be furnished through an interactive telephonic or web-based program (Element 2)
- 3) may be offered during the encounter with a health care professional or through community-based prevention programs (Element 3)
- 4) may be provided through any other means appropriate to maximize accessibility and ease of use by beneficiaries, while ensuring the privacy of beneficiaries (Element 4)

Section 4103(b)<sup>3</sup> further requires the Secretary to establish standards for interactive or web-based programs used to furnish HRAs. Following a review of current literature, CDC identified 6 areas that were important to address in the development of a HRA and delivery. The 6 areas

are: 1) content and design, 2) mode of administration, 3) primary care office capacity, 4) consumer/patient perspectives, 5) data, and 6) evaluation and quality assurance. Certification issues were also addressed as a part of evaluation and quality assurance. Additional detail regarding these areas is provided in the proceedings document referenced above.

## **Guidance Development Process**

- CDC published two Federal Register Notices (FRNs) on 11/16/10<sup>4</sup> and 12/30/10<sup>5</sup>, respectively; the former requesting information from the field and the latter announcing a public forum on February 1-2, 2011.
- CDC received approximately 50 comments from the field and about 100 individuals attended the public forum. The public forum attendees were experts from the field of HRA development and other interested parties and provided individual input into areas of emphasis, such as content and design, mode of administration, primary care office capacity (including health information technology (HIT), data collection, security, and utility).
- CDC convened an internal subject matter expert workgroup, and Partnership for Prevention convened an external expert workgroup and gathered additional information from the field. These groups addressed the 6 domains identified as critical for HRA.
- Partnership for Prevention compiled the information from the external workgroup. CDC reviewed the comments received from the FRN Request For Information and provided that information to Partnership for Prevention. Additional information was obtained during the public forum and was used to further inform the guidance.

## **Health Risk Assessment—Overall**

The HRA is intended to be a self-reported assessment completed before or during the annual wellness visit and may include some reconciliation with biometrics obtained by the provider. (e.g., blood lipids and glucose, blood pressure, etc.). During the visit, the HRA information, and other biometrics available are utilized by the practitioner in a thought process intended to develop a prevention plan for the patient to improve health status and delay the onset of disease known to be caused by the reported behavioral risks or the patient's current health status. The practitioner can, in a shared decision making process with the patient provide feedback in the form of educational messages, counseling or referrals related to changing high risk behaviors and health habits. This feedback can potentially improve health behaviors and/or alter one's risk of disease, improve chronic disease management or likelihood of premature death<sup>6</sup>.

## **General Guidance**

- All questions included in the HRA must be actionable (e.g., for a question about smoking behavior to be included, a smoking cessation program must be shown to be efficacious in reducing that behavior and available, if the patient chooses to attend).
- Feedback the patient receives from the provider regarding the HRA results should be the result of shared decision making, (i.e., following the provider's development of a risk behavior profile, prioritization of risks, and goal setting). The evidence suggests that focusing on what matters to the patient is more likely to elicit change in high risk behaviors.
- The HRA should be written at a 5<sup>th</sup> or 6<sup>th</sup> grade literacy level and in plain language.
- The HRA should be linguistically, age, gender, and culturally appropriate for the patient.
- To ensure compliance with current science related to health promotion and disease prevention and to take advantage of anticipated advances in new technology, the HRA and the delivery systems should be reviewed no less than every 2 years.

There are 4 elements to the HRA that evidence suggests can result in reduction of some risk factors.

### **HRA element 1. Identification of chronic diseases, injury risks, modifiable risk factors, and urgent health needs**

The HRA will provide information related to patient behaviors that only the patient knows (e.g., self perception of health, self-efficacy, smoking behavior, etc.). It can provide a more efficient use of resources, if information related to patient demographics, biometric values, medical history, and clinical preventive services use is prepopulated in the HRA record.

The HRA could supplement data collected through other means, such as physical examination, laboratory tests and clinical preventive screening results. The provider will use all of this information to identify urgent health needs, existing chronic disease(s), and high risk behaviors (including risk of injury) that cause morbidity and disability.

### **CDC guidance**

The following questions/topics to be addressed in the HRA is a compilation of the current scientific evidence and are intended for Medicare beneficiaries as appropriate for their age:

- Demographic data collected, such as age, gender, race and ethnicity data should be consistent with current federal standards
- Self assessment of health status, frailty, and physical functioning.

- Biometric assessments
  - Height, weight, body mass index (BMI)
  - Systolic/diastolic blood pressure
  - Blood lipids (HDL/LDL and total cholesterol, triglycerides)
  - Blood glucose
- Psychosocial risks
  - Depression/life satisfaction
  - Stress/anger
  - Loneliness/social isolation
  - Pain/fatigue
- Behavioral risks
  - Tobacco use
  - Physical activity
  - Nutrition and oral health
  - Alcohol consumption
  - Sexual practices
  - Motor vehicle safety (seat belt use)
  - Home safety
- The US Preventive Services Task Force (USPSTF) provides guidelines and recommendations based on current scientific evidence. The USPSTF recommendations are generally accepted standards for preventive clinical health care. Questions related to compliance with screenings, behavioral counseling, and chemoprophylaxis receiving an “A” or “B” recommendation from the U.S. Preventive Services Task Force for the age and gender of the population served should be included in the HRA
- **Current evidence suggests that the following domains specific to the  $\geq 65$  year-old Medicare population be included in the HRA:**

- **Memory**—note that cognition assessment is not part of the HRA itself, but rather an additional aspect of the AWW, as are routine measures of vision and hearing.
- **Activities of daily living (ADLs)**—i.e., dressing, feeding, toileting, grooming, physical ambulation, including balance/risk of falls, and bathing.
- **Instrumental activities of daily living (IADLs)**—i.e., shopping, food preparation, using the telephone, housekeeping, laundry, mode of transportation, responsibility for own medications, and ability to handle finances.

## HRA elements 2, 3, 4. Delivery of the HRA

The HRA should be available to all individuals who are eligible to receive the Medicare Part B AWV and should be furnished via web-based, interactive telephonic or paper-based systems. The HRA should take no longer than 20 minutes to complete.

### CDC guidance

- Access to a meaningful HRA requires accommodations for individuals with physical, sensory, or cognitive limitations. For patients with low vision or blindness, alternative formats such as large print, versions in Braille, or audio administration may be required. Individuals with cognitive limitations may need the support of a caregiver.
- In compliance with the Office for Civil Rights; Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as It Affects Persons With Limited English Proficiency, the HRA should be available in a patient's preferred language.<sup>7</sup>
- Section 508 of the Rehabilitation Act of 1973 and Rehabilitation Act Amendments of 1998 mandates that all software developed by federal agencies allow access to and use of information and data by individuals with disabilities.<sup>8</sup>
- **Web-based** —The preferred modality for HRA administration is Internet. The Internet mode should ideally communicate with the physician Electronic Medical Record (EMR) or Personal Health Record (PHR) systems, or both. The standards should be consistent with guidance from the Office of the National Coordinator for Health Information Technology (ONC).<sup>9</sup> Physician offices have varying capacity in terms of adoption and readiness for electronic medical records, so the following stratified approach should be considered:
  - Patients with functioning electronic PHR systems: When the patient has a functioning PHR system they could complete and store the information within the PHR (potentially the PHR could pre-populate some data). In tethered EHR-PHR systems (i.e., the PHR is provided as an element of the clinician's EHR) the information could be accessed by the provider directly. In untethered PHRs, patients could send or bring data to the provider, either electronically or in hard copy.
  - Medical provider offices with a functioning EMR system: The HRA can be tied into the EMR system so the data entered by the patient can be seen by the provider at the time of the visit and noted within the EMR.
  - The HRA data entry should use a secure web-based system from home or a kiosk/computer-based or paper-based instrument at the time of visit. Both of those data entry mechanisms can be tied to the tethered EMR-PHR system.
  - Physician offices without a functioning EMR system could use the web-based or kiosk-based data entry mechanism. The health assessment data could be stored in a secure untethered PHR system or alternatively stored on a physical device such as

CD or DVD that can be made available by the patient to the health provider at the time of visit.

- **Interactive telephonic**—Furnishing HRA via an interactive telephonic system will sometimes be necessary for those patients with physical disabilities, such as blindness or other print disabilities.
  - The system should be programmed using generally accepted standards of nationally recognized professional technology organizations.
  - The system should be developed with potential future expansion or changes and health risks and information technology advances in mind.
  - Similar to the HRA administered by other modes, the interactive telephonic system should be reviewed periodically (at least every 2 years).
- **Paper based**—A paper-based HRA should be deployed in places where neither EMR nor Internet access is available or patient’s disability, accessibility, or literacy limitations do not allow them to participate in other modes. Paper-based questionnaires could be scanned into digitized format.

## Conclusion and Future Activities

To maximize the benefits of the HRA, follow-up interventions are necessary for skill building, developing new health habits, and maintaining behavior change. Experts agree that HRAs alone are not adequate to realize improved health outcomes or even long-term change in health behavior.<sup>10</sup> To realize the full potential for improved health outcomes in the elderly population and others, further development is needed to guide health professionals through the ongoing follow-up that patients require to make changes in their behavior and to successfully self-manage their chronic diseases. The following next step will be taken by CDC with input from other federal agencies and experts:

*A Framework for Patient-Centered Health Assessments, a Morbidity and Mortality Weekly Report (MMWR)*, will be published by CDC later this year. The *MMWR* will include information critical for the successful implementation of the HRA, such as this report, as well as information related to implementation, feedback, and follow-up that evidence suggests is critical for improving health outcomes using this process. Additional concepts to be addressed in the *MMWR* include the following:

- **Framework**—context of AWP and the HRA, including moving the US health system from illness-based to wellness-based care, including the tools and support required to accomplish the change.



- **Patient-centeredness**—concept of patient responsibility and control of one’s health, patient expectations of providers and the system.
- **Health Assessment (more than risk)** —includes patients who can improve self-management of chronic diseases, those who are currently well, and remaining so (even becoming healthier) and living independently longer.
- **Issues regarding implementation of follow-up care and monitoring of health promotion interventions or activities**—i.e., how to monitor follow-up, and by whom? Current models utilizing community health teams, medical homes, accountable care organizations (ACOs), health coaches, and wellness providers have shown promise in improving outcomes.
- **Additional issues**—include reimbursement models and incentives for both the provider to offer the AWV and for the beneficiary to access it? What metrics will be utilized to measure success?
- **Quality assurance**—issues regarding what aspects of the AWV, the HRA and personalized prevention planning should be evaluated, how and by whom?
- **Certification**—if the HRA and/or wellness process is certified, what guidance should be provided to certifying agencies?
- **Data**—in the ever changing environment of health information technology, data access, use, storage, and security are critical issues that should be further delineated to enable the HRA to reach its full potential of improving health outcomes.

## References

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