REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3-I-17

Subject: Non-Physician Screening Tests (Resolution 901-I-16)

Presented by: Paul A. Wertsch, MD, Chair

Referred to: Reference Committee J (Peter C. Amadio, MD, Chair)

At the American Medical Association's (AMA) 2016 Interim Meeting, the House of Delegates referred Resolution 901, "Disclosure of Screening Test Risk and Benefits Performed without a Doctor's Order," submitted by the American College of Radiology, and the Virginia, Alabama, Georgia, Kentucky, District of Columbia, Mississippi, West Virginia, and South Carolina Delegations. The Board of Trustees referred this issue to the Council on Medical Service for a report back to the House at the 2017 Interim Meeting. Resolution 901-I-16 asked:

> That our AMA (1) advocate that if a screening test is being marketed as having a medical benefit and is offered and performed by a wellness program vendor without a specific order by the individual's physician or other licensed provider, they must provide the patient with the test specific evidence based guidance that supports the utility of the test; (2) advocate that if the procedure is not supported by specific evidence based guidance as a screening test for that patient and the patient still would like the screening test, the Wellness Program Vendor must offer the patient the opportunity to discuss the risks, benefits, and alternatives with a physician licensed to practice medicine in the state in which the test is being performed; (3) engage with federal regulators on whether vendors of health and wellness programs are in compliance with regulations applicable to marketing to patients in view of the impact of such programs on patients; and (4) where possible, continue to work with state medical societies, interested medical specialty societies and state agencies to provide public education regarding appropriate use of vendor wellness programs.

This report provides background on wellness program vendors, particularly focusing on employer-offered wellness programs, discussion on payment for vendor screenings, an overview of the clinical guidelines for screenings, an outline of the relevant legislation, and a series of policy recommendations regarding vendor wellness screenings.

BACKGROUND

Much of today's health care system was created to provide diagnosis and treatment versus wellness and prevention. However, not only are many diseases preventable but also there are sustained concerns about health care spending. Accordingly, recent years have brought a focus on wellness and prevention. Codified in statutes like the Affordable Care Act (ACA), wellness programs have become a cornerstone in employer and health plan behavior.

More than 5,600 vendors reportedly generate annual revenue of $8 billion in the wellness industry, of which $6 billion is attributable to the workplace wellness industry.[1] Many employers now provide wellness programs to employees in an effort to help employees maintain their health and reduce health care costs. The workplace wellness industry generally consists of vendors that sell companies stand-alone wellness programs or programs that are an optional part of the employee's health insurance. In addition, some screening services are provided outside of the employer-based wellness program and are often accessed at wellness centers. The Council notes that the scope of this report is limited to basic screenings by a wellness vendor and does not encompass genetic testing. Notably, CMS/CSAPH Joint Report, "Precision Medicine," also presented at the 2017 Interim Meeting, addresses payment and coverage of genetic testing.

Several companies market wellness screenings, personalized health screenings, and biometric screenings. These services are performed outside of the traditional patient-physician setting and are often marketed to employers as wellness screening programs for their employees. The services provided vary, but they usually include a number of blood tests; ultrasound imaging for conditions, such as abdominal aortic aneurysm, carotid artery disease, and bone density; ankle-brachial index for peripheral artery disease and cardiovascular disease; and sometimes electrocardiogram. Other services include body composition analysis (e.g., body fat percentage, visceral fat, muscle mass and distribution, body water balance, total body weight, body mass index).

The increasing availability of direct-to-consumer screening tests may undermine physician efforts to provide high-quality, cost-conscious screening services to patients through shared decision-making. The wellness vendor screening services at issue are not usually administered by physicians but instead by technicians or other non-physician health professionals outside of traditional health care settings. However, many of these vendor companies have physicians as part of their leadership teams serving as medical directors or members of an advisory board. Some companies are located in retail settings, and others offer services via the internet. Occasionally, the websites of these vendor companies include a disclaimer encouraging those who are interested in testing, or those who have received abnormal test results, to contact their physicians with questions. Some companies offer follow-up with a physician staff member if patients have questions about results.

PAYING FOR WELLNESS SCREENING TESTS

Employers continue to show interest in wellness and screening programs that help employees identify health issues and manage chronic diseases. Therefore, many firms pay for such screenings and tests and some offer financial incentives to encourage employees to complete the health assessments.[2] Many large employers offering health assessments, biometric screenings, and wellness programs offer participating employees lower premium contributions or reduced cost-sharing.[3]

Outside of the workplace wellness program paradigm, health insurance generally does not cover screenings that have not been recommended by physicians. Further, vendors generally make more money the more screenings they perform and therefore often recommend screenings for otherwise healthy people, a practice that has the effect of increasing overall health care costs.[4]

CLINICAL GUIDELINES FOR WELLNESS SCREENINGS

There is concern that the screening services provided by wellness vendors are not always supported by clinical guidelines. Vendor programs do not need to follow screening guidelines from the US Preventive Services Task Force (USPSTF) or other guideline-making bodies. For example, the USPSTF found insufficient evidence to recommend several wellness tests including high sensitivity

C-reactive protein testing for coronary heart disease risk and ankle-brachial index to determine risk for peripheral artery disease and cardiovascular disease.[5] Additionally, concerns exist about providing screening tests to large numbers of patients who may not need them. Wellness programs offer blanket screening tests for nearly anyone while most screening guidelines are tailored based on age, gender, and other factors. For example, the USPSTF recommends abdominal aortic aneurysm screening only in men ages 65-75 who are or have been smokers, and when these guidelines are not followed it leads to unnecessary tests for which a given individual may have no indication. Additionally, the larger the screened population, the higher the number of false positive and false negative results. False positive results could set off a cascade of invasive, expensive, and potentially harmful follow-up tests, and false negative results could lead patients to forego necessary care.

EFFECTIVENESS OF WELLNESS PROGRAMS

The return on investment for wellness programs and screenings is mixed. Often the programs fail to pay for themselves and confer no proven health benefit.[6] Commonly, wellness programs focus on two components: a lifestyle management program and a disease management program. The lifestyle management program focuses on individuals with health risks such as obesity and smoking while the disease management program is designed to help those who already have a chronic disease.[7] Programs focusing on disease management provide a greater return on investment than lifestyle management.[8] Overall, it is estimated that wellness programs reduced average health care costs by about $30 per member per month; however, 87 percent of savings were attributable to disease management programs that focus on interventions for individuals with already-diagnosed conditions in order to reduce complications and related health care utilization.[9] Additionally, it is expensive for employers to pay for wellness program screenings and incentives, and interventions such as subsidizing healthy food choices and reimbursing employees for gym memberships may prove more beneficial.[10,11]

RELEVANT REGULATIONS

Many states have laws allowing patients to order their own laboratory tests. Additionally, the claims of efficacy made by the vendors are subject to Federal Trade Commission rules on truth-in-advertising, and therefore the claims must be truthful, not misleading, and must be substantiated. Many companies providing these services include language on their websites and other publications stating that test results do not constitute medical advice or diagnoses, thereby limiting their liability.

In response to public health concerns over an unregulated industry, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) to establish standards for diagnostic testing including standards related to safety guidelines, standards to ensure the accuracy and reliability of test results, and standards for laboratory staff, including appropriate level of training.[12] In order to operate, wellness vendors are expected to comply with these guidelines with respect to good practices and may then apply for and receive CLIA certification. Three federal agencies are responsible for the CLIA: The Food and Drug Administration, the Centers for Medicare and Medicaid Services, and the Centers for Disease Control and Prevention.[13] Eighteen states have rules and regulations in addition to CLIA, and some states require vendor licensure in their public health codes.[14]

Additionally, wellness programs must comply with a host of federal laws. These laws include the Employee Retirement Income Security Act (ERISA), the Americans with Disabilities Act (ADA), the Genetic Information Nondiscrimination Act (GINA), the ACA, and the Health Insurance Portability and Accountability Act (HIPAA).[15] HIPAA applies to wellness programs offered as part

of an employer's group health plan. Therefore, information collected from or created about participants in the wellness program as part of the group health plan is considered personal health information and is protected by HIPAA.[16]

RELEVANT AMA POLICY AND ADVOCACY

Policy H-425.996 on multiphasic health screening programs states that entities that operate or sponsor such multiphasic health screening programs should be urged to include in their promotional and explanatory materials about the availability of the program, a definitive statement that reports on the screening test results will be furnished to the individual participants only and that each participant is responsible for obtaining any needed medical evaluation or follow-up should the results of the tests deviate from the normal range. Those operating or sponsoring multiphasic health screening programs also should be urged to utilize report forms that state in bold type that the report does not constitute a medical diagnosis or evaluation and that the participant should consult a physician of his or her choice if the screening test results are not within the normal limits indicated on the report. Policy H-425.997 more generally states that preventive care should ideally be coordinated by a patient's physician.

Policy H-425.994 states that the evaluation of a healthy person by a physician can serve as a convenient reference point for preventive services and for counseling about healthful living and known risk factors and that the testing of individuals should be pursued only when adequate treatment and follow-up can be arranged for the abnormal conditions and risk factors identified.

To promote continuity of care, Policy H-160.921 states that retail health clinics must establish protocols for ensuring continuity of care with practicing physicians within the local community and that retail health clinics should be encouraged to use electronic health records as a means of communicating patient information and facilitating continuity of care. Further, Policy H-160.921 states that retail health clinics should encourage patients to establish care with a primary care physician to ensure continuity of care.

Policy D-35.985 recognizes non-physician providers as valuable components of the physician-led health care team. With respect to the health care team, Policy H-275.976 states that the health professional who coordinates an individual's health care has an ethical responsibility to ensure that the services rendered are provided by those whose competence and performance are suited to render those services safely and effectively.

Policy H-330.879 on providers and Medicare's Annual Wellness Visit (AWV) articulates principles reinforcing the need to protect against vendors fragmenting care and the need to preserve the physician-patient relationship. Specifically, Policy H-330.879 recognizes the need for safeguards in such circumstances and states that the AWV is a benefit most appropriately provided by a physician or a member of the physician-led health care team that establishes or continues to provide ongoing continuity of care. Further, this policy supports that, at a minimum, any clinician performing the AWV must enumerate all findings from the visit and make provisions for all appropriate follow-up care.

DISCUSSION

Though well intentioned, the wellness industry often has the effect of duplicating care that physicians are already providing, unnecessarily increasing physician workload, and obstructing the physician-patient relationship.[17] The Council believes wellness programs often incentivize unnecessary testing and practices that are contrary to evidence-based medicine and medical

judgment. Accordingly, the Council offers a number of principles intended to address these issues and advance the goal of reducing cost of care that does not add value and promoting quality care.

If protections are in place, evidence-based wellness programs can have a positive impact on health by encouraging healthy behaviors and proper disease management strategies. To that end and consistent with the intent of Resolution 901-I-16, the Council recommends that wellness program vendors must disclose for whom a screening test is indicated on the basis of accepted evidence-based guidelines. Additionally, the Council believes vendors must inform patients of the potential benefits and risks of performing a test and of positive or negative screening test results before a test is performed. The Council believes these principles will help bring vendor practices in line with evidence-based guidelines and aid patients in informed decision-making.

Further, the Council believes it is important that wellness program vendors disclose the qualifications of any individual performing the test as well as those individuals interpreting the test results. Moreover, wellness program vendors should use local physicians as medical directors or supervisors. These recommendations advance the goals of patient education and recognition that physicians are best suited to lead health care teams pursuant to AMA policy. In addition, the Council believes it is important that any policy on vendor screenings limits a physician's liability and protects against physician administrative burden. To that end, the Council recommends that results of a screening test should only be sent to the individual and that test results showing a positive or otherwise abnormal test result should require a consultation with the patient's primary care physician or usual source of care. Additionally, the Council recommends that physicians not be held liable for delayed or missed diagnoses indicated on third party vendor tests. The Council believes that this recommendation expressly reaffirms the rule that physician liability be limited when stemming from tests that have not been shared with the physician. Finally, the Council believes that Policy H-425.996 is outdated and that its recommendations herein regarding non-physician screenings supersede the policy and therefore recommends that Policy H-425.996 be rescinded.

The following recommendations complement the body of AMA policy on non-physician tests and care including that on the Medicare Annual Wellness Visit and retail health clinics. The Council approaches this issue with the belief that, if proper safeguards and guidelines are in place, such wellness program vendors can have an appropriate role in the health care system and help advance the goals of better, more cost effective care.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 901-I-16 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-425.994 stating that the evaluation of a healthy person by a physician can serve as a convenient reference point for preventive services and for counseling about healthful living and known risk factors. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-425.997 stating that preventive care should be coordinated by a patient's physician and encouraging development of policies and mechanisms to assure the continuity, coordination, and continuous availability of patient care, including preventive care and early-detection screening services. (Reaffirm HOD Policy)

3. That it be the policy of our AMA that any wellness program vendor providing non-physician ordered screenings should adhere to the following principles:

    a. Must disclose for whom a screening test is indicated on the basis of accepted evidence-based guidelines;

    b. Must inform patients of the potential benefits and risks of performing a test and of the implications of positive or negative screening test results before a test is performed;

    c. Must disclose the qualifications of any persons in contact with the patient and of any persons interpreting the results of any screening test;

    d. Should use local physicians as medical directors or supervisors in the appropriate specialty with the requisite state licensure;

    e. Should send results of any screening to the individual patient and to the primary care physician or usual source of care, upon patient request;

    f. Should require a consultation with the patient's primary care physician or usual source of care if a screening test shows a positive or otherwise abnormal test result; and

    g. If the test results are of a critical level or value, the patient should be contacted immediately and notified of the need for urgent or emergent medical evaluation. (New HOD Policy)

4. That our AMA support that physicians not be held liable for delayed or missed diagnoses indicated on wellness program vendor non-physician ordered screenings. (New HOD Policy)

5. That our AMA rescind Policy H-425.996. (Rescind HOD Policy)

Fiscal Note: Less than $500.

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