Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The evidence is adequate to conclude that screening for depression in adults, which is recommended with a grade of B by the U.S. Preventive Services Task Force (USPSTF), is reasonable and necessary for the prevention or early detection of illness or disability, and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

Therefore CMS proposes to cover annual screening for depression for Medicare beneficiaries in primary care settings that have staff-assisted depression care supports in place to assure accurate diagnosis, effective treatment, and follow-up. For the purposes of this decision memorandum:

- A primary care setting is defined as one in which there is provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, outpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospice are not considered primary care settings under this definition.

- At a minimum level, staff-assisted depression care supports consist of clinical staff (e.g., nurse, physician assistant) in the primary care office who can advise the physician of screening results and who can facilitate and coordinate referrals to mental health treatment.

- More comprehensive care supports include case management by a nurse or nonphysician working with the primary care physician; planned collaborative care between the primary care provider and mental health clinicians; patient education and support for patient self-management; plus attention to patient preferences regarding counseling, medications, and referral to mental health professionals with or without continuing involvement by the patient's primary care physician.

We are requesting public comments on this proposed determination pursuant to section 1862(l) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

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Proposed Decision Memo

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SUBJECT: Proposed Coverage Decision Memorandum for Screening for Depression in Adults
DATE: July 19, 2011

I. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The evidence is adequate to conclude that screening for depression in adults, which is recommended with a grade of B by the U.S. Preventive Services Task Force (USPSTF), is reasonable and necessary for the prevention or early detection of illness or disability, and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

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We are requesting public comments on this proposed determination pursuant to section 1862(l) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

II. Background

The USPSTF Recommendation Statement on "Screening for Depression in Adults" (December 2009) states the following:

- The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.
  Grade: B recommendation.

Depression is a mental disorder characterized by alterations in mood. "Mood disorders are recurrent, life threatening (due to the risk for suicide), and a major cause of morbidity worldwide."[1] The symptoms of depression have been recognized as far back as ancient times, with Hippocrates referring to it as melancholia. The diagnosis of depression is not based on objective diagnostic tests (such as biopsies or serum chemistries) but on a highly variable set of symptoms. Nestler and others have suggested that "…depression should not be viewed as a single disease, but a heterogeneous syndrome comprised of numerous diseases of distinct causes and pathophysiologies."[2,3] The origin of depression is believed to be multifactorial and includes psychological, social and biological factors.[4]

Among persons older than 65 years, one in six suffers from depression.[5] Depression in older adults occurs in a complex psychosocial and medical context, and the prevalence of clinically significant depression in later life is estimated to be highest (~25%) in those with comorbidities including cancer, arthritis, stroke, chronic lung disease and cardiovascular disease. Frequency of other stressful events, such as the loss of friends and loved ones, increases with age; and bereavement is an important and well-established risk factor for depression. Opportunities are missed to improve mental health and general medical outcomes when mental illness is under-recognized and undertreated in primary care settings; and a significant number of older adults with depression are not diagnosed or treated in the primary care setting. Beliefs that depression is normal with older age, as well as difficulties presented by patients with cognitive deficits, make identification of depression in older adults challenging.[6]

Depression wields significant public health impacts and economic costs. Pignone, *et al.* (2002), for instance, noted that depressive illness has substantial effect on healthcare utilization and is projected to be the second leading source of disability worldwide by 2020.[7] In 2003 Greenberg, *et al.* reiterated that the economic burden of depression is substantial and estimated that the combined U.S. direct and indirect costs of depression were $83.1 billion, including $31.5 billion in direct costs and the remainder in indirect, mostly workplace costs.[8]

Critically, older adults have the highest risk of suicide of all age groups. In fact, a 1992 NIH Consensus Development Panel on depression in older adults found most of these patients were experiencing their first episode of major depressive disorder, which had gone unrecognized and untreated.[9] Such patients are important in the primary care setting because > 50-75% of older adults who commit suicide saw their medical doctor during the prior month for general medical care, and 39% were seen during the week prior to their death.[10]

In the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV)[11] the criteria for a major depressive episode include five or more of the following symptoms, that have been present during the same two week period and represent a change from previous functioning, with at least one of the symptoms being either depressed mood or loss of interest or pleasure:

- Depressed mood most of the day, nearly every day, as indicated either by subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful);
- Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated either by subjective account or observation made by others);
- Significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day;
- Insomnia or hypersonic nearly every day;
- Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down);

- Fatigue or loss of energy nearly every day;
- Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick);
- Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others);
- Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or specific plan for committing suicide.

This decision memorandum does not deal with treatment options for depression but, in keeping with the USPSTF (2009) recommendation for depression screening, focuses on the identification of depressed patients in primary care settings and the need for staff-assisted support systems to be in place to assure their accurate diagnosis, effective treatment and follow-up.

More specifically, the scope of this memorandum is limited to the depression screening services described, and we are not considering our coverage policy for treatments of depression or any diseases, complications or chronic conditions resulting from depression. This analysis does not address therapeutic interventions such as pharmacotherapy, combination therapy (counseling and medications), or other interventions for depression. Self-help materials, telephone calls and web-based counseling are not separately reimbursable by Medicare and are not part of this analysis.

III. History of Medicare Coverage

Pursuant to §1861(ddd) of the Social Security Act, CMS may add coverage of "additional preventive services" if certain statutory requirements are met. Our regulations provide:

§ 410.64 Additional preventive services

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of “preventive services” under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.
(2) Recommended with a grade of A or B by the United States Preventive Services Task Force.
(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.[12]

Benefit Category

Additional Preventive Services

IV. Timeline of Recent Activities

March 3, 2011	CMS initiates this national coverage analysis for screening for depression. The initial 30-day public comment period begins.
April 1, 2011	Initial 30-day public comment period closes.

V. FDA Status

These services do not generally fall under the purview of the FDA.

VI. General Methodological Principles

When making national coverage determinations concerning additional preventive services, CMS applies the statutory criteria in §1861(ddd)(1) of the Social Security Act and evaluates relevant clinical evidence to determine whether or not the service is reasonable and necessary for the prevention or early detection of illness or disability, is recommended with a grade of A or B by the USPSTF, and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B of the Medicare program.

Public comment sometimes cites the published clinical evidence and gives CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

Consistent with §1861(ddd)(1)(A) and 42 CFR 410.64(a)(1), additional preventive services must be reasonable and necessary for the prevention or early detection of illness or disability. With respect to evaluating whether screening tests conducted on asymptomatic individuals are reasonable and necessary, the analytic framework involves consideration of different factors compared to either diagnostic tests or therapeutic interventions. Evaluation of screening tests has been largely standardized in the medical and scientific communities, and the "value of a screening test may be assessed according to the following criteria:

i. *Simplicity.* In many screening programmes more than one test is used to detect one disease, and in a multiphasic programme the individual will be subjected to a number of tests within a short space of time. It is therefore essential that the tests used should be easy to administer and should be capable of use by para-medical and other personnel.
ii. *Acceptability.* As screening is in most instances voluntary and a high rate of co-operation is necessary in an efficient screening programme, it is important that tests should be acceptable to the subjects.
iii. *Accuracy.* The test should give a true measurement of the attribute under investigation.
iv. *Cost.* The expense of screening should be considered in relation to the benefits resulting from the early detection of disease, i.e., the severity of the disease, the advantages of treatment at an early stage and the probability of cure.
v. *Precision (sometimes called repeatability).* The test should give consistent results in repeated trials.
vi. *Sensitivity.* This may be defined as the ability of the test to give a positive finding when the individual screened has the disease or abnormality under investigation.
vii. *Specificity.* This may be defined as the ability of the test to give a negative finding when the individual screened does not have the disease or abnormality under investigation."[13]

As Cochrane and Holland (1971) further noted, evidence on health outcomes, i.e., "evidence that screening can alter the natural history of disease in a significant proportion of those screened", is important in the consideration of screening tests since individuals are asymptomatic and "the practitioner initiates screening procedures".

1. Screening Tests for Depression

Screening tests do not diagnose depression but rather indicate severity of depression symptoms within a given time period, i.e., the past several days, past week, or past two weeks including today. To evaluate the large number of available screening tools for older and elderly adults, readers are referred to:

- “Screening for Depression Across the Lifespan: A Review of Measures for Use in Primary Care Settings” by Sharp and Lipsky (2002),
- “Meeting the Mental Health Needs of Older Adults: Implications for Primary Care Practice” by Karlin and Fuller (2007), and
- “Tests for the Evaluation of Depression in the Elderly: A Systematic Review” by Colasanti, et al. (2010).

The National Institute for Health and Clinical Excellence (NICE) National Clinical Practice Guideline on Depression in Adults (October 2009) also contains tables and discussion regarding commonly available depression screening instruments, including detailed information regarding sensitivity, specificity, positive and negative predictive validity, receiver operator characteristic (ROC) curves, likelihood ratios, and diagnostic odds ratios of screening tools.[14]

Screening Tests for Adults

- **Hamilton Depression Rating Scale (HAM-D)**

  This 20-item instrument is widely used in a 17-item version in clinical trials to measure remission and treatment response. The scale’s length limits clinical utility, but versions of varying length are available. The HAM-D is not suited to assess patients affected by cognitive impairment and requires administration by trained personnel.[15]

- **Beck Depression Inventory (BDI)**

  This 21-question self-report was developed to quantitatively measure depression severity over time. The 1996 revision (BDI-II) occurred when the DSM-IV changed diagnostic criteria for major depressive disorder (MDD). The length of this tool limits its utility for screening; but because patients must choose a level of gravity (corresponding to a distinct definition of the patient’s condition, with reference to the previous week), the BDI lends itself to monitoring of variations in the intensity of depression over time.[16]

- **Zung Self-Assessment Depression Scale (SDS)**

  This 20-item measure of depression severity for those already diagnosed with depression is now also used in primary care as a screening tool. The SDS is available in a number of languages and can be completed by most persons in 5 minutes.[17] Disadvantages include that it does not cover symptoms of atypical depression, and that it may be less sensitive to change that other scales. Although devised to identify depression in adults in general, the SDS is also used to study depression and cognitive symptoms/disturbances in the elderly.

- **Center for Epidemiological Studies Depression Screen (CES-D)**

  This 20-item self-administered screening test, a hybrid of the Zung SDS, the BDI and the Minnesota Multiphasic Personality Inventory Depression Scale (MMPI-D), was designed to assess depression and gravity of depressive symptoms in normal elderly people.[18] A concise 10-item version, whose sensitivity has proved to be only slightly lower than that of the original version, is also available.

- **Geriatric Depression Scale (GDS and GDS-SF)**

  This 30-item self-reported tool for assessment of depression in the elderly requires yes or no answers describing patients' feelings on the day of completion.[19] There is a 15-item short form version (GDS-SF) where a score >5 may indicate depression warranting follow-up and >10 usually indicates depression.

- **General Health Questionnaire (GHQ)**

  This 60-item test is an assessment of psychological well-being to detect those likely to have or be at risk for developing psychiatric disorders. It is a measure of the common mental health problems or domains of depression, anxiety, somatic symptoms and social withdrawal. Developed in the 1970s, the GHQ comes in 38 languages.[20] A 28-item version is most often used.

- **Patient Health Questionnaire (PHQ-2 and PHQ-9)**

  The purpose of the 2-item Patient Health Questionnaire (PHQ-2) is not to establish a final diagnosis or to monitor depression severity, but to screen for depression in a first step approach. Patients who screen positive on the PHQ-2 require further testing and can be evaluated with the PHQ-9, a self-reported 9-question version of the Primary Care Evaluation of Mental Disorders (PRIME-MD). The PHQ-9 is a more detailed test with a scoring system based on duration/severity of particular symptoms.[21]

- **Cornell Scale for Depression in Dementia (CSDD)**

  This 19-item scale has the best sensitivity (93%) and specificity (97%) for identifying depression in a demented population.[22] In patients with severe cognitive impairments who cannot reliably answer the PHQ-9, the scale can be completed by a caregiver.

B. United States Preventive Services Task Force (USPSTF)

The USPSTF Recommendation Statement on "Screening for Depression in Adults" (December 2009) states the following:

- The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.
  Grade: B recommendation

- The USPSTF recommends against routinely screening adults for depression when staff-assisted depression care supports are not in place. There may be considerations that support screening for depression in an individual patient.
  Grade: C recommendation

USPSTF Grade Definitions after May 2007

What the Grades Mean and Suggestions for Practice

The U.S. Preventive Services Task Force (USPSTF) has updated its definitions of the grades it assigns to recommendations and now includes "suggestions for practice" associated with each grade. The USPSTF has also defined levels of certainty regarding net benefit. These definitions apply to USPSTF recommendations voted on after May 2007.

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.	Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	

Grade	Definition	Suggestions for Practice
		Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Levels of Certainty Regarding Net Benefit

Level of Certainty[23]	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: • The number, size, or quality of individual studies. • Inconsistency of findings across individual studies. • Limited generalizability of findings to routine primary care practice. • Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies. • Important flaws in study design or methods. • Inconsistency of findings across individual studies. • Gaps in the chain of evidence. • Findings not generalizable to routine primary care practice. • Lack of information on important health outcomes. More information may allow estimation of effects on health outcomes.

Level of Certainty[23]	Description

Inclusion criteria for O'Connor, *et al.'s* (2009) systematic evidence review– which formed the basis for the USPSTF recommendations – required that all studies be conducted in a general primary care population.[24] For the purposes of this decision memorandum, as defined by the Institute of Medicine (1996), "primary care is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community."[25]

Explaining the rationale for its recommendations, the USPSTF further categorized the evidence base and their assessment as follows:

Detection

"The USPSTF found good evidence that screening improves the accurate identification of depressed patients in primary care settings."

Benefits of Detection and Early Intervention

"The USPSTF found good evidence that treating depressed adults and older adults identified through screening in primary care settings with antidepressants, psychotherapy, or both decreases clinical morbidity."

"The USPSTF found good evidence that programs combining depression screening and feedback with staff assisted depression care supports improve clinical outcomes in adults and older adults."

"The USPSTF found fair evidence that screening and feedback alone without staff-assisted care supports do not improve clinical outcomes in adults and older adults."

Harms of Detection and Early Intervention

“The USPSTF found no evidence of harms of screening for depression in adults or older adults.”

USPSTF Assessment

“The USPSTF concludes that for adults who receive care in clinical practices that have staff-assisted depression care supports in place, there is at least moderate certainty that the net benefit of screening for depression is at least moderate.”

“The USPSTF concludes that for adults who receive care in clinical practices without staff-assisted depression care supports in place, there is at least moderate certainty that the net benefit of screening adults for depression is small.”[26]

C. Literature Search

In addition to the prerequisite USPSTF recommendations, CMS must consider not only whether an additional preventive service is reasonable and necessary for the prevention or early detection of illness or disability, but whether the service is appropriate for individuals entitled to benefits under part A or enrolled under part B of the Medicare program.

To facilitate these determinations, we searched PubMed from 1990 to 2011 for research studies, systematic reviews and clinical guidelines for depression screening in older and elderly adults, as well as disparities in provision or receipt of these services, with keywords including depression, mental health, screening, health outcomes and effectiveness. Cost and cost-effectiveness studies were also searched, as §1861(ddd)(2) expressly authorizes the agency to “conduct an assessment of the relation between predicted outcomes and the expenditures for such services”. Studies must have been published in peer-reviewed English language journals. Abstracts were excluded.

Using these general parameters, CMS identified four clinical guidelines and ten research studies, which included six reviews and/or meta-analyses plus three randomized controlled trials (RCTs).

D. Discussion of evidence reviewed

1. Evidence Questions

Our discussion focuses upon the adequacy of the evidence to draw conclusions about the risks and benefits of screening for depression for Medicare patients. CMS analyzed these questions:

- *Is the evidence sufficient to determine that screening for depression is recommended with a grade of A or B by the USPSTF for any indications?*
- *Is the evidence sufficient to determine that screening for depression is reasonable and necessary for the prevention or early detection of illness or disability?*
- *Is the evidence sufficient to determine that screening for depression is appropriate for Medicare beneficiaries?*

2. External technology assessments and systematic reviews

Health Outcomes

Gilbody, *et al.* (2008)

Observing that depression screening and case-finding has been proposed as a simple, quick and cheap method to improve the quality of care, Gilbody and colleagues attempted to establish the effectiveness of screening to improve recognition and management of depression, as well as outcomes of patients with depression. The authors performed a Cochrane systematic review of RCTs in non-mental health settings that included case-finding or screening instruments for depression, and conducted an analysis which explored heterogeneity using meta-regression techniques. Sixteen studies with 7576 patients met inclusion criteria, and results showed that use of screening or case-finding instruments were associated with modest increase in recognition of depression by clinicians (relative risk [RR] 1.27, 95% confidence interval [CI] 1.02 - 1.59). Questionnaires, when administered to all patients and results given to clinicians irrespective of baseline score, had no impact on recognition (RR 1.03, 95% CI 0.85 - 1.24). Screening or case finding increased use of any intervention by a relative risk of 1.30 (95% CI 0.97 - 1.76). There was no evidence of influence on prescription of antidepressant medications (RR 1.20, 95% CI 0.87 - 1.66). Seven studies provided data on outcomes of depression, and no evidence of effect was found (standardized mean difference –0.02, 95% CI –0.25 - 0.20). Gilbody, *et al.* concluded that if used alone, case-finding or screening questionnaires for depression appeared to have little or no impact on detection and management of depression by clinicians. The authors emphasized that recommendations to adopt depression screening using standardized questionnaires without organizational enhancements are not justified.[27]

Screening Tools

Sharp and Lipsky (2002)

Sharp and Lipsky conducted a review of screening measures for use in primary care settings. The authors observed that identifying patients with depression can be difficult in busy practices where time is limited, but stated that certain screening measures may help physicians diagnose the disorder. Sharp and Lipsky explained that depression screening measures do not diagnose depression, but rather provide an indication of the severity of symptoms and assess that severity within a given time period of, e.g., within the past 7-14 days. Although screening tools have unique scoring systems, higher scores generally reflect more severe symptoms; and measures have a statistically predetermined cutoff score at which symptoms are considered significant. Patients who score above predetermined cut-off levels should be interviewed more specifically for a diagnosis of a depressive disorder and, as clinically indicated, be treated within the primary care physician's scope of practice or referred to a mental health subspecialist. Sharp and Lipsky further suggested that targeted screening in high-risk patients – those with chronic diseases, pain, unexplained symptoms, stressful home environments, social isolation, or the elderly – may provide an alternative approach to better identify depressed patients.[28]

Colasanti, *et al.* (2010)

Colasanti and colleagues performed a systematic review of screening tools for the evaluation of depression in the elderly. Since symptoms of depression in the elderly can be difficult to identify and interpret, diagnosing depression can be difficult in the elderly, especially when concomitant pathologies mask signs and symptoms of depression. The authors categorized rating scales and questionnaires for depression as either hetero-evaluation scales administered by an assessor or as self-rating scales taken by the patient themselves. Hetero-evaluation tools that were compared and contrasted included the Hamilton depression rating scale (HAM-D or HDRS), the Cornell scale for depression in dementia (CSDD), the depressive signs scale (DDS), the post-stroke depression rating scale (PSDRS), non-verbal evaluation scales such as the aphasic depression rating scale and the visual analogue mood scales (VAMS), the Montgomery–Asberg depression rating scale (MADRS), and the retardation rating scale (RRS) focusing on psychomotor slowing. Self-rating scales that were evaluated included the Beck depression inventory (BDI), Zung's self-assessment depression scale (SDS), the geriatric depression scale (GDS), and the Center for Epidemiological Studies depression (CES-D) scale. Colasanti, *et al.* concluded that there is a need to standardize the hetero-evaluation and self-rating scales used to differentiate between normal and depressed geriatric patients.[29]

3. Internal technology assessment

Health Outcomes

Magruder-Habib, *et al.* (1990)

Magruder-Habib and colleagues conducted an RCT to assess whether results of the Zung Self-rating Depression Scale (SDS), when provided to physicians, could influence the recognition and treatment of depression patients in a primary care setting. Their trial used a staged screening approach and consisted of randomly informing physicians (N = 48 patients) or not informing physicians (N = 52 patients) of the depression status of male veterans (mean age = 60 years) screening positive for depression on both the SDS (index score of ≥ 50) and a DSM-III screen. The patients (not physicians) were randomized, and patients were the unit of analysis. Only SDS scores were fed back to the physicians; and of 112 potential study patients, 12 scored so high (≥ 75) on the SDS that they were excluded from randomization and their physicians were immediately informed of the screening results. The remaining patients (N = 100) were followed for 12 months to assess depression status. The main outcomes of interest were the recognition of depression (either specific notation in chart, listing of depressive symptoms, or referral to mental health services) and the treatment of depression (antidepressant prescription, mental health consultation, mental health clinic visit, or counseling by a physician) determined by audit of patients' medical records. Results showed that physician feedback of SDS scores of previously unrecognized depressed patients significantly increased recognition (56.2% versus 34.6%) and treatment (56.2% versus 42.3%) of depression over the 12-month study period. This was especially true for patients with high somatic ($P < 0.05$) or low psychologic symptoms of depression ($P < 0.05$). In other words, patients with high somatic complaints and symptoms suggesting organic diseases or patients with low psychological complaints were most likely to be missed. Magruder-Habib, *et al.* concluded that routine use of a screening instrument such as the SDS improves physician recognition of depression in primary care.[30]

Kales and Valenstein (2002)

Acknowledging that late-life depression is a heterogeneous syndrome, Kales and Valenstein stated that while depression in elderly patients is highly treatable, patient factors interact with physician factors to complicate overall clinical management of depression. Three confounding patient-level factors were reviewed – medical illness, neuropsychiatric comorbidity including concurrent dementia and anxiety, plus race – which impact not only the screening, diagnosis and treatment of depression, but also outcomes and health utilization in late-life depression. Medical illness, for instance, is common in depressed elderly patients, with 88% diagnosed with at least one significant medical disorder and 48% having three or more medical disorders. Depression in older adults with medical illness, the authors noted, potentially delays recovery by decreasing motivation and compliance, interfering with rehabilitation, and prolonging hospitalizations. Moreover, depression is associated with greater use of medical services, and prolonged recovery from hip fracture and stroke. Kales and Valenstein concluded that health outcomes and services research indicate that especially medical comorbidity affects whether late-life depression is appropriately detected and treated. The authors emphasized such factors must be included in a future mental health services research agenda in order to create best-practice models, guidelines, and tailored interventions to improve depression screening and detection, as well as diagnosis and treatment, in elderly primary care patients.[31]

Solberg, *et al.* (2005)

Solberg and colleagues described in considerable detail the main components of a systematic approach to care management in follow-up and follow-through of depressed patients in primary care. Having reviewed earlier trials of depression care, the authors stated that key care concepts demonstrated to be effective include: 1) care management by a nonphysician working with the primary care physician; 2) planned collaborative care between physicians and mental health clinicians; 3) education and support of patients for self-management; and 4) attention to patient preferences. According to the authors, a systematic care management system assumes that there is some type of team that includes a nonphysician (usually a nurse) with the ability to provide patient self-management support, not mental health counseling, in a closely integrated way with the primary physician. Their description assumes that all physicians within a clinic system have agreed on a depression guideline such as from the Institute for Clinical Systems Improvement, as well as use of a patient questionnaire such as the PHQ-9 to validly assess presence of depression during initial screening or appraisal and in follow-up visits to measure severity and outcomes.[32]

Screening Tools

Williams, *et al.* (1999)

At three university-affiliated and one community-based medical clinic, Williams and colleagues conducted a randomized controlled trial to evaluate the use of two case-finding instruments as compared to usual care. Consecutive patients were randomly assigned to be asked a single question about mood ("Have you felt depressed or sad much of the time in the past year?"), to fill out the 20-item validated Center for Epidemiologic Studies Depression (CES-D) Screen, or to usual care. Within 72 hours, patients were assessed for Diagnostic and Statistical Manual of Mental Disorders Third Revised Edition (DSM-III-R) disorders by assessors blinded to the screening results. Process of care was assessed using chart audit and administrative databases; and patient and physician satisfaction was assessed using Likert scales. At 3 months, depressed and nondepressed patients were re-assessed for DSM-III-R disorders and symptom counts. Of 1,083 patients approached, 969 patients consented to screening and were assigned to a single question (n = 330, mean age = 58), 20-item questionnaire (n = 323, mean age = 59), or usual care (n = 316, mean age = 56). The interview for DSM-III-R diagnosis was completed in 863 (89%) patients; and major depression, dysthymia, or minor depression was present in 13%. Of the 863 participants, patients were predominately female (71%), of Hispanic ethnic background (60%), and had low income (76% with personal income < $16,800). Eleven percent were making their first visit to the study physician; and medical comorbidity was moderate, with a median Duke Severity of Illness Score of 34 and a mean of three chronic medical conditions. Results showed that both instruments (single question or 20-item CES-D screen) were sensitive, but the 20-item CES-D questionnaire was more specific than the single question (75% versus 66%, $P = 0.03$). Case-finding with the 20-item questionnaire or single question modestly increased depression recognition, 30/77 (39%) compared with 11/38 (29%) in usual care ($P = 0.31$), but did not affect treatment (45% versus 43%, $P = 0.88$). Recovery from depression was more likely in the case-finding than usual care groups, 32/67 (48%) versus 8/30 (27%, $P = 0.03$), but mean improvement in symptoms did not differ significantly (1.6 versus 1.5 symptoms, $P = 0.21$). Williams, *et al.* concluded that a simple question about depression has similar performance characteristics as a 20-item questionnaire and is more feasible due to brevity. While there was a trend for case-finding to benefit outcomes, the effects were not statistically significant; and the authors believed that the lack of consistent benefit may in part be related to characteristics of the largely Hispanic study population.[33]

Scogin and Shah (2006)

Scogin and Shah reviewed evidence supporting screening older adults for depression in primary care setting, as well as barriers to recognition of depression, and screening instruments utilized for geriatric depression. Although depression screening has been shown to improve recognition, the authors noted past reviews have been mixed about whether screening improves depression outcomes in primary care patients; and they posited that the critical element appears to be the nature of the treatment provided following screening. Potential barriers to systematic depression screening included time required, negative patient reaction and patient stigmatization according to the physicians surveyed, as well as older adults' concerns regarding confidentiality, plus older women's concerns about intrusiveness and lack of appropriateness of screening. Based on the authors' own survey of older adults' attitudes toward screening, there may be less resistance to broaching the depression topic than currently believed. Scogin and Shah stated that the Geriatric Depression Scale – Short Form (GDS–SF) and the Center for Epidemiologic Studies Depression Scale (CES–D) likely have the greatest potential. Primary care older adults, they noted, found the GDS–SF "acceptable and neither too difficult nor stressful"; but an advantage of the CES–D is that it includes somatic items like "appetite" and "sleep" that providers likely inquire about as part of their routine assessment. Also, since the CES–D has been validated with adults, primary care offices would not have to use a separate screen for older adults. Scogin and Shah concluded that, when taken together, existence of validated screening tools, probable willingness on the part of older adults to be screened, and efficacious care models enable improved depression care.[34]

Lamers, *et al.* (2008)

Lamers and colleagues assessed the psychometric properties of the PHQ-9 as a screening tool for depression in elderly patients with diabetes and chronic obstructive pulmonary disease (COPD) without known depression. Diabetic and COPD patients aged >59 years were selected from 89 general practices. Mean age was 71.4 years (SD 6.9); 51.2% of patients had DM; 51.8% were male; and 40.1% had primary education only. PHQ-9 depressed patients more often had only received primary education compared to nondepressed patients (41.7% versus 27.0%, P = 0.001); and in the total sample (N = 713), 19.3% had ADD and 10.7% had MDD according to the PHQ-9. Criterion validity, using the Mini International Neuropsychiatric Interview Psychiatric interview to diagnose major depressive disorder (MDD) and any depressive disorder (ADD) as diagnostic standard, was evaluated (N = 713 patients) for both summed and algorithm-based PHQ-9 score. Correlations with quality of life and severity of illness were calculated to assess construct validity; and in addition to the validity study, a test-retest study of the PHQ-9 was conducted (N = 105 patients) to evaluate its reliability. Results showed that Cohen's kappa for the algorithm-based score was 0.71 for MDD and 0.69 for ADD. Correlation for test-retest assessment of the summed score was 0.91. The algorithm-based score had low sensitivity and high specificity, but both sensitivity and specificity were high for the optimal cut-off point of 6 on the summed score for ADD (sensitivity 95.6%, specificity 81.0%). Correlations between the summed score and the quality of life and severity of illness were acceptable. Lamers, *et al.* concluded that algorithm-based scoring of the PHQ-9 is not advisable for screening purposes in this elderly population because sensitivity is low, i.e., in more than half of cases, depression is unrecognized. However, the authors concluded that the PHQ-9 summed score (applying cut-offs of 6 and 7) is a valid and reliable screening tool for, respectively, ADD and MDD in older primary care patients with diabetes and COPD. In those patients scoring above the cut-off point for ADD or MDD, a more thorough mental health diagnostic examination is appropriate.[35]

Cost-Effectiveness

Simon, *et al.* (2007)

Simon and colleagues evaluated incremental cost and cost-effectiveness of systematic depression treatment for older diabetics. Their RCT (the Pathways Study) compared a multicomponent depression treatment program with care as usual in nine primary care clinics of a group-model prepaid health plan. A two-stage population-based depression screening program, utilizing the PHQ-9 plus telephone screening two weeks later for those with a PHQ-9 score ≥ 10, identified diabetics with concurrent depressive disorder. A total of 329 participants (88% of those invited) attended a baseline visit and agreed to be randomized. Baseline characteristics showed the mean age ± standard deviation was 58 ± 12 years and 57 ± 12 years for, respectively, the intervention group and usual care patients, including 35% female patients. Three specialized nurses delivered a 12-month, stepped-care program beginning with problem-solving treatment psychotherapy or structured antidepressant pharmacotherapy; and subsequent treatment combining psychotherapy and medication, medication adjustments and specialty referral was adjusted according to clinical response. Main outcome measures were depressive symptoms assessed by blinded telephone assessments at 3, 6, 12 and 24 months; and health service costs were assessed using health plan accounting records. Results showed that over 24 months, patients assigned to multicomponent depression management accumulated a mean of 61 additional depression-free days (95% confidence interval [CI], 11 to 82 days) adjusted for age, sex and baseline depression, and had outpatient health services costs that averaged $314 less (95% CI, $1007 less to $379 more) compared to patients in usual care. Where an additional depression-free day was valued at $10, net economic benefit of the systematic program was $952 per patient treated (95% CI, $244 to $1660). Simon, *et al.* concluded for adults with diabetes and depression, systematic treatment significantly increases time free of depression and has economic benefits from the health plan perspective. The authors believed that depression screening and systematic depression treatment should become routine components of diabetes care.[36]

4. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

CMS did not hold a MEDCAC meeting on this topic.

5. Evidence-Based Clinical Guidelines

United States Preventive Services Task Force (USPSTF) 2009 *(see also Section VII.B. above)*

Clinical Summary of USPSTF Recommendation intended for use by primary care clinicians:

Population	**Nonpregnant adults 18 years or older**	
Recommendation	Screen when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up. Grade: B	Do not routinely screen when staff-assisted depression care supports are not in place. Grade: C
Risk Assessment	Persons at increased risk for depression are considered at risk throughout their lifetime. Groups at increased risk include persons with other psychiatric disorders, including substance misuse; persons with a family history of depression; persons with chronic medical diseases; and persons who are unemployed or of lower socioeconomic status. Also, women are at increased risk compared with men. However, the presence of risk factors alone cannot distinguish depressed patients from nondepressed patients.	
Screening Tests	Simple screening questions may perform as well as more complex instruments. Any positive screening test result should trigger a full diagnostic interview using standard diagnostic criteria.	
Timing of Screening	The optimal interval for screening is unknown. In older adults, significant depressive symptoms are associated with common life events, including medical illness, cognitive decline, bereavement, and institutional placement in residential or inpatient settings.	

Population	Nonpregnant adults 18 years or older	
Balance of Harms and Benefits		Limited evidence suggests that screening for depression in the absence of staff-assisted depression care does not improve depression outcomes.
Suggestions for Practice	"Staff-assisted depression care supports" refers to clinical staff that assists the primary care clinician by providing some direct depression care and/or coordination, case management, or mental health treatment.	

Veterans Affairs/Department of Defense Clinical Practice Guideline (May 2009)

The 2009 Clinical Practice Guideline for the Management of Major Depressive Disorder (MDD) for the Department of Veterans Affairs (VA) and Department of Defense (DoD) was developed to reduce current practice variation and provide facilities with a structured framework to help improve patient outcomes, as well as to provide evidence-based recommendations to assist providers and their patients in decision-making.

Notable among key elements addressed by this Guideline is that: "Annual screening for MDD is recommended in the primary care setting as an important mechanism for reducing morbidity and mortality."

According to the VA/DoD Clinical Practice Guideline (2009), "Despite its high prevalence and substantial economic impact, depression often goes unrecognized or undertreated. Depressed patients have increased disability, healthcare utilization, and mortality from suicide and other causes, as well as reduced productivity and health-related quality of life."

"…Brief screens (e.g., PHQ-2) appear to perform comparably to longer screens (e.g., Geriatric Depression Scale [GDS] or Patient Health Questionnaire [PHQ-9]). Although depression questionnaires may perform more poorly in adults > 75 years, the performance is adequate to improve initial recognition of depression. Patients with severe chronic medical illness are at higher risk for depression than the average patient seen in primary care…."

VA/DoD Recommendations:

- The Patient Health Questionnaire (PHQ) 2-item should be completed annually by all patients seen in primary care settings. [A] Strong recommendation that the clinicians provide the intervention to eligible patients.

  Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.

- Patients who screen positive on the Patient Health Questionnaire (PHQ) 2-item should have both a documented assessment using a quantitative questionnaire to further assess whether the patient has sufficient symptoms to warrant a diagnosis of clinical major depression and a full clinical interview that includes evaluation for suicide risk. [B] Recommendation that clinicians provide (the service) to eligible patients.

  At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.

The Institute for Clinical Systems Improvement (ICSI) 2010

According to the ICSI's Health Care Guideline "Major Depression in Adults in Primary Care" (May 2010), an evidence-based document based on the best care that has evolved to include information on best-practice systems for implementation, the primary objective of depression screening is "to use a standardized instrument that will quantify and document future progress, including response and remission rates".

"While the two-question screen – "Over the past two weeks, have you been bothered by: Little interest or pleasure in doing things? Feeling down, depressed or hopeless?" – is effective with a broad population in primary care, a recent meta-analysis concluded that for high-risk patients, screening with a nine-item Patient Health Questionnaire (PHQ-9) is more valid.

The PHQ-9 has been validated for measuring depression severity. It can be administered telephonically and read to the patient. The factor structure of the nine items is comparable when tested with African Americans, Chinese Americans, Latino and non-Hispanic white patient groups. Other language versions that are validated for use in primary care are Spanish and Chinese…

Elderly patients with mild cognitive impairment can reliably fill out the PHQ-9…

Clinicians should choose the method that best fits their personal preference, the patient population served and the practice setting."[37]

The ICSI Guideline contains information regarding "Cultural Considerations", an appendix outlining "Suicidality Screening" for adults in primary care, and provides the following insights regarding screening older and elderly Medicare beneficiaries:

Geriatrics

"The rate of depression in adults older than 65 years of age ranges from 7% to 36% in medical outpatient clinics and increases to 40% in the hospitalized elderly. Comorbidities are more common in the elderly. The highest rates of depression are found in those with strokes (30% to 60%), coronary artery disease (up to 44%), cancer (up to 40%), Parkinson's disease (40%), and Alzheimer's disease (20% to 40%). The recurrence rate is also extremely high at 40%. Similar to other groups, the elderly with depression are more likely than younger patients to underreport depressive symptoms. They often present with nonspecific somatic complaints, such as insomnia, appetite disturbances, lack of energy, fatigue, chronic pain, constipation and musculoskeletal disorders."

Depression and dementia

"Patients with more severe cognitive impairments cannot reliably answer the PHQ-9 questions. For those patients, a scale completed by a caregiver such as the Cornell Scale for Depression in Dementia (CSDD) is more appropriate… The 19-item Cornell Scale has the best sensitivity (93%) and specificity (97%) with a cutoff of greater than or equal to six for identifying depression in a demented population. The more commonly used Geriatric Depression Scale (GDS) had sensitivity ranging from 90% to 82% (for the 15-item version to the 4-item version) and specificity of 94% to 75% depending on the version. Sensitivity and specificity represented a typical mix of primary care patients."[38]

The ICSI's Health Care Guideline "Preventive Services for Adults" (September 2010) advises:

"Routine depression screening should be performed for adult patients (including older adults) but only if the practice has staff-assisted "systems in place to ensure that positive results are followed by accurate diagnosis, effective treatment, and careful follow-up." The optimum interval for rescreening is unknown.

Efficacy

When combined with systematic management, screening can be very effective. There is now considerable evidence from many randomized trials that it is possible to improve treatment (both medications and psychotherapy) in primary care settings for patients with depression, but these trials have all implemented systematic ways to:

- provide care management with close follow-up by a team working with the primary care clinician,
- enhance planned collaboration with mental health providers,
- provide education and self-management support.

Benefits from screening are unlikely to be realized unless such systems are functioning well."[39]

Canadian Task Force on Preventive Health Care (2005)

The 2005 Canadian Task Force on Preventive Health Care (CTFPHC) practice guideline stated "a positive screen must be followed by accurate diagnosis, effective treatment and follow-up to ensure that the benefits of screening are realized." Closely paralleling the current USPSTF recommendation, the CTFPHC outlined the following in Table 1 of its practice guideline:

Maneuver

Screening adults in the general population for depression in settings with integrated feedback and treatment systems [defined as]:

Screening programs integrated with both feedback to the clinician regarding depression status and a system for managing treatment (antidepressant medications and psychotherapeutic interventions). Trials that included access to case management or mental health care as part of the system of care were particularly effective in reducing depressive symptoms.

Effectiveness

There is evidence that screening improves the accuracy of identifying depressed patients. In studies where an integrated system of screening and follow-up was available, there was improvement in patient outcomes.

Recommendation

There is fair evidence to recommend screening adults in the general population for depression in primary care settings that have integrated programs for feedback to patients and access to case management or mental health care (grade B recommendation).[40]

- Grade B: There is fair evidence to recommend the clinical preventive action.

6. Professional Society Position Statements

The American Academy of Family Physicians (AAFP)

On its website containing policy recommendations for clinical preventive services, the AAFP position statement parallels precisely the current USPSTF (2009) recommendations:

Depression, Adults

The AAFP ***recommends*** screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.

"Staff-assisted depression care supports" refers to clinical staff that assist the primary care clinician by providing some direct depression care and/or coordination, case management, or mental health treatment. (2010)

(Grade: B recommendation)

Depression, Adults

The AAFP ***recommends against*** routinely screening adults for depression when staff-assisted depression care supports are not place. There may be considerations that support screening for depression in an individual patient.

"Staff-assisted depression care supports" refers to clinical staff that assist the primary care clinician by providing some direct depression care and/or coordination, case management, or mental health treatment. (2010)

(Grade: C recommendation)

Grade Definition: http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm
Clinical Consideration: http://www.uspreventiveservicestaskforce.org/uspstf/uspsaddepr.htm

The American College of Preventive Medicine (ACPM)

In October 2009, the ACPM published online the following:

Position Statement

"The American College of Preventive Medicine (ACPM) maintains that primary care providers should screen all adults for depression and that all primary care providers should have systems in place, either within the primary care setting itself or through collaborations with mental health professionals, to ensure the accurate diagnosis and treatment of this condition. The earliest and best opportunities to identify depression are in the clinics of primary care providers. Thus, the ACPM supports the recommendations of the U.S. Preventive Services Task Force (USPSTF), and further suggests that all primary care practices should have such systems of care in place."

The American Diabetes Association (ADA)

The ADA's position statement on "Standards of Medical Care in Diabetes" (January 2010) offered the following recommendations regarding psychosocial assessment and care:

- Assessment of psychological and social situation should be included as an ongoing part of the medical management of diabetes.
- Psychosocial screening and follow-up should include, but is not limited to, attitudes about the illness, expectations for medical management and outcomes, affect/mood, general and diabetes-related quality of life, resources (financial, social, and emotional), and psychiatric history.
- Screen for psychosocial problems such as depression and diabetes-related distress, anxiety, eating disorders, and cognitive impairment when self-management is poor.

7. Public Comments

During the initial 30-day public comment period (03/02/2011 – 04/01/2011), CMS received 22 comments, all of which supported Medicare coverage of screening for depression. Those who self-identified when submitting comments came from organizations serving the elderly, physician groups, industry, psychologists, educators and other healthcare professionals. Of these commenters, 14 spoke to treatment for depression with regular re-screening at various intervals (i.e., longitudinal tracking) to help ascertain treatment effectiveness.

For commenters expressing a preference for depression screening instruments in the primary care setting, the following tools were mentioned: the Patient Health Questionnaire-9 (PHQ-9), the Patient Health Questionnaire-2 (PHQ-2), the M-3 Checklist, the Geriatric Depression Scale-15 (GDS-15), and the Center for Epidemiologic Studies Depression (CES-D) scale.

A comment from the American Psychiatric Association (APA) supports the USPSTF Grade B recommendations, encourages annual screening by qualified clinicians with referral to a psychiatrist when primary care resources are lacking, and states that screening should be performed regardless of whether staff-assisted depression care supports are in place. The APA further commented that it is critically important for physicians, especially those providing primary care, to be reimbursed to perform depression screening; and the APA emphasized the importance of linking screening with follow-up diagnostic evaluation and treatment by a qualified clinician. The APA believes that CMS should reimburse for the USPSTF's Grade C recommendation, in that other considerations such as comorbid medical conditions may support screening for an individual patient.

A comment from the American Medical Association (AMA) supports views expressed in the APA comment. The AMA additionally states that it has developed measures regarding depression screening, diagnostic evaluation, appropriate treatment and coordination of care that are undergoing formal review.

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum. The 22 comments can be reviewed in their entirety on our website at: http://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=251&NcaName=Screening+for+Depression+in+Adults&ExpandComments=y&ver=3&bc=ACAAAAAAIIAA&

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage.

Pursuant to §1861(ddd) of the Social Security Act, CMS may add coverage of "additional preventive services" if certain statutory requirements are met. Our regulations provide:

§410.64 Additional preventive services

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of "preventive services" under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.

(2) Recommended with a grade of A or B by the United State Preventive Services Task Force.
(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.[41]

Is the evidence sufficient to determine that screening for depression is recommended with a grade of A or B by the USPSTF for any indications?

The USPSTF Recommendation Statement on "Screening for Depression in Adults" (December 2009) states the following:

- The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.
  Grade: B recommendation.

We conclude that screening for depression is recommended with a grade of B by the USPSTF for Medicare beneficiaries when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.

Is the evidence sufficient to determine that screening for depression is reasonable and necessary for the prevention or early detection of illness or disability?

Magruder-Habib, *et al.* (1990) showed that use of a depression screening instrument improves physician recognition and treatment of depression, but it is the nature of the treatment provided following screening that appears to be the critical concept for improving depression outcomes.[42] That is, screening alone – without organizational enhancement of care – is not enough.[43] Actual improvement in outcomes requires careful follow-up and monitoring, and the care process steps for depression are hence no different than those taken for any other chronic disease:

> "Imagine a system in which providers screened for hypertension and started medical treatment, only to neglect follow-up blood pressure checks and adjustment of therapy. Is the patient taking his or her antihypertensive medication? Is it working? Are there side effects? Does the dose of medication need to be increased, or should an alternative agent be used? The same principles apply to diabetes, high cholesterol, asthma, congestive heart failure, and many other conditions [such as depression] requiring patient education, ongoing treatment, outcome monitoring, and vigilance for episodic exacerbations."

In 2009, the USPSTF reported good evidence exists which demonstrates that: 1) screening improves accurate identification of depressed patients in primary care settings; 2) treating depressed adults and older adults identified through screening in primary care settings decreases clinical morbidity; and 3) programs combining depression screening and feedback with staff-assisted depression care supports improve clinical outcomes in adults and older adults.[44]

O'Connor, *et al.'s* (2009) "Screening for Depression in Adult Patients in Primary Care Settings: A Systematic Evidence Review" – upon which the USPSTF based its recommendation – only evaluated non-pregnant adults (ages 18 and over) treated in a primary care setting. Excluded from review were studies that focused on inpatient, residential treatment, psychiatric or non-health care community settings; on interventions that are not primary care feasible or referable; or that were not conducted in a general primary care population. In an earlier systematic review[45] applicable to primary care settings, the following definition recommended by the Institute of Medicine (IOM) was used to identify relevant primary care settings: "Primary care is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patient, and practicing in the context of family and community."[46] Accordingly, we again use the IOM's definition of primary care in this proposed decision memorandum and conclude that emergency departments, inpatient hospital settings, outpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospice are not primary care settings for Medicare beneficiaries.

Potential harms of depression screening include false-positive results, the inconvenience of additional diagnostic workup, costs and adverse effects of treatment for patients incorrectly identified as being depressed, and potential adverse effects of labeling. O'Connor, *et al.'s* (2009) systematic review found no evidence on any of these potential harms of screening for depression in adults or older adults. Older adults (>65 years) were also noted to be at lower risk for suicide-related harms during antidepressant treatment.

While the USPSTF (2009) stated the optimum interval for depression screening is unknown, the VA/DoD Clinical Practice Guideline (2009) strongly recommends annual depression screening and uses the PHQ-2 in primary care settings as an important mechanism to reduce morbidity and mortality. Similarly, the American Psychiatric Association (APA) supports annual depression screening.

The USPSTF, however, found little evidence to recommend one screening method over another, and in 2009 stated that "clinicians may choose the method most consistent with their personal preference, the patient population being served, and the practice setting." Nonetheless, Scogin and Shah (2006) believed that, while older adults find the GDS-SF neither too difficult nor stressful, the CES-D (which has been validated with adults) may better fit provider needs since primary care offices would not have to use a separate screen for older adults. Further, Lamers, *et al.* (2008) tested reliability, construct validity and criterion validity of screening and reported that the PHQ-9 summed score was reliable and valid for depression screening in elderly primary care patients with diabetes and chronic obstructive lung disease.

Improving actual depression outcomes in primary care, Kroenke (2001) noted, typically involves three components – provider education, introduction of a care manager, and improved access to and communication with a mental health specialist. The care manager is often a nurse who not only assists in screening and patient education, but who, in particular facilitates and coordinates follow-up to monitor both adherence to and effectiveness of depression treatments.[47]

Similarly, the USPSTF noted that "the effects of screening cannot be separated from the effects of staff-assisted depression care" and clarified that the "staff-assisted depression care supports" which it recommends be in place means "clinical staff that assist the primary care clinician by providing some direct depression care, such as care support or coordination, case management, or mental health treatment." In its "Clinical Considerations" section, the USPSTF (2009) then practically described that:

"In the available evidence, the lowest effective level of staff-assisted depression care supports consisted of a screening nurse who advised resident physicians of positive screening results and provided a protocol that facilitated referral to behavioral treatment.

At the highest level, staff-assisted depression care supports included screening; institutional monetary commitment; staff and clinician training (one or two day workshops); clinician manuals; monthly training lectures; academic detailing; many materials for clinicians, staff, and patients; an initial visit with a nurse specialist for assessment, education, and discussion of patient preferences and goals; a visit with a trained nurse specialist for follow-up assessment and ongoing support for adherence to medication for those prescribed antidepressant medications; a visit with a trained therapist for cognitive behavioral therapy; and a reduced copay for patients referred for psychotherapy."[48]

Emphasizing the importance of such care supports in real-world primary care settings, O'Connor and colleagues (2009) noted that as many as 40-67% of patients discontinue their antidepressant medication within 3 months, and few receive adequate follow-up. "Thus, efforts to increase appropriate treatment and improve adherence to treatment are likely to provide the greatest effect. Given the burden on the primary care clinician, it is not surprising that the greatest gains are seen in programs in which other staff provides some of the depression care. Considerable research in recent years has focused on treatment approaches that do just this, such as disease management and collaborative care, which are generally effective and cost-effective."[49]

To that end, O'Connor, *et al.* (2009) elaborated on particular components of effective programs; and as best outlined by Solberg, *et al.* (2005) in a review of critical missing components in the follow-up and follow-through of depressed primary care patients, key care concepts of include:

- Care management by a nonphysician working with the primary care physician,
- Planned collaborative care between physicians and mental health clinicians,
- Education and support of patients for self-management, and
- Attention to patient preferences [regarding counseling, medications, referral].[50]

Most recently, Butler, *et al.* (2011) reviewed 26 clinical trials of integrated depression care in primary care settings and utilized a scoring system composed of ten elements, beginning with screening.[51] Butler and colleagues offered this perspective regarding the path forward:

> "Ultimately, the adoption of integrated care models for the care of persons with mental health problems will involve consideration of both effectiveness and costs… Integrating general medical and psychiatric service delivery increases the likelihood but does not guarantee that effective interventions are administered. Indeed, integration may not be necessary at all if primary care physicians provide evidence-based psychiatric care. However improvement in the care taken by primary care physicians is achieved, it seems likely to require decreasing their patient panels to accommodate the increased time requirement unless some other type of personnel, such as a case manager [e.g., a nurse], is used to handle the added work. Ultimately, a combination of integration and guideline adherence, using some variant of case managers and supportive health professionals, is the most likely approach to succeed."[52]

We conclude the evidence is sufficient to determine that annual depression screening for adults in primary care settings, when accompanied by staff-assisted depression care supports consisting (at minimum) of a clinical staff person (such as a nurse or physician assistant) who advises physicians of screening results and who facilitates and coordinates referrals to mental health treatment, is reasonable and necessary for the prevention or early detection of illness or disability.

Is the evidence sufficient to determine that screening for depression is appropriate for Medicare beneficiaries?

In 2009, the USPSTF highlighted that "the effects of screening cannot be separated from the effects of staff-assisted depression care" and recommended screening adults for depression when those care supports are in place. But of four screening studies identified by the USPSTF which focused on older adults, only Rubenstein and colleagues' (2007) trial found improved depression outcomes in an intervention group beyond usual care. Notably, this VA ambulatory care center trial was the only study that expanded the role of clinical or office staff to assist with depression care. Rubenstein's trial of a screening, case finding and referral system for older veterans in primary care (mean age = 74 years) involved the assistance of a case manager, who interviewed and referred patients to either primary or specialty care or to a multidisciplinary geriatric assessment team. The case manager (a physician assistant with geriatric expertise) also provided patient education and follow-up. While the intervention[53] increased recognition and evaluation of target geriatric conditions (depression, cognitive impairment, urinary incontinence, falls and functional impairment), it did not improve functional status or decrease hospitalization. The authors acknowledged, however, that because participants with new, treatable symptoms were not distinguished from those with irreversible or progressive conditions, participants who did not change or who declined may have diluted overall intervention-related improvements.

The USPSTF additionally stated that "significant depressive symptoms are associated with common life events in older adults, including medical illness, cognitive decline, bereavement, and institutional placement in residential or inpatient settings." Nonetheless, the presence of risk factors alone – such as particularly spousal death and chronic illness in geriatric patients – cannot distinguish depressed patients from nondepressed patients.

Investigating the impact of confounding factors and the complexity of depression, Kales and Valenstein (2002) critically noted that:

> "Late-life depression is a heterogeneous syndrome leading to diagnostically ambiguous or complex presentations in many patients. Although depression in elderly patients is highly treatable, the complexity of patients' clinical presentations may result in underdiagnosis and undertreatment, which, in turn, leads to poor outcomes and increased health care utilization... Although provider factors, such as ageism and time constraints, may explain part of the underdiagnosis and undertreatment of elderly patients, the complexity of patient presentations also plays an important role. For example, among patients with significant medical illness, clinicians may assume that symptoms of anorexia, weight loss, sleep impairment, or fatigue are secondary to physical illness as opposed to depression… Depression is often undetected in elderly primary care patients, and 70% to 90% of depressed elderly medically ill patients may not receive a depression diagnosis."

Furthermore, older depressed adults typically have three or more co-occurring chronic illnesses; and among older diabetics (mean age = 70 years) in the IMPACT (Improving Mood-Promoting Access to Collaborative Treatment) trial, systematic depression treatment demonstrated clinical benefit with no increase in overall health care costs.[54] Moreover, "the public health importance of this question is underscored by the increasing prevalence of diabetes and the consistent finding that depression is twice as common among people with diabetes as in the general population."[55]

Also evaluating collaborative care in older diabetic patients with comorbid depression, Katon and colleagues' (2004) Pathways study identified potential participants by using a population-based depression screening program (the 9-item PHQ), where all case management intervention services were provided by three registered nurses. In a follow-up cost-effectiveness analysis of the Pathways study, Simon, *et al.* (2007) clarified that:

> "Abundant research demonstrates a strong and consistent association between depression and increased use of health services. Total health care costs for outpatients with current depression are 50% to 100% higher than for those without depressive disorder. Increased costs are overwhelmingly due to greater use of general medical services rather than use of depression treatment, and these differences persist after attempting to account for comorbid chronic medical illness. Improvement in depression is followed by decreases in use of general medical care."[56]

Accordingly, Simon, *et al.'s* (2007) study concluded that systematic treatment of older adults with diabetes – who screened positive for at least moderate depressive symptoms – produced significant and sustained increase in days free of depression, as well as reduced outpatient health services costs. Simon and colleagues thus stated depression screening and systematic depression treatment should become routine components of diabetes care. The 2010 American Diabetes Association (ADA) position statement also recommends assessment of psychological and social situation be included as an ongoing part of the medical management of diabetes - including screening and follow-up for psychosocial problems, such as depression.

We conclude that the evidence is sufficient to determine that screening for depression is appropriate for Medicare beneficiaries.

Disparities in Screening and Behavioral Counseling

Disparities exist in screening for depression. Kales and Valenstein (2002), for example, noted that "patient race may impact on the patient's symptom presentation or interact with physician bias to decrease detection of depression or affect the types of treatments received by patients. Undetected and undiagnosed depression in such patients can lead to a vicious cycle of increasing disability, further depression, and even suicide."[57]

Evidence also exists in the literature that there may be disparities in health outcomes following screening for depression. For instance, while case-finding for depression trended to benefit patient outcomes in Williams, *et al.* (1999) randomized trial, the authors believed that the lack of consistent benefit could in part have been related to characteristics of the largely (60%) Hispanic study population. That is, chronic social stresses seen in an urban, low-income, and ethnically diverse group of patients may make depression more refractory to treatment. Further, Williams, *et al.* noted that cross-cultural studies have shown that Hispanic patients may interpret symptoms of depression more benignly, are more likely to use prayer and other nonmedical therapies, and are less likely to receive treatment in the mental health specialty setting than non-Hispanic white patients. Hence, following screening and recognition of depression, there may not consistently be positive effects on health outcomes for Hispanic patients.[58]

Summary

Depression is often unrecognized and untreated in elderly patients; and older individuals whose depression remains undetected (and who are thus only identified through screening) tend to be less impaired and have milder depression. Both major and minor depression, however, are associated with decreased quality of life, increased morbidity, increased functional disability, increased health care utilization, and increased medical costs. Depression additionally impairs an elderly person's ability to adhere to disease management regimens such as regularly taking medications, diet, exercise and quitting smoking. Since depression and disability mutually reinforce each other, depression can thus worsen the course of chronic illness and may cause progressive clinical deterioration in older chronically ill patients.[59]

There is no gold standard for depression screening, and the USPSTF states that "clinicians may choose the method most consistent with their personal preference, the patient population being served, and the practice setting." Evaluating only studies conducted in general primary care populations, O'Connor, *et al.* (2009) concluded that good evidence supports the health benefits of programs which combine depression screening and feedback with the support of additional staff to provide some depression care in adults who visit primary care. Based on that systematic evidence review, the USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place and recommends against routinely screening when supports are not in place.

Nevertheless, screening tests for depression do not diagnose depression but rather indicate the severity of depression symptoms within a given time period. Patients who score above a test's predetermined cut-off level for significance should be interviewed more specifically to assess for a diagnosis of a depressive disorder and, as clinically indicated, receive appropriate treatment..

IX. Conclusion

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The evidence is adequate to conclude that screening for depression in adults, which is recommended with a grade of B by the U.S. Preventive Services Task Force (USPSTF), is reasonable and necessary for the prevention or early diagnosis of illness or disability, and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

Therefore CMS proposes to cover annual screening for depression for Medicare beneficiaries in primary care settings that have staff-assisted depression care supports in place to assure accurate diagnosis, effective treatment, and follow-up. For the purposes of this decision memorandum:

- A primary care setting is defined as one in which there is provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, outpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospice are not considered primary care settings under this definition.

- At a minimum level, staff-assisted depression care supports consist of clinical staff (e.g., nurse, physician assistant) in the primary care office who can advise the physician of screening results and who can facilitate and coordinate referrals to mental health treatment.

- More comprehensive care supports include case management by a nurse or nonphysician working with the primary care physician; planned collaborative care between the primary care provider and mental health clinicians; patient education and support for patient self-management; plus attention to patient preferences regarding counseling, medications, and referral to mental health professionals with or without continuing involvement by the patient's primary care physician.

We are requesting public comments on this proposed determination pursuant to section 1862(l) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

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1 Nestler, *et al.* (2002.

2 Nestler, *et al.* (2002)

3 Thase, *et al.* (2000)

4 Baghai, *et al.* (2006)

5 Wang, *et al.* (2005)

6 Surgeon General's Report (1999)

7 Pignone, *et al.* (2002)

8 Greenberg, *et al.* (2003)

9 O'Connor, *et al.* (2009)

10 O'Connor, *et al.* (2009).

11 American Psychiatric Association: DSM-IV (1994)

12 42 CFR 410.64 See also 75 Federal Regulations 73, 170, 73, 615 (November 27, 2010).

13 Cochrane and Holland (1971)

14 http://www.nice.org.uk/nicemedia/live/12329/45896/45896.pdf (pages 102-111)

15 Hamilton (1960)

16 Beck, *et al.* (1960)

17 Zung and King (1983)

18 Radloff (1977)

19 Yesavage, *et al.* (1982)

20 Jackson (2007)

21 Kroenke, *et al.* (2001)

22 Alexopoulos, *et al.* (1988)

23 The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

24 O'Connor, *et al.* (2009)

25 Committee on the Future of Primary Care. *Primary Care: America's Health in a New Era* (1996)

26 http://www.uspreventiveservicestaskforce.org/uspstf09/adultdepression/addeprrs.htm (USPSTF Full Recommendation Statement, December 2009)

27 Gilbody, *et al.* (2008)

28 Sharp and Lipsky (2002) Available online: http://www.aafp.org/afp/2002/0915/p1001.pdf

29 Colasanti, *et al.* (2010)

30 Magruder-Habib, *et al.* (1990)

31 Kales and Valenstein (2002)

32 Solberg, *et al.* (2005)

33 Williams, *et al.* (1999)

34 Scogin and Shah (2006)

35 Lamers, *et al.* (2008)

36 Simon, *et al.* (2007)

37 http://www.icsi.org/depression_5/depression__major__in_adults_in_primary_care_3.html (page 13)

38 http://www.icsi.org/depression_5/depression__major__in_adults_in_primary_care_3.html (pages 26-27)

39 http://www.icsi.org/preventive_services_for_adults/preventive_services_for_adults_4.html (page 25)

40 http://www.cmaj.ca/cgi/reprint/172/1/33.pdf

41 42 CFR 410.64

42 Scogin and Shah (2006)

43 Gilbody, *et al*. (2008)

44 http://www.uspreventiveservicestaskforce.org/uspstf09/adultdepression/addeprrs.htm

45 http://www.uspreventiveservicestaskforce.org/3rduspstf/alcohol/alcomissum.htm

46 Committee on the Future of Primary Care. *Primary Care: America's Health in a New Era* (1996)

47 Kroenke (2001)

48 http://www.uspreventiveservicestaskforce.org/uspstf09/adultdepression/addeprrs.htm#discussion (See “Staff-Assisted Depression Care Supports” under “Clinical Considerations”)

49 http://www.uspreventiveservicestaskforce.org/uspstf09/adultdepression/addeprart1.htm#discussion

50 Solberg, *et al.* (2005)

51 Ten elements: screening, patient education/self-management, medication, psychotherapy, coordinated care, clinical monitoring, assessment of medication adherence, standardized follow-up, formal stepped care, supervision.

52 Butler, *et al.* (2011)

53 The intervention consisted of a structured assessment of specific risks and unmet needs via a structured telephone interview by a physician assistant case manager; specific referrals and recommendations by the case manager to further assess, treat, and manage these unmet needs; selected referral by the case manager to a geriatric assessment clinic for intervention participants who could not be adequately assessed by telephone evaluation and referral; and coordinated outpatient follow-up by the case manager. From Rubenstein, *et al.* (2007)

54 Katon, *et al.* (2006)

55 Simon, *et al.* (2007)

56 Simon, *et al.* (2007)

57 Kales and Valenstein (2002)

58 Williams, *et al.* (1999)

59 Lamers, *et al.* (2008)

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http://care.diabetesjournals.org/content/33/Supplement_1/S11.full (ADA position statement on standards of medical care in diabetes, 2010)

http://www.cmaj.ca/cgi/reprint/172/1/33.pdf (Canadian Task Force On Preventive Health Care recommendation, 2005)

http://www.healthquality.va.gov/mdd/mdd_full09_c.pdf (VA/DoD Clinical Practice Guideline for Management of Major Depressive Disorder, May 2009)

http://www.icsi.org/depression_5/depression__major__in_adults_in_primary_care_3.html (ICSI Health Care Guideline “Major Depression in Adults in Primary Care”, May 2010)

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